

Developing healthcare non-technical skills training through educational innovation and synthesis of educational research

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ACKNOWLEDGEMENTS

The PHD by published works has offered me a unique opportunity. Whilst working as a full time clinician, I have been following a personal programme of research in key areas of interest.

Dissemination to support the scholarly conversations in the field has been crucial and my publishing output has allowed me to rapidly enhance my own research skills. This programme has offered me support in achieving these goals and the opportunity to receive recognition for this output.

Firstly, I wish to thank Alison Brettle and Paula Ormandy. Their support in directing my evolving portfolio of work and the development of these works into a cohesive thesis has been invaluable.

Secondly, most of these works have been collaborative. Some authors have been highly expert, some at earlier stages of their scholarly development than me. This has offered me the chance to learn and teach, to be supported and to offer my own guidance. To all my co-authors, I offer my thanks.

Thirdly, I wish to single out Paul Baker. I have collaborated with Paul on three of these studies, but his guidance through my earlier master's work right through these projects has been constant, proportional and crucial. Without this input, this output would not have been possible.

Fourthly, Ken Catchpole. An inspirational figure in the field, his collaboration and sage advice from the city of Angels has helped shape my vision and the scholarly output of this programme.

Finally, to my wife and two children. I have written some works with a crying child in my hand, some whilst starved of sleep and some whilst feeling the sheer exhilaration that only a loving family can offer. Without you, these works would be meaningless.

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Declaration

As a PhD by Published Works, this thesis comprises a portfolio of papers which have been published in peer reviewed journals. Furthermore these are supported by a range of previously published evidence, as well as original writing that presents the authors initial and evolving understanding of the state of the field. The published works are listed on pages two and three. The nature of the majority of the publications is collaborative, in line with the research projects from where the publications originate. The extent of the author's original contribution is listed in Appendix three and verified by the collaborating authors in Appendix four.

Abstract

This thesis presents a programme of nine key published works, as well as twelve published supporting works focusing on two areas. Firstly, an investigation of how non-technical skills education in healthcare can be used to enhance outcomes for patients. Secondly, an exploration of how evidence synthesis be used as a tool to direct educational innovation and, in this context, enhance patient safety.

Non-technical skills are the interpersonal, communication, team working and decision making skills that support safe patient care. Existing theory was applied to build new conceptual frameworks to understand how non-technical skill learning occurs. Educational innovations were developed, allowing outcomes for patients to be enhanced and the theory to be refined. Ultimately, this has led to the proposal of the SECTORS model, combining three key elements: The generic knowledge and skills in core areas that contribute to and support learning in non-technical skills (**S**ystems and technology use, **E**rror awareness, **C**ommunication, **T**eam working), a situated cognition approach to formal and experiential learning that develops these skills (**O**bservation and simulation) and developments in analytical skills that can integrate these and support decision making (**R**isk assessment and **s**ituational awareness). SECTORS can support curricula design, educational innovation and design of assessments. SECTORS will support future scholarly research, allowing the field to move from theory generation to theory testing and refinement.

Additionally, synthesis of educational evidence to support the development of this new knowledge has been employed. Building on existing guidance and in response to calls for more theoretical generation in primary educational research, a complete method for health education evidence synthesis has been developed and applied. This method allows clarification of educational questions through generation of conceptual frameworks and new theory within a systematic framework that employs qualitative synthesis techniques such as thematic generation and meta-ethnography, representing a significant contribution to the field.

ARTICLES INCLUDED IN THE PORTFOLIO OF PUBLISHED WORKS

For ease of distinguishing papers in the portfolio from other citations, throughout the thesis, papers included in the submission are cited in bold (e.g. **Gordon, Darbyshire and Baker, 2012**). Full texts of these papers are located in Appendix One, in the order in which they appear in the portfolio (this is based on the order in which they were completed).

- 1) Gordon, M., Findley, R. (2011). Educational interventions to improve handover in health care: a systematic review. *Med Educ*, 45, 1081-9.
- 2) Gordon, M. (2013a). Training on handover of patient care within UK medical schools. *Med Educ Online*, 18, 20169.
- 3) Darbyshire, D., Gordon, M., Baker, P. (2013). Teaching handover of care to medical students. *Clin Teach*, 10, 32-7.
- 4) Gordon, M., Catchpole, K., Baker, P. (2013). Human factors perspective on recent medical graduates' prescribing behaviour: Implications for educators. *Adv Med Educ Pract*, 4, 1–9.
- 5) Gordon, M., Darbyshire, D., Baker, P. (2012). Non-technical skills training to enhance patient safety: a systematic review. *Med Educ*, 46, 1042-54.
- 6) Gordon, M., Bose-Haider, B. (2012). A novel system of prescribing feedback to reduce errors: A pilot study. *Int J Risk Saf Med*, 1, 207-14.
- 7) Gordon, M., Holt, K., Lythgoe, J., Mitchell, A., Hollins-Martin, C.J. (2013). Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals. *J Interprof Care*, 27, 191-3
- 8) Gordon, M. (2013b). Non-technical skills training to enhance patient safety. *Clin Teach*, 10, 170-175
- 9) Gordon, M. (2013c). Building a theoretically grounded model to support the design of effective non-technical skills training in healthcare: The SECTORS model. *J Contemp Med Edu*, 2013, 1(2): 77-82

CONTRIBUTION OF INCLUDED ARTICLES

Study	Objectives of study	Contribution to body of work	Relevant thesis research objectives (see page 25)
Paper 1: Gordon, M., Findley, R. (2011). Educational interventions to improve handover in health care: a systematic review	To determine the characteristics of educational interventions employed to enhance handover amongst health professionals and to establish the effectiveness of these interventions	Identified relevant theoretical elements that have been used to underpin handover education and used these elements to develop a conceptual model to guide design. This was achieved through a progressive form of evidence synthesis.	Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare Develop and clarify methods for evidence synthesis in health professional education that consider development of theoretical models and can be applied outside of Best Evidence Medical Education (BEME) collaboration
Paper 2: Gordon, M. (2013a). Training on handover of patient care within UK medical schools.	To determine the current state of handover training within undergraduate medical schools in the United Kingdom and institutional attitudes to identify any common facilitators or barriers to handover education	A number of non-technical skill constructs, including team working, communication and leadership, were identified by expert participants as relevant. Pedagogical concepts that would become key to the model synthesised, including situated cognition, were suggested by participants	Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare
Paper 3: Darbyshire, D., Gordon, M., Baker, P. (2013). Teaching handover of care to medical students.	To describe an educational intervention for improved handover designed for medical students in clinical practice. This intervention is described with clear pedagogy and is based on current theoretical models to facilitate replication and dissemination	Developed a framework for educational design that became a foundation for the wider model produced. Clarified key pedagogical techniques. Reported in line with key gold standards identified within these works.	Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare

			Identify and evaluate key educational outcomes from the use of such non-technical skills education
Paper 4: Gordon, M., Catchpole, K., Baker, P. (2013). Human factors perspective on recent medical graduates' prescribing behaviour: Implications for educators.	To investigate the internal and external factors which impact on recent graduate prescribing, understand their responses to these factors, and by considering the conceptual elements discussed, use this to model safe prescribing behaviour from a human factors and nontechnical skills perspective to support educational design in this area	Grounded work identified key constructs that would underpin the final model synthesised. The relationship between core skills, methods of skill acquisition and analytical skills was identified. Additionally, the impact of error on enhancing further skills was discovered.	Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare
Paper 5: Gordon, M., Darbyshire, D., Baker, P. (2012). Non-technical skills training to enhance patient safety: a systematic review	To review the evidence regarding educational interventions to enhance patient safety using a non-technical skills training approach, with the aim of exploring the effectiveness and theoretical underpinnings of such interventions.	The theoretical findings were integrated to develop a rudimentary model of learning that contained new and original elements. An innovative form of evidence synthesis was employed that used primary data to allow secondary level theoretical clarification.	Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare Identify methodological elements from clinical evidence synthesis that can inform such techniques in the health professional education context
Paper 6: Gordon, M., Bose-Haider, B. (2012). A novel error feedback system to enhance paediatric prescribing.	To investigate the impact of a process of prospective error feedback to enhance awareness on error rates.	The role of error awareness in enhancing safety attitudes was confirmed, as well as the significant impact on prescribing behaviour in practice.	Identify and evaluate key educational outcomes from the use of such non-technical skills education
Paper 7: Gordon, M., Holt, K., Lythgoe, J., Mitchell, A., Hollins-Martin, C.J. (2013). Application of the	An interprofessional team of healthcare educators set out to pilot the use of TOSCE as an IPL teaching tool to support team	Confirmed the impact of teamwork training tool on patient safety attitudes and the role of such skills in the model	Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare

team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals.	working skill development and assessment in a group of postgraduate health professionals and assess its acceptability and effectiveness.	being developed. Clarified pedagogical elements relevant to the model.	Identify and evaluate key educational outcomes from the use of such non-technical skills education
Paper 8: Gordon, M. (2013b). Non-technical skills training to enhance patient safety.	The theoretical elements being developed were used to design an intervention. It is presented to allow local non-technical skills patient safety educational innovation, as well as the replication of this intervention.	Impact on perceived non-technical skills and attitudes were confirmed. Reporting was in line with high quality educational articles.	Identify and evaluate key educational outcomes from the use of such non-technical skills education To examine whether the results of such evidence synthesis can guide educational design
Paper 9: Gordon, M. (2013c). Building a theoretically grounded model to support the design of effective non-technical skills training in healthcare: The SECTORS model	To present the theoretical model developed throughout this programme of works	The model is proposed and presented in a manner to support future educational design and research works.	Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare To examine whether the results of such evidence synthesis can guide educational design

SUPPORTIVE EVIDENCE

In addition to the nine papers integral to the thesis, there are a number of published works that provide additional information or perspectives on the papers included in the portfolio. These papers are listed as supportive evidence. For ease of identification, they are cited throughout the thesis in bold italics (e.g. ***Gordon, 2012***). Further supporting works in the form of presentations at scientific meetings and conferences are presented in Appendix 5.

10) Gordon, M., Isaac, A., Prakash, N. (2007). Pre-mixed intravenous infusions on a neonatal unit: A potential danger. *J Neonatal Nurs*, 13, 75-76.

11) Gordon, M., Roberts, H., Odeka, E. (2007). Knowledge and attitudes of parents and professionals to neonatal BCG vaccination in light of recent UK policy changes: a questionnaire study. *BMC Infect Dis*, 24, 7,82.

12) Gordon, M., Prakash, N., Padmakumar, B. (2008). Factor XIII deficiency: a differential diagnosis to be considered in suspected nonaccidental injury presenting with intracranial hemorrhage. *Clin Pediatr (Phila)* 47, 385-7.

13) Gordon, M., Cervellione, R. M., Morabito, A., Bianchi, A. (2010). 20 years of transcrotal orchidopexy for undescended testis: results and outcomes. *J Pediatr Urol*, 6, 506-12.

14) Gordon, M., Chandratilake, M., Baker, P. (2011). Improved junior paediatric prescribing skills after a short e-learning intervention: a randomised controlled trial. *Arch Dis Child*, 96, 1191-4.

15) Gordon, M., Naidoo, K., Thomas, A.G., Akobeng, A.K. (2011). Oral 5-aminosalicylic acid for maintenance of surgically-induced remission in Crohn's disease. *Cochrane Database Syst Rev*, 19, (1):CD008414

16) Gordon, M. (2012). Handover education in UK medical schools: Current practices and implications for educators. *Med Teach*, 34, 84-85

17) Gordon, M., Naidoo, K., Akobeng, A. K., Thomas, A. G. (2012). Osmotic and stimulant laxatives for the management of childhood constipation. *Cochrane Database syst rev*, 11, 7:CD009118

18) Gordon, M., Darbyshire, D., Baker, P. (2013). Separating the wheat from the Chaff. Systematic review in Medical Education. *Med Educ*, 47,632

19) Gordon, M., Chandratilake, M., Baker, P. (2013). Low fidelity, but high quality: A model for e-learning. *Clin Teach*, 10, 258-263

20) Gordon, M. (2013). When shifting context...the role of context dynamics when understanding and educating on handover. *Med Educ* 47, 438-440

21) Gordon, M., Darbyshire, D., Saifuddin, A., Vimalasvaran, K. (2013). Limitations of poster presentations reporting educational innovations at a major international medical education conference. *Med Educ Online* 18, 20498

Introduction

For millennia doctors have begun their careers by making a pledge that starts with a declaration of the principle to 'do no harm' (Donaldson, 2005). These words are the culmination of a training period that has traditionally followed the time honoured practice apprenticeship, with knowledge a commodity passed directly to the learner (Drabkin, 1957). As such, once knowledge had been digested, medical professionals were essentially always right. Indeed despite the starting pledge, it was often acceptable to believe that harm to patients was unavoidable and to rationalise that the majority of patients did not suffer from such events (National Health Service [NHS] Education, 2013). After all, healthcare is complex and the 'doctor knows best' (Hartwell, 2005).

Attitudes to errors in health care began to change towards the later end of the 20th century with a string of high profile incidents reported in the media (Department of Health [DOH], 2000). The report *To Err is Human: Building a Safer Health System in the USA* (Kohn, Corrigan & Donaldson, 2000:p39) was a game changer, making the infamous comparison of a '*Jumbo Jet of patients dying every day from medical errors*'. This work was the first to use large amounts of actual patient data to estimate the national scale of the problem caused by avoidable medical error. Public awareness of these statistics since the publication of Kohn, Corrigan & Donaldson's report (2000) led to a furore that prompted immediate action across the globe (Watcher, 2011). This formed the foundation on which an industry of 'patient safety' was built. However, error continues to occur in health care with shocking frequency (National Patient Safety Agency [NPSA], 2012).

In section one, these issues will be explored further to explain how the aims and objectives of this thesis were developed. In section two, works are presented that clarified and developed the theoretical elements that led to significant new knowledge in the form of the SECTORS theoretical model. In section three, works are discussed that developed methodological principles to support health education evidence synthesis in a novel manner that integrates theory recognition and generation with the principles of systematic review. Whilst the term 'medical education' is often used, the focus of these works is not limited to medical staff, but considers all health professional education related to non-technical skills.

A number of the supporting works that developed the background knowledge and understanding required for these works were completed as early as 2006. The earliest works included in the portfolio of this thesis were conceived in 2009, as well as the concepts presented in section one, with active research and synthesis of the published works commencing in 2010. The projects rapidly progressed, with the final works completed in late 2012. However, the publication timeframe is relatively short. This does not accurately reflect the timeline over which the research was completed, but merely delays in peer review, acceptance and final publication of included studies.

SECTION ONE: Background and works leading to this programme of research

The scale of error in health care

Despite the stark findings of Kohn, Corrigan & Donaldson's work (2000), there has been and still is a general paucity of high quality systematic error data in the literature. The focus of such work often tends to be on medication or prescribing errors, with these topics easier to categorise and track, leading to a clearer idea of the scale of error. A follow up study to Kohn, Corrigan & Donaldson's work (2000) found that medication errors harm at least 1.5 million people every year in the USA (National Research Council, 2006). In 2000 alone, the extra medical costs incurred by preventable drug related injuries approximated \$887 million. In the UK, estimates are equally alarming (DOH, 2001), occurring in around 10% of admissions – or at a rate in excess of 850,000 a year. It was also estimated that this costs the service £2 billion a year in increases to the length of hospital attendances alone, without taking any account of human or wider economic costs. The latest National Patient Safety Agency [NPSA] data (2012) is probably the best reflection of the current UK error situation. This shows that the situation is not improving, with over 1.3 million reports of error in the 12 months to March 2012 in England and Wales alone. It may be argued that this is a positive development, with an element of enhanced reporting reflected in these figures. However, this viewpoint still cannot temper the fact that these statistics demonstrate an error is reported within health care in the UK every 25 seconds.

Addressing the problem of error in health care

The need to tackle the patient safety problem globally has indeed permeated all areas of healthcare for the last 15 years. Essentially, there are three key approaches that have been taken: best practice determined by best evidence, the person approach to error, and a systems based approach.

The first involves ensuring that the care offered is the right care that can and should be offered in the first place, essentially focussing on technical skills and delivery of health care (Wong, Etchells, Kuper, Levinson & Shojania, 2010). This is characterised by clinical

governance, which is now pervasive. Audit cycles, incident analysis and reporting, morbidity and mortality monitoring and protocol design have all become commonplace (Philibert, 2009; Temple, 2010). Studies to enhance patient outcomes that focus on ensuring dissemination of and adherence to already established or recently changed principles of practice are the focus for much published research (**Gordon, Isaac & Prakash, 2007; Gordon, Prakash & Padmakumar, 2008; Gordon, Cervellione, Morabito & Bianchi, 2010**). These are often underpinned by more systematic approaches to establish what indeed constitutes best practice, such as evidence synthesis. This is discussed in more detail in Section Three.

The second approach is aligned to the more traditional view of error in complex organisations. The person approach advocates identifying the culpable party as the cause of an error (Reason, 1998). Historically, this health care error investigation process focuses on the 'who did it' instead of the 'why did it happen' (Rasmussen, 1999; Kohn, Corrigan & Donaldson, 2000; Reason, 2000). Reason (2000) discusses this person approach to error that focuses on the unsafe acts of people at the sharp end and highlights how this is an ineffective approach to error reduction, but muses that it is preferred because *'blaming individuals is emotionally more satisfying than targeting institutions'* (Reason, 2000: p70). This views unsafe acts as arising primarily from aberrant mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness. Approaches to tackling specific aberrant behaviour within the NHS target include: poster campaigns (NHS Midlands and East, 2012; NHS Kidney Care, 2012), writing another procedure or adding to existing ones (British Medical Association [BMA], 2002; Royal College of Nursing, [RCN], 2010), threat of litigation (Quick, 2012), retraining (World Health Organisation, 2008), naming (NHS Choices, 2013), blaming and shaming (DOH, 2001). This wider ranging body of work is inherently flawed (Berwick & Leape, 1999; Baker & Norton, 2001). They focus on the individual committing error (Dennison, 2005; Reason, 2000) and as such the specific remediation actions taken, as outlined above, often do not have impact on the wider department, organisation or health service (Bates & Gawandi, 2000; Berta & Baker, 2004). Adopting the person approach to error management can lead to a culture of fear and lead to reduced reporting of such behaviours (Cohen, 2000). In the majority of cases for health professionals such errors can and will go unnoticed and bear no

consequences (Rosenthal, 1994). It is well recognised that from a psychological perspective, this lack of consequences for the individual can further enforce the aberrant behaviour (Hammond, 1996; Kruger 2007) and exacerbate the problem. Despite all these limitations, the person centred view is still highly cited, particular in the wider public and political landscape, recently exemplified in the extensive recommendations in the Francis report (2013) into the healthcare scandal in Mid-Staffordshire hospital and the resulting Keogh report (2013) into high mortality rates.

The alternative viewpoint to the person centred view of error is the system based approach to error. This third systems based approach to error was endorsed and encouraged by the NHS response to the Kohn, Corrigan & Donaldson's report (2000), Organisation with a Memory (DOH, 2001). This report theoretically aligned itself with the now ubiquitous Swiss cheese model of accident causation (Reason, 1990). Reason (1990) hypothesizes that most accidents can be traced to one or more of four levels of failure: Organizational influences, unsafe supervision, preconditions for unsafe acts, and the unsafe acts themselves. In the Swiss cheese model, an organization's defences against failure are modelled as a series of barriers, represented as slices of Swiss cheese (Figure 1). The holes in the cheese slices represent individual weaknesses in individual parts of the system, and are continually varying in size and position in all slices. The system as a whole produces failures when all of the holes in each of the slices momentarily align so that a hazard passes through all of the holes in all of the defences, leading to a failure (Reason, 2000).

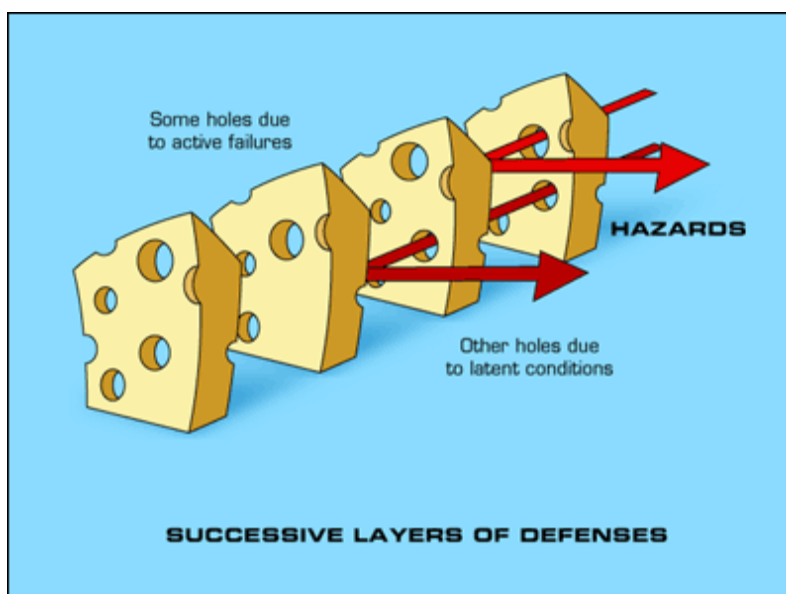


Figure 1. The Swiss cheese model of error (Reason, 2000)

(Reproduced with permission from
http://patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html)

Both the Swiss cheese model and three approaches to error reduction can be exemplified in the context of neonatology (**Gordon, Isaac & Prakash, 2007**). This concerns the incorrect administration of antibiotics instead of saline by a neonatal nurse to a baby. In considering this error, it was highlighted that a potential for confusion between two similar bags of fluid existed. However, this case highlights that all three methods to address error could be applied. The knowledge and skills of the professionals could be considered, as clearly the checking process may have been incorrect. The person centred view of error would seek to punish, publicise or retrain the individuals involved. Finally, the systems based approach would seek to change the storage, appearance or use of the fluid to put barriers in place to prevent a similar incident. This final systems based approach is the primary focus of human factors ergonomics (Carayon, Xie & Kianfar, 2013).

Misconceptions of Human Factors in health care

Ergonomics, also known as human factors, is a recognised scientific discipline concerned with *‘the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance’* (International Ergonomics Association, 2012). However, it should be noted that experts in the field recognise there is a lack of consensus on a definition, with a number of proposals in existence (Clinical Human Factors Group, 2011).

Human factors is a term many involved in healthcare delivery are now familiar with and has led to increasing acknowledgement of the value of human-centred systems thinking in healthcare, even though a decade ago most had never heard of the concept (Catchpole, 2013a). There are a number of different ways expertise within the field has been used to enhance safety in healthcare, including changing systems, environments or technology (Carayon, Xie & Kianfar, 2013). However, it is becoming clear that the term is being increasingly misappropriated in the literature (Ross, Rothnie, Parmalee, Masta-Gornic &

Pohl, 2009; Cahan et al, 2011; Bleetman, Sanusi, Dale & Bruce, 2012; Turner, 2012). Russ (2013) points out that a common misconception is that researchers refer to human factors, yet they detail the underlying cause as being human errors, a stance that clearly opposes human factor ergonomics as described above. Indeed, the term itself is not helpful as ironically human factors are essentially not interested in humans, but designing resilient systems around them (Scanlon & Karsh, 2010).

This misinterpretation is problematic as human factors are often described as a focus for training in healthcare (NHS Institute for Innovation and Improvement, 2006; Merseyside and Cheshire Health, Innovation and Education Cluster, 2013), which is not achievable goal in this context. Human factors approaches by their very nature try to avoid using training to compensate for poor system design and instead change the system itself (Salvendy & Karwowski, 2006). This symbiotic link between human factors and training has at least partially occurred due to the fact that many healthcare professionals received their introduction to human factors through courses based on crew resource management (Sundar, Sundar & Pawloski, 2007), a particular type of practice derived from aviation (Finn & Patey, 2009). Active debate in the literature has occurred on the issue of the relevance of this aviation model (Maurino, Reasonson, Johnston & Lee, 1995; Rogers & Gaba, 2011). However, Catchpole (2013a) argues that the human factors perspective missed the point, highlighting the erroneous view that aviation provided the 'principle', rather than one of many exemplar applications of deeper, scientifically based principles of human factors. Therefore, transposition with a cursory understanding of the principles at play is likely to be ineffective (Karsh, Weinger, Abbott & Wears, 2010). Additionally, when this body of literature on human factors training is considered (Ross, Rothnie, Parmalee, Masta-Gornic & Pohl, 2009; Cahan et al, 2011; Bleetman, Sanusi, Dale & Bruce, 2012; Turner, 2012), it becomes clear these conversations are not occurring within the social science or education literature, but within the discipline specific or quality improvement literature, as evident in a previous review of the field (Wong, Etchells, Kuper, Levinson & Shojania, 2010). This lack of educationalist involvement may help to further explain the limitations of such training.

Catchpole (2013a) articulates as a scholarly conversation the view that we have personally conversed on for a significant period of time, that transposition of industry based approaches to enhancing human factors are flawed. Healthcare is completely different to

aviation; transport, defence and nuclear power industries which are technology mediated, and have largely been engineered in the last 150 years to achieve specific goals (Catchpole, 2013a).

An example of how this engineering has impacted safety is in the development of the B17 bomber in the 1940's (Carroll, 1997). The introduction of a checklist could be attributed with reducing crashes, but the deeper understanding Catchpole (2013a) presents actually demonstrates it was actually a simple design change to the layout of the cockpit controls that stopped most accidents. The flap and gear levers were the same size and shape and were right next to each other, so it was easy to mistake one for the other, with disastrous consequences. A redesign addressed most of the problem (Carroll, 1997), with the checklist there as a final safety barrier, in line with the Swiss cheese model (Reason, 2000).

This is an important illustration of the problems within the human factors field in healthcare. Human factors experts primarily seek to engineer the clinical environment from the ground up. However, as the extensive body of literature that has been presented demonstrates, currently a focus on training as a proxy for appropriate human factors environments and systems exists, explaining why error rates have not reduced (NPSA, 2012). This is further exacerbated by the lack of educationalist involvement or social science to support such training (Wong, Etchells, Kuper, Levinson & Shojania, 2010). The major contribution that human factors ergonomics has to offer will not be tapped until human factors engineers are brought in at all stages of health care infrastructure design and development to engineer a safe environment (Wears & Kneebone, 2012).

Education and non-technical skills

A need to address error, teamwork and communication issues, a homologous set of outcomes to those encountered in aviation, led to the desire to transpose aviation education models (Leonard, Graham & Bonacum, 2004). Such education is usually based on checklists, simulation and non-technical skills as discrete components of an improvement training (Dunn et al., 2007).

The concept of non-technical skills has grown from human factors ergonomics within the field of aviation, but remains difficult to define in healthcare (Flin, 2008). Within the aviation context, non-technical skills are understood as referring to cockpit authority, crew co-ordination and co-operation, communication and collective decision-making, human error and conflict management, stress and workload management, attention, vigilance and monitoring (Civil Aviation Authority, 2003). Within healthcare, they have been described as skills possessed by an individual, outside of their technical ability, that enable someone to operate safely within an environment, viewed from a human factor perspective (Glavin & Maran, 2003; Dunn et al, 2007). Alternative definitions consider them to be a mix of social and cognitive skills (Baldwin, Paisley & Brown, 1999) or to include items such as communication, team working, leadership, situational awareness and risk assessment skills (Glavin & Maran, 2003; Dunn et al., 2007).

The premise of this thesis and its body of sustained work is underpinned by the notion that non-technical skills, although considered a small part within the human factors field, play a central role within error reduction. Non-technical skills, often a last line of defense, don't seek to stop errors, but embrace understanding, awareness and active behaviors to in essence act as a human system to prevent error (Thomas, 2004). By focusing on non-technical skills, modifications to an individual, their interactions and behaviours, can impact on the wider healthcare system (Barnett, Gatfield, & Pekcan, 2006). Within error reduction, pivotal role of non-technical skills can be captured within a diagrammatic model that demonstrates its relationship to the three error reduction concepts: reducing aberrant acts, clinical governance and human factors (Figure 2).

These skills allow individuals to understand and work effectively in both a human factors engineered or flawed environment. Additionally, evidence from other industries has shown that aberrant acts can and will be impacted by increasing education on non-technical skills (Civil Aviation Authority, 2003; Leonard, Graham & Bonacum, 2004) as part of a package integrating the other measures already discussed (Figure 2). Enhanced situational awareness and risk assessment, which are non-technical skills, are believed to address forgetfulness or inattentiveness or allow others to identify these deviations in the individual and as such have become central to the selection and testing of staff in certain medical

subspecialties (Gale et al, 2010). It has been noted that non-technical skills work symbiotically with technical skill enhancement (Roberts, Lamb & Gale, 2011) and as such have been recognised as an element of learning when enhancing skills in clinical governance (Hainey & Pearson, 2013). Further identification as to how non-technical skills may impact safety in healthcare at the start of this programme of works was lacking.

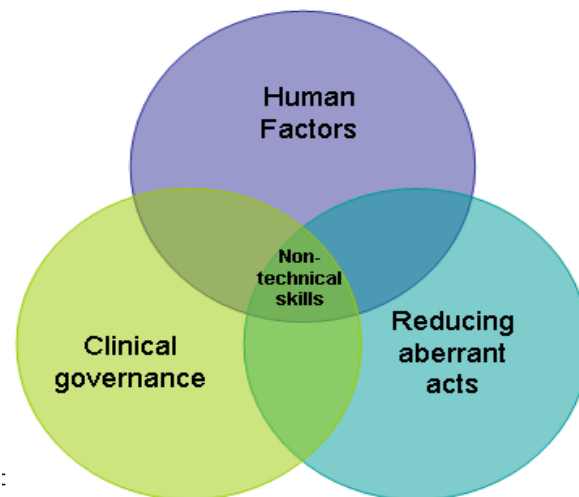


Figure 2. The relationship of non-technical skills to methods of error reduction in healthcare

Other industries have clearly demonstrated errors can be avoided by considering non-technical skills of individuals (Odell, 2011). Given the central role of non-technical skills in error reduction, producing appropriate training to enhance professional's non-technical skills in health care must be a priority. However, this is where a significant gap in the literature exists. Reports of non-technical skills training packages are extremely sparse and focus on effectiveness of interventions often through consideration of satisfaction of learners of changes to attitudes (Blum, Raemer, Carroll, Felstein & Cooper, 2004; Haller et al., 2008; Lindamood, Rachwal, Kappus, Weinstock & Doherty, 2008; Blegen, Sehgal, Alldredge, Gearhart & Wachter, 2009; Cox, Scott, Hall, Aud, Headrick & Madsen, 2009; Jankouskas, 2010). Whilst this is not inherently a problem for an emerging new field of education, more problematic is the nature of such scholarly reports. Not one of these reports of non-technical skills educational interventions have presented any form of educational underpinning descriptions of pedagogy or useful descriptions to support replication. It is difficult to ascertain if this reflects poor reporting or a more concerning

underlying weakness in design, although given the consistent lack of such details, the latter seems most likely and this represents a significant gap in the literature.

Indeed, the researchers cited (Blum, Raemer, Carroll, Felstein & Cooper, 2004; Haller et al., 2008; Lindamood, Rachwal, Kappus, Weinstock & Doherty, 2008; Blegen, Sehgal, Alldredge, Gearhart & Wachter, 2009; Cox, Scott, Hall, Aud, Headrick & Madsen, 2009; Jankouskas, 2010) all mention an affiliation to aviation crew resource management techniques, but nothing further, suggesting a low fidelity transposition of these teaching methods. From an educational perspective, it is inappropriate to simply transpose training from one discipline to another. Doing so without considering a theoretically grounded and pedagogically sound approach is poor science and no different or no less inherently flawed than assuming a medication that has been trialled in mice will be effective in humans. If this analogy is continued, it is more concerning in the context of educational dissemination to make such assumptions, education being very difficult commodity to quantify. Clinical teachers can't simply prescribe 300mg of 'non-technical skills education'. Similar problems have been seen in healthcare in the past when transposing techniques from other industries. An example is the introduction of staffing ratios on acute wards, now accepted as crucial for patient safety, but grounded in experience from other areas such as education, the military and aerospace industries (Wu, Fujita, Seto, Matsumoto, Huang & Hasegawa, 2013). As such, early work in introducing these ratios was arbitrary and not based on evidence (Shekelle, 2013). It is only with increasing experience that the place of such staffing ratio policies in healthcare is becoming grounded more appropriately based on empirical evidence rather than subjective judgements (Scott, 2003).

Up till now, the introduction of non-technical skills training in healthcare has been nothing other than good intentioned (Catchpole, 2013a), but it appears a similar low fidelity transposition has occurred with a lack of evidence to guide both design and assess (Russ, Fairbanks & Karsh, 2013). This lack of evidence based educational practice is not limited to this context, but been seen across many other subject areas. Previous works in the area of prescribing education found a lack of theoretical underpinning, pedagogical alignment and scholarly rigour (Cook, Levinson, Garside, Dupras, Erwin & Montori, 2008) and this restricts future replication or dissemination, limiting the value of the research (**Gordon, Chandratilake and Baker, 2013**). These same weaknesses have also been seen in the

context of interprofessional education. Hean, Craddock and Hammick (2012) highlighted the limitations of much educational innovation in this field due to poor theoretical underpinning. Educational innovation within the healthcare setting must seek to be grounded in appropriate theory and pedagogically sound, with the same scholarly rigour applied as in all areas of scientific enquiry, but with a different scientific alignment (Berliner, 2002; Dornan 2008; Bordage, 2009).

Much energy within the published body of work on non-technical skills education seeks to assess 'whether' such training is effective (Blum, Raemer, Carroll, Felstein & Cooper, 2004; Haller et al., 2008; Lindamood, Rachwal, Kappus, Weinstock & Doherty, 2008; Blegen, Sehgal, Alldredge, Gearhart & Wachter, 2009; Cox, Scott, Hall, Aud, Headrick & Madsen, 2009; Jankouskas, 2010). This is a moot point, as by its very nature offering training to professionals will teach them something (Eva, 2009). The question of 'how' it achieves this, 'why' the teaching is effective, 'for who and when' such training can be effective and finally 'how these elements impact on outcomes' are far more useful questions. For clinical teachers in all contexts, the lack of research to answer these questions simply means that they cannot instigate non-technical skills training to enhance safety in any other way than by offering a cursory alignment to freely available material on the topic. Research must seek to build non-technical skills from the ground up, rather than transposing fashionable education from other areas (Norcini & Handa, 2011) and ignoring the tenants of quality educational innovation (Haji & Dozier, 2013). Theory forms a key cornerstone of this work, illuminating and magnifying issues at hand (Bordage, 2009). Theory has been observed to be a product of practice, proposed after observation and confirmed by practice (Hean, Craddock & Hammond, 2012), so it is vital that the published works of educators seek to contribute to theory through interpretation of their practice.

Summary

Human errors do occur and will always occur (DOH, 2000; Reason, 2000). Measures to ensure healthcare delivery is in line with expected best practice are crucial and can be delivered through clinical governance and evidence based health care (expanded in section three) (Philibert, 2009; Temple, 2010). A person approach to error, employing blame, retraining and personal legal consequences for error has historically been a common approach (Berwick & Leape, 1999; Rasmussen, 1999). In the recent Francis report (2013), the person centred approach to future error reduction was key in the recommendations made. However, such approaches have been clearly demonstrated to increase errors (Rosenthal, 1994). Human factors ergonomics is a psychology discipline that has underpinned much safety work in other industries for many years (International Ergonomics Association, 2012), focusing not on humans, but the systems and environments in which they work to stop inevitable errors from causing harm (Reason, 2000).

Work to apply human factors in healthcare to enhance systems and environments has shown the potential to enhance safety (Carayon, Xie & Kianfar, 2013). This work is being undermined by now pervasive misconceptions regarding the focus of human factors work that have led to many designing training to deal with human factors, a notion that is at odds with the very principles of system focused human factors ergonomics (Russ, 2013). Non-technical skills are the one area of the field of human factors that focuses on educating professionals (Dunn et al, 2007). A paucity of research in this field represents a significant gap in the literature, with the limited publications that exist focusing on 'whether' such education can be successful in healthcare, but ignoring questions such as 'how', 'why', 'when' and 'for whom' (Blum, Raemer, Carroll, Felstein & Cooper, 2004; Haller et al., 2008; Lindamood, Rachwal, Kappus, Weinstock & Doherty, 2008; Blegen, Sehgal, Alldredge, Gearhart & Wachter, 2009; Cox, Scott, Hall, Aud, Headrick & Madsen, 2009; Jankouskas, 2010). This renders them of no use to clinical teachers and health professional educators in all contexts and representing poor quality educational research (Norcini & Handa, 2011).

A paradigm shift in approach is needed, starting from an educational stance and building new theory to support new non-technical skills education (Haji & Dozier, 2013). This thesis of published works draws together empirical educational research and theory, alongside the

innovative application of evidence synthesis in medical education to not only assess and extend the current evidence base, but to support evolution of the educational complexity presented in a manner that can enhance patient safety.

Aims and objectives

The primary aim (Section two) of this programme of research was to investigate the use of non-technical skills training in healthcare to enhance outcomes for patients. The key focus was to investigate how learning occurs in this context to guide future educational innovation, in line with highest quality health professional education methods (Norcini & Handa, 2011). This was achieved by completing three key objectives.

- 1) Develop and define the key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare
- 2) Adapt and apply appropriate pedagogical elements to develop non-technical skills education in healthcare
- 3) Identify and evaluate key educational outcomes from the use of such non-technical skills education

The secondary aim was to explore how independent health professional education evidence synthesis can best be used as a tool to direct educational innovation and, in this context, enhance patient safety (section three). This was an exploration of methodology and reporting of such research, achieved by completing the following three key objectives.

- 4) Develop and clarify methods for evidence synthesis in health professional education that consider development of theoretical models and can be applied outside of Best Evidence Medical Education (BEME) collaboration
- 5) Identify methodological elements from clinical evidence synthesis that can inform such techniques in the health professional education context
- 6) To examine whether the results of such evidence synthesis can guide educational design

SECTION TWO: Non-technical skills training in healthcare

Introduction

In the UK, recent nationwide campaigns to target falls within hospital (NPSA, 2007) or pressure ulcers (DOH, 2010) as preventable causes of harm are both described as having elements of patient safety education (Patient Safety First, 2013), but neither explicitly addresses non-technical skills. Whilst non-technical skills form a discrete and important skill set that intersect many elements of professional behaviour (Glavin & Maran, 2003; Dunn et al, 2007), there is a lack of consensus as to what exactly these skills are (Clinical Human Factors Group, 2011). This undoubtedly presents a challenge in addressing the question of how to design such education without simple flawed transposition from other industries.

When errors caused by adverse events are considered in an educational context, the situation is noted to be complex given that the cause of such errors are multi-factorial, with several active failures and error-provoking elements involved (Lynskey, Haigh, Patel, & Macadam, 2007; Ross, Rothnie, Parmalee, Masta-Gornic & Pohl, 2009). This author's previous works in designing prescribing education (**Gordon, Chandratilake & Baker, 2011**) clearly found understanding of error key to education. Whilst lack of knowledge or skills is important, error is often caused by people just '*making a mistake*' (Aronson, 2009: p599), or aberrant acts external to knowledge and skills (Reason, 2000). As such, when tested after causing an error, professionals will often perform well in simulated situation, such as a prescribing mathematics test, yet they are still offered unnecessary extra remedial teaching (Agrawal et al, 2009). Reflecting on these issues in light of the model synthesised (Figure 2) does elude to the role that non-technical skills will play in enhancing safety.

The role of included works

The relevance of the works presented in this section will be to the first three objectives of the thesis (Develop and clarify theory to guide non-technical skills learning, identify relevant pedagogy to support instructional design and evaluate key educational outcomes).

Gordon and Findley, (2011). Educational interventions to improve handover in health care: a systematic review

In considering what elements should constitute non-technical skills teaching in healthcare, it was decided to consider a specific thematic area. The area chosen was handover of care. Handover or hand-off is the accurate, reliable communication of task-relevant information across shift changes (Lardner, 1996) and is vital to facilitate high-quality health care (Philbert, 1999; BMA, 2002). This area was selected for a number of important reasons. Firstly, with the increasing frequency of handover in recent years the potential for error from this activity has become recognised source of potential harm for patients (Joint Commission on Accreditation of Healthcare Organizations, 2010). Secondly, handover of care is clearly an area that falls out of the strict confines of technical skills. Involving communication, team working, leadership and often integration with systems in the organisation for transmitting information, this was seen as an example of a skill that clearly covers many elements of the non-technical skills construct (Glavin & Maran, 2003; Dunn et al., 2007). Finally, at the point of carrying out the study, there had been no published attempt to synthesise the current evidence regarding handover education in healthcare.

Contribution and critique of study

This work involved qualitative descriptive analysis (Patton, 2002), as is common in the field, but a more in depth analysis of the content of published education on this issue was completed. This allowed existing conceptual frameworks (Arora, Johnson, Meltzer, & Humphrey, 2008; Chang, Arora, Lev-Ari, D'Arcy & Keysar, 2010) to be examined and through the analysis, new theoretical elements to be proposed to construct a model for underpinning handover education.

This paper made a significant and new contribution to the field, offering the first theoretical framework through which future handover educational design can be underpinned (objective one). This contrasts with a previous framework that was iteratively produced, but not in any way underpinned (Jeffcott, Evans, Cameron, Chin & Ibrahim, 2009). The study identified a paucity of published literature regarding education and highlighted that those works that existed were mostly devoid of educationally meaningful insights (Berkenstadt et al., 2008; Lyons, Standley & Gupta, 2010; Malter & Weinshel, 2010). More importantly within the wider context of this programme of works, this uncovered the contribution of non-technical skills to a key healthcare activity and as such began to point the way towards relevant theoretical elements to underpin such education.

From a methodological perspective, an educational systematic review was performed (Gordon & Findley, 2011). Whilst the methodological issues are discussed more in section three, this choice highlights a key weakness surrounding the wider literature in such key safety and specifically non-technical skills issues in healthcare. In section one, the paucity of evidence in this context was discussed in detail, but that is not to say there is a paucity of published work. Handover is an example of an area in which there is much work published, but at the time of completing this study, this almost exclusively fell in to the categories of opinion (Toeima, 2011), narrative (Kerr, Lu, McKinlay & Fuller, 2011), audit of current practice (Pfeffer, Nazareth, Main, Hardoon & Choudhury, 2011) or consensus advice (West, 2011). This work can set an agenda, highlight gaps in the literature, but does little to guide educators. This situation led to some of the key choices in designing and implementing this study. In particular, the use of evidence synthesis and the exclusion of all research except that which reported educational innovations to address handover education.

Gordon, (2013a). Training on handover of patient care within UK medical schools

The systematic review of handover educational interventions (Gordon & Findley, 2011) identified that the published literature on handover education in healthcare was significantly limited. Despite this paucity of interventional research work, an exponential increase in narrative reports on the topic suggests such education existed in medical

education and was simply not being reflected fully in the literature (Johner et al., 2013; Ten Cate & Young, 2012)). The study (**Gordon, 2013a**) sought to examine the educational realities on the front line and how these could inform non-technical skills training developments. The cross-sectional study involved a large sample of undergraduate medical schools. Findings demonstrated that whilst undergraduate medical schools recognised handover as an important education issue, there was lack of consensus as to where and when such education should take place, leading to inequalities in provision (**Gordon, 2013a**). As such, this work highlights that curriculum developers as well as the General Medical Council (GMC) must reach agreement on the role of such education. In particular, it was identified that as the aim of educators delivering such teaching was to enhance outcomes and safety, specifically mentioning a number of non-technical skill constructs, including team working, communication and leadership. Finally, simulation was mentioned by many as a key educational technique, in particular highlighting how this situates learning in context (Pimmer, Pachler & Genewein, 2013). This construct became key to the educational understanding of non-technical skills learning developed through these works.

Contribution and critique of the study

This study was the first in the globe to highlight through a large geographical sample (which included 16 medical schools from all four countries of the UK) the state of education in the rapidly growing new area, handover of care. Additionally, the identification that patient safety and specifically a number of non-technical skills are the motivation and inspiration for educational innovations led this study to be the first to suggest in the literature that handover is viewed by educators as a construct of patient safety and non-technical skills. Finally, this study highlighted a key question for the educational community and those planning non-technical skills teaching. If education can be produced to enhance these skills and ultimately safety for patients, it could be argued that it is the responsibility of educators to situate this learning at a time before the learner can and often will harm patients. The study demonstrated disparity between this view and the educational reality that often such learning is deemed to be a postgraduate issue learnt 'on the job' and this author proposed that such a view is not reasonable, possibly not even ethical. Whilst this specific question is not further addressed throughout this programme of research, the model formulated

through these works (**Gordon, 2012**) can be applied in all settings and as such facilitates training in both the undergraduate and postgraduate settings.

As a qualitative study, rather than simply presenting descriptive or simple qualitative responses in a non-analysed form, a grounded theory approach was taken, with coding of responses and thematic generation (Patton, 2002). The analysis proceeded through three stages, consisting of open, axial and selective coding, with constant comparisons taking place throughout each phase, in line with the methodology proposed by Strauss (1998). Whilst this is a conceptually appropriate methodology, there were several limitations to how it was implemented. There was only one source of data, with no triangulation of data streams (Walsh, 2013) and only one researcher coded the data, with no co-researcher analysis and measure of concordance (Armstrong, Gosling, Weinman, & Martaeu, 1997). This limits the strength of the conclusions made.

Darbyshire, Gordon and Baker, (2013), Teaching handover of care to medical students

This study sought to describe the design and implementation of a new education innovation to address non-technical skills learning. The proposed model (**Gordon & Findley, 2011**) was used to underpin this work within the undergraduate setting (**Gordon, 2013a**). This educational translation research (**Darbyshire, Gordon, & Baker, 2013**) allowed the model for handover education to be formally proposed as a design tool, applied and the intervention reported in a way that allowed active replication and synthesis in other education environments, in line with a high quality educational research approach (Dornan, Peile & Spencer, 2008). It demonstrated that non-technical skill elements formed a key pillar of such teaching.

Contribution and critique of the study

This study was the first to fully describe an educational intervention to enhance handover of care within medicine. This involves theoretically underpinning, description of the pedagogy

of design, details of resources needed and how to carry out the teaching and finally assessment of the educational innovation, in line with the second objective of these works. The study encouraged dissemination and replication, addressing the key weakness of the other published work in the field (**Gordon & Findley, 2011**). Theory is presented in a manner that facilitates further refinement, encouraging a scholarly discourse that previously did not exist (Kupper and Whitehead, 2013). However, the study did not make the educational resources used (lesson plans, handouts, video scenarios) available to readers, such as via online links or appendices. As the literature highlights this as a key failing of reports of educational innovations (**Gordon, Darbyshire, Saifuddin & Vimalasvaran, 2013**), this must be acknowledged as a weakness.

Gordon, Catchpole and Baker, (2013), Human factors perspective on recent medical graduates' prescribing behaviour: Implications for educators

This paper (**Gordon, Catchpole & Baker, 2013**) examined the elements of non-technical skills education in a completely different context to explicate and observe further elements exposed in the previous educational model for handover of care (**Gordon & Findley 2011**). Given the predominance of medication errors in the reported epidemiological data, this was chosen as an area for further study (NPSA, 2012). Whilst examining prescribing education design (**Gordon, Chandratilake & Baker, 2011**), it was conceived that an independent and large qualitative study to investigate recent graduate perspectives on error and safety would illuminate and inform future education innovations. Non-technical skills factors were significant in handover of care (**Darbyshire, Gordon & Baker, 2013**) and medication error is a huge problem, but there was a lack of clarity as to how these different non-technical skills elements interact to affect prescribing. This paper reports a large study, with multiple methods of data collection and a grounded theory analysis (Patton, 2002). Through the analysis, human factors and non-technical skill behaviour that guide prescribing in recent graduates were modelled. As these factors were related to a number of recognized elements of non-technical skills training within health care, the synthesis of new knowledge indicated the relevance of such education in enhancing safety and outcomes in the context

of prescribing. In addition the model began to shape understanding of how non-technical skills learning in all areas of healthcare may and should be underpinned (Objective one). As a result of this work, it became clear that a generic model to understand learning and teaching in non-technical skills was close to being synthesised. This model would draw on a number of conceptual frameworks and would be able to guide educational design and contribute significantly to the issue globally, so the focus of the next few pieces of work was on achieving this goal.

Contribution and critique of the study

This was the first piece of work to consider the pathogenesis of medication errors within a human factors construct. Given the pivotal role of non-technical skills within error reduction strategies (Figure 2), there was a clearly a need to prospectively investigate how clinicians perceived that such skills contributed to their behaviours. This work demonstrated that non-technical skills are employed by doctors prescribing in the workplace and that these can support safe prescribing. Considering that it has been proposed that non-technical skills learning should occur before the potential to harm patients exists (**Gordon, 2013a**), the model of learning synthesised can and should inform topics for undergraduate or pre-prescribing learning. This is particularly topical in the UK as a new independent pre-prescribing assessment is being developed for all new UK doctors to complete before graduation (British Pharmacological Society [BPS], 2013). The extent to which non-technical skill competencies will be considered within this assessment is currently unclear, but available materials would suggest that this may be neglected, highlighting the importance of this study's findings in the wider scholarly conversation. This study used a comprehensive grounded theory methodology (Strauss, 1998; Patton, 2002), which leads to the synthesis of a conceptual framework that is robust and of great significance, particularly as this view of prescribing behaviour has never been studied before. However, a key criticism of this paper is its confusing use of the terms human factors and non-technical skills. As already discussed in Section one, in this context human factors would discuss the environmental and system based strategies to enhance new graduate prescribing, however, most of the behaviours the participants discussed were indeed non-technical skills they observed or exhibited. Whilst

this misappropriation is almost universally seen in other studies on this topic (Ross, 2009; Cahan, 2011; Bleetman, 2012; Turner, 2012), as this thesis has challenged researchers for perpetuating this confusion of terms in the general literature, the same weakness in this piece must be highlighted and its potential effects considered. If the open and axial coding phases of data analysis are reviewed, this misappropriation does not exist within the data. In fact, the final model synthesised does not exhibit any confusion of the wider human factor elements with the participant's non-technical skills. This appears to simply be a nomenclature issue in the general writing of the discussion and title of the paper which does not invalidate the findings.

Gordon, Darbyshire and Baker, (2012), Non-technical skills training to enhance patient safety: A systematic review

A concordance appeared to exist between the theoretical elements that underpin handover and prescribing education. This concordance was not focussed on key knowledge or skills, but a core set of non-technical skills. These findings began to meet objective one of this area of study, but still did not form a unified conceptual framework for understanding learning and supporting education design. Additionally, clarity as to the pedagogy and educational content of interventions to enhance these skills remained. This study set out to triangulate the theoretical elements identified to confirm their utility. It set out to integrate the theoretical findings and consider them in the context of translation to teaching progressing both primary objectives of the project. This was achieved through an educational systematic review that investigated the evidence regarding educational interventions to enhance patient safety using a non-technical skills training approach. This work explored the effectiveness and theoretical underpinnings of such interventions and considered these elements in the context of the existing theoretical constructs identified, but identified new and original elements.

Contribution and critique of the study

Gordon, Darbyshire & Baker (2012) was conceived to further address the first three objectives of this thesis by trying to frame what non-technical skills education may 'look

like'. This was the first use of qualitative methods within evidence synthesis to develop new knowledge from primary evidence. As well as confirming the relevance of key theoretical elements to underpin non-technical skills education that had already been identified by prior works (**Gordon & Findley, 2011; Gordon, Catchpole & Baker, 2013**), this work also proposed new theoretical elements of relevance to learning in this area. These included a situated cognition approach to education, the importance of addressing situational awareness and team working skills and the use of contemporaneous error awareness to enhance professional responsibility. This work advanced the field for educators, both in terms of clarifying an evidence-based and theoretically underpinned direction for educational innovation of non-technical skills learning (objective one) and for the first time in the literature considered pedagogical aspects of such educational interventions, suggesting key evidence based methods (objective two). Finally, this work also began to illuminate key educational outcomes that can be addressed and also identified relevant gaps in the published evidence, in line with the third objective of these works.

In critically considering this piece, there is one key area of weakness that can be identified. The search strategy was focussed on non-technical skills education in the context of enhancing safety. This produced a relatively limited set of included studies when considered in the wider context of the field. The published study is very clear to highlight and explain the limits of this strategy, as pointed out in Kilminster's commentary (2012) on this piece. Certainly this focus prevented the common and already discussed confusion between human factor and non-technical skill research and was motivated by this issue. Nevertheless, the focus prevented a much larger scoped project that may have included all such education from many industries (for example aviation or aerospace). It also prevented the authors seeking to analyse works purporting to report human factors education research that in reality were descriptions of non-technical skills. This larger scoped review may have not changed the results, but would certainly have increased the reliability, generalisability and relevance of these findings to a wider educational readership. However, it should be noted that this focus allowed a complete and systematic exploration of this field and as such what is lost in undue focus is counterbalanced by the relevance of these findings within the context of this thesis. The methodological aspects of this issue are further explored in section three.

Gordon and Bose-Haider, (2012), A novel system of prescribing feedback to reduce errors: A pilot study

This study set out to address all three primary objectives of these works. Translational in nature, this study set out to confirm the relevance of a key element of the evolving model of non-technical learning, error awareness. This was achieved by the application of an educational intervention that had a very clear and well described pedagogy and was evaluated through the consideration of how this intervention could enhance outcomes for patients in practice. The study demonstrated a significant reduction in technical prescribing errors through a low cost and easily repeated technique of continuing education. This was situated in the environment of the learners and consisted of content that was based on their prospective experience thus ensuring a pedagogical alignment to the principles of situated cognition and being mindful of context dynamics and how they impact on learning (**Gordon, 2013b**). This intervention was packaged in a manner as to allow easy dissemination and replication. Statistical analysis revealed a significant improvement in prescribing after this simple intervention (objective three), a significant contribution to the wider safety and medication error reduction literature.

Contributions and critique of the study

Embedded within the study was the assessment of change of behaviour, level 3 of Kirkpatrick's hierarchy, (Barr et al, 2000). This hierarchy, whilst not necessarily denoting different levels of importance from a social science perspective (Yardley & Dornan, 2012), does describe the difference impacts of outcomes on patients: level 1 describing learner satisfaction, level 2 a change in attitudes and skills, level 3 a change of workplace behaviour, and level 4 institutional outcome enhancements. The top two levels of outcomes are difficult to assess and rarely reported within medical education research (Yardley & Dornan, 2012), reinforced from the evidence exposed in the systematic reviews completed in this programme of studies, as well as other key works in the area (Ross & Loke, 2009). In the context of the wider literature, demonstrating such levels of outcome is rare, with most focussed on attitude or knowledge change (Ross & Loke, 2009; **Gordon, Chandratilake & Baker, 2010**). This is the first study published to demonstrate the simple enhancement in

error wisdom can impact behaviour in the work place. Additionally, the extent of improvement in the wider context of prescribing error reduction programmes is unprecedented for an essentially cost neutral intervention, highlighting the role simple adherence to non-technical skills behavioural elements can have on a principle source of healthcare error.

Gordon, Uppal, Holt, Lythgoe, Mitchell and Hollins-Martin, (2012), Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals

This educational translational research piece focussed on a key element of the emerging model for non-technical skills education. Team working is an area often discussed in healthcare, but poorly investigated, particularly in terms of structured training and summative assessment (Borrill, West, Shapiro & Rees, 2000). The team objective structured clinical encounter (TOSCE) is a teaching and assessment tool developed within a national funded study in Canada (Marshall, Hall, & Taniguchi, 2008), but up till this study only used in the undergraduate setting amongst homogenous teams of medics. Both these limitations were addressed with its application to a group of nurses and midwives within the postgraduate setting, adding to the overall knowledge base regarding teamwork assessment in healthcare and demonstrating the feasibility and acceptability of this type of education (objective three). TOSCE demonstrated a change in patient safety attitudes after just one session, cementing the role of such types of education within a wider view of learning in non-technical skills (objective three).

Contributions and critique of the study

This is the first published work regarding the TOSCE since its initial reporting (Marshall, Hall, & Taniguchi, 2008) and rather than just repeating this work, the study significantly built on the evidence base. This study demonstrated that a multiprofessional teamworking assessment and training tool actually has utility in the context of multiprofessional teams. This seems to be a self-evident truth, but in fact throughout the entire development and piloting of the tool in Canada, it was only used with medical students. Additionally, in the

wider context of the model being developed, this important study highlighted the role of simulation and simulated encounters in non-technical skills education. As a practical implementation and translation piece, this work also demonstrated that the type of education being proposed can be achieved within the boundaries of cost and resource available to many educational institutions, suggesting potential utility. The main weakness of this piece was the extent to which it considered 'how' such education is effective or contributes to the wider non-technical skills of participants (Deputy Editors, 2012). Whilst this work has confirmed utility, feasibility and effectiveness, an opportunity to address this question was not taken. Insight as to 'how' this education may work could have further enhanced the model being developed and in particular address issues of the application of the particular teaching method used. Understanding regarding simulation as an educational strategy has rapidly increased in the last 20 years, with questions of fidelity, supervisor training, feedback and debrief easily considered (Issenberg, McGaghie, Petrusa, Lee Gordon & Scalese, 2005). However, relevant issues that further investigation during this study may have addressed include individualisation of simulation and clinical variance of scenarios (Cook, Brydges, Zendejas, Hamstra & Hatala, 2013).

Gordon, (2013b) - Non-technical skills training to enhance patient safety

The previous studies (**Gordon & Findley, 2011; Gordon, Darbyshire & Baker, 2013; Gordon & Bose-Haider, 2012**) had identified all the key elements of a model of non-technical skills learning, with apparent triangulation and theoretical saturation reached (Walsh, 2013). This study was completed (**Gordon, 2013b**) to assess the application of the complete model to instructional design. The manuscript clearly describes the process of instructional innovation, the key theoretical elements and conceptual frameworks on which the intervention was built and the resources required to deliver this intervention. The purpose of this study was to examine replication and dissemination, in line with the high quality approach to medical education research that has been investigated and applied as part of the secondary outcomes for this programme of research (section three). Assessment of the resulting intervention demonstrated its acceptability, feasibility and ability to change attitudes towards safety outcomes, as well as confidence regarding non-technical skills.

Contributions and critique of the study

This study was the first published work focussed generically on non-technical skills within medical education that incorporated any form of theoretical underpinning. Based on the elements of the model synthesised (**Gordon, 2012**), this clearly sets out how they can be applied to produce an educational intervention, the resources required to carry out the intervention and the materials needed to do so. Therefore, this work manages to adhere to all the tenants of high quality that have been proposed throughout this report and in previously published studies (**Gordon , Darbyshire, Saifuddin & Vimalasvaran, 2013**). This addresses the key and inexplicable weakness in the literature that this work identified, namely the lack of information in publications supporting dissemination or further interventional design. This piece assessed the intervention produce on a number of levels of Kirkpatrick's hierarchy (Yardley & Dornan, 2012). However, a criticism of this paper is that it does not reflect back on its self and ask the question 'how' this intervention supports non-technical skills learning. This may seem irrelevant as the thrust of these works has been to design a model that has been constantly asking this theoretical and conceptual question. Despite the robustness of this programme of works in achieving this goal and addressing all three of the primary outcomes identified, the application of this retrospective triangulation of data could have supported, refuted or enhanced the model being proposed. Indeed, from a methodological standpoint this highlights the issue of triangulation within medical education research and its goals. Rather than reach consistency, the true aim is to explore and highlight inconsistency and use this to deepen knowledge (Patton, 2002). This is eloquently summarised by Thurmond (2001; p254) who describes triangulation '*as increasing confidence in research data, creating innovative ways of understanding a phenomenon, revealing unique findings, challenging or integrating theories, and providing a clearer understanding of the problem*'. The last element of this definition would suggest that this form of further inquiry would certainly have been beneficial.

Gordon, (2013c) - Building a theoretically grounded model to support the design of effective non-technical skills training in healthcare: The SECTORS model

In this manuscript, the SECTORS model (Figure 3) was synthesised and presented. The model describes the key knowledge and skill elements developed, the methods of learning and the analytical skills acquired through this learning that support safer decision making. SECTORS describes: - The generic Knowledge and skills in core areas that contribute to and support learning in nontechnical skills (**S**ystems and technology use, **E**rror awareness, **C**ommunication, **T**eam working), a situated cognition approach to formal and experiential learning that develops these skills (**O**bservation and simulation) and developments in analytical skills that can integrate these and support decision making (**R**isk assessment and **S**ituational awareness).

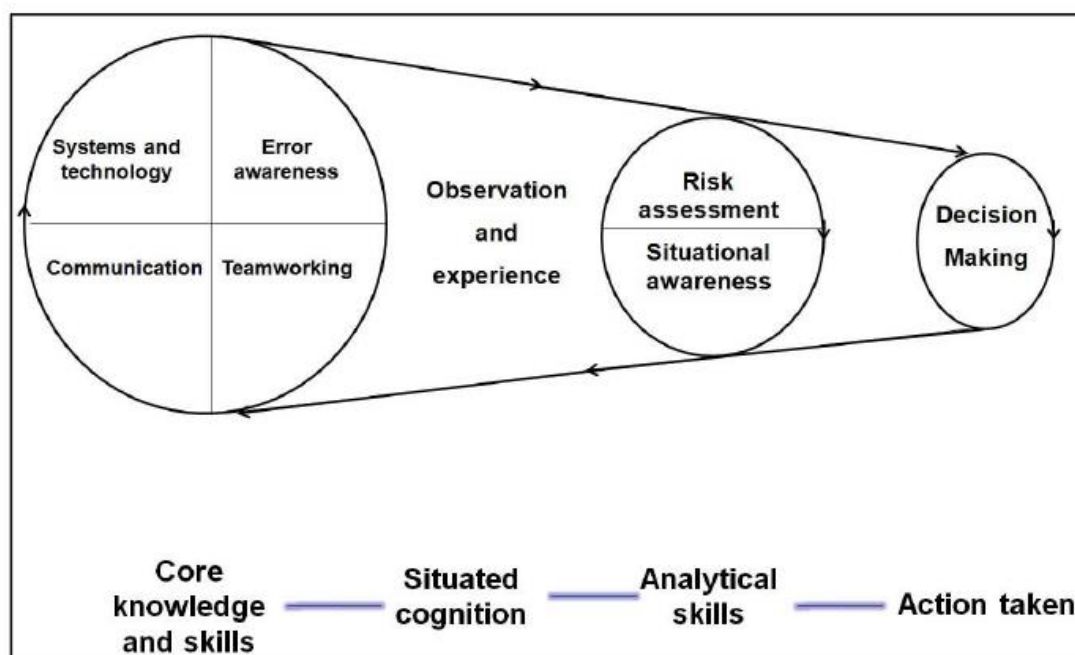


Figure 3. The SECTORS model

The building of this model, underpinned by a number of conceptual frameworks (**Gordon, Darbyshire & Baker, 2012**) offered a way to understand these phenomena (Bordage, 2009) and will aid instructional design in all spheres of education. The programme of study that led to its synthesis and proposal involves triangulation of a number of different studies, methods of inquiry, settings, learners groups and forms of analysis (Thurmond, 2001;

Patton, 2002). Whilst clearly professionals are increasingly recognising the importance of such teaching (Ross, 2009; Cahan, 2011; Bleetman, 2012; Turner, 2012) and many non-technical skills educational interventions exist within healthcare (**Gordon, Darbyshire & Baker, 2012**), to date no such model or framework existed. This clearly explains the heterogeneous nature of existing published interventions and lack of constructive developments in education within the field (**Gordon & Findley, 2011; Gordon, Darbyshire & Baker, 2012**).

Contributions and critique of the study

The innovative model developed within this longitudinal programme of sustained research is evidence based, theoretically grounded, reflective of the current body of published works, providing constructive developments in health care education. SECTORS is by no means a complete or proven educational model. Theories are dynamic entities (Norman, 2004), with emerging research challenging existing work and in turn leading to new theories. The development of SECTORS will help move the field forward in three key ways. Firstly, it will offer a simple and readily accessible option for those continuing research in the field. This will be particularly useful for those researchers who were aware of the lack of such a theoretically underpinned model, but due to local requirements and simple constraints on time and resources did not have the ability to synthesise their own. Lack of theory in medical education leads to descent into stagnation and dogmatism (Bordage, 2007). SECTORS will allow the amount of educational research that incorporates theory to simply increase and combat this decline. Secondly, the provision of a theoretical model to understand non-technical learning allows research activities to become theory testing, as well as theory driven (Norman, 2004) and as such move to explanatory (clarification) studies and facilitate deeper understanding (Cook, Bordage & Schmidt, 2008). Finally, the proposal of a theory or framework of understanding in the context of non-technical skills learning allows theory to be used not just to answer questions, but support the asking of new questions (Reeves, Albert, Kuper & Hodges, 2008). This illustrates the dual role of conceptual frameworks in framing questions and interpreting results (Bordage 2009). In a deductive qualitative inquiry, a conceptual framework can be used to formulate the questions and identify important variables to be analysed. In an inductive, grounded theory

approach, theories are postulated de novo as the researcher analyses the data (Harris, 2003).

Given that this study is the proposal of the model produced through the various works completed in previous studies in this programme of works, many of the criticisms that can be made of this model have already been discussed in the context of the individual studies. Despite this, two key issues need highlighting. Firstly, any one conceptual framework presents only a partial view of reality (from Schwab in Harris, 1991, p285-307). Despite the methodological robustness and sheer volume of work completed before proposing this model, readers must interpret SECTORS with this in mind. Future work will be needed to identify to what extent it represents this reality. This highlights the second major criticism that can be made of this study. SECTORS will only be of any importance if it is employed, refined or rejected. Any of those alternatives will be beneficial, even rejection, but without such scholarly discourse this endeavour will not move the field forward. So much focus of scholarly output is on the impact of the journal, but it can be argued that this does not have any actual significance, outside of the political or financial incentives (Saha, Saint & Christakis, 2003). In the context of such a social science innovation as the SECTORS model, to achieve the goals identified above that can move the field forward, such considerations are indeed important. The publication of SECTORS in a single manuscript does not achieve this and as such further works to enhance awareness of this model are required.

Summary of section two

A paucity of non-technical skills research represents a significant gap in the literature. Existing work confuses human factors with non-technical skills and focuses on ‘whether’ such education can be successful in healthcare, but ignores questions such as ‘how’, ‘why’, ‘when’ and ‘for whom’ (Blum, Raemer, Carroll, Felstein & Cooper, 2004; Haller et al., 2008; Lindamood, Rachwal, Kappus, Weinstock & Doherty, 2008; Blegen, Sehgal, Alldredge, Gearhart & Wachter, 2009; Cox, Scott, Hall, Aud, Headrick & Madsen, 2009; Jankouskas, 2010). This does not support educational design and represents poor quality educational research (Norcini & Banda, 2011).

This programme of works heralds a changing zeitgeist in this field, achieved through a paradigm shift in approach that has built theory to support new non-technical skills education (Haji, 2013). This research had developed and defined the key theoretical elements that underpin non-technical skills learning (**Gordon & Findley, 2011; Gordon, Catchpole & Baker 2013**) previously missing from all published works in the field (**Gordon, Darbyshire & Baker, 2012**). Appropriate pedagogical elements have been identified that support educational design area through confirmation of the relevance of existing elements identified (Chang, Arora, Lev-Ari, D’Arcy & Keysar, 2010; Marshall, Hall, & Taniguchi, 2008) through translation and triangulation works (**Darbyshire, Gordon & Baker 2013; Gordon, Uppal, Holt, Lythgoe, Mitchell and Hollins-Martin 2012**). Additionally, new methods have been applied to the area. These include in situ enhancement of error wisdom through a novel feedback mechanism (**Gordon & Bose-Haider, 2012**) and the identification of the key role of context within teaching design (**Gordon, 2012**). Finally, the ability of such educational interventions to be effective over a number of levels of educational outcome (Yardley & Dornan, 2012) has been demonstrated (**Gordon, 2013a**).

These various works have been integrated to allow the proposal of the SECTORS model (**Gordon, 2012**). This model has been formulated through appropriate medical education methodology (Norcini, 2011) and presents new knowledge and understanding of how and why non-technical skills learning occurs (Cook, Bordage & Schmidt, 2008) in a manner that illuminates and magnifies the field for educators (Bordage, 2009). This model will support dissemination and replication of better quality educational design, allow a move into theory

testing research (Norman, 2004) and support the asking of new questions (Reeves, Albert, Kuper & Hodges, 2008) moving the field forward in a manner that existing none theory driven works have not allowed (Bordage, 2007). Since the publication of this model, I have founded the Non-technical skills in Medical Education Special Interest Group (NOMESIG) to support these objectives through global collaboration.

SECTION THREE: Evidence synthesis as a tool to support educational innovation and enhancements in patient outcomes

Introduction

The origins of medical education were grounded in the practice apprenticeship as a long as two millennia ago, with knowledge a commodity passed directly to the learner (Drabkin, 1957). This knowledge could develop as expertise, but essentially was seen as truth. The twentieth century saw a paradigm shift in this viewpoint, with acceptance that knowledge and truth are contextual and in flux and so have to evolve (Sackett, 1997). Indeed, the information technology explosion led to a massive increase in the body of knowledge available to professionals. This offers great potential for increased clinical truth, but great risk (Altman, 1994). The thousands of irrelevant studies that may be thrown up by an online search form the fool's gold of the digital age (***Gordon, Darbyshire & Baker, 2013***). This is an even greater problem in the field of medical education, where multiple research methodologies are used by researchers from ideologically polarised backgrounds to answer the same question (Creswell, Klassen, Clark & Smith, 2010). The theme of this programme of works has sought to explore how evidence synthesis can be used as a tool in educational research and to move forward the body of knowledge and international conversation in this area.

In this section, it must be pointed out that as the state of knowledge in the limited and heavily cited literature regarding health professional education evidence synthesis has progressed significantly during the last 5 years. This must be considered when assessing the narrative of research works. The background section reflects a far more developed view of the field than the individual studies that indicates the spiral development of new knowledge through this thesis and the evolution of knowledge within the wider body of literature during the timeline of studies.

Background

The history of evidence synthesis in health care

The search for clinical truth to support health care delivery has always been at the heart of enhancing outcomes for patients (Kereiakes & Antman, 2006). The apprenticeship model of learning that had been the source of almost all knowledge in previous centuries gave way to an increasing information revolution (Laing, Hogg & Winkelman, 2004). There was an explosion in medical textbooks at the turn of the century, which were then superseded by an increasing range of medical journals (Claridge, 2005). However, on its own, this knowledge revolution could not deliver enhanced outcomes for patients (Forkner-Dunn, 2003), with research suggesting mild improvements in outcomes (Mckay, King, Eakin, Seeley & Glasgow, 2001). The most prominent concern raised by doctors at the outset of this revolution was the poor quality of much available information (Schactman, 2000). For many decades, there have been voices within health care raising alarm at the lack of evidence to support widespread clinical practice (Mulrow, 1987; Sackett & Rosenberg, 1995). This explosion in information in many ways compounded the problem and led to the development of a new movement to harness the great potential of such knowledge, Evidence-Based health care, first proposed in 1992 (Evidence-based medicine working group). One of the most widely accepted definitions of evidence-based health care was proposed by Sackett (1996: p71):-

'The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.'

Evidence-based health care involves the systematic collection, synthesis and application of all available scientific evidence, when available, not just the opinion of experts (Mohor, 1999). This represented a seismic shift from a position of expert based consensus guidance to evidence led guidance for evolving clinical knowledge (Burgers, Grol, Klazinga, Makela &

Zaat, 2003. The most important element of the Evidence-Based health care movement is an acceptance of the evolving nature of clinical truth. Researchers have sought to quantify this, no more elegantly than Hall and Platell (1997). They demonstrated that the half-life of clinical truth in the surgical field is 45 years and therefore within half a century 50% of what is known is wrong. This more than anything cements the need for a contemporaneous and evidence based knowledge base, rather than an expert led knowledge base (Poynard et al., 2002).

As the field of evidence-based health care evolved, new organisations spearheaded the development of such techniques (Social Science Research Unit, 2009), as well as supporting the dissemination of the required methodologies (Oxman, 1994). A central part of these new methodologies was the use of meta-analysis – literally an analysis of analyses (Glass, 1976). Meta-analyses pool individual study data to provide an overall estimate of the effect under consideration, leading to a stronger conclusion than any of the individual studies (Abrams, Jones, Sheldon & Song, 2000).

The use of this technique has proliferated, particularly within evidence based medicine, because of its ability to estimate the effect of an intervention (Chan & Arvey, 2012). The strength of meta-analysis in this context was demonstrated in a key review describing the efficacy of corticosteroids given to pregnant women who deliver premature babies (Crawley, 1990). The results of the meta-analysis of data demonstrated that administration of maternal corticosteroids significantly reduced morbidity and mortality among premature infants. The celebration of this discovery was tempered by the realisation that a similar meta-analysis of data up to a decade earlier in 1980 showed the same result. If the techniques of evidence synthesis been applied, the outcomes for premature babies across the globe could have been impacted and much harm avoided (Woloshin, 2013).

So uneasy was the impact of this realisation, that it inspired the formation of one of the key entities in the globe in the field of evidence-based health care, the Cochrane Collaboration (2013). The Cochrane Collaboration is an international network of more than 28,000 dedicated people from over 100 countries. They work together to help healthcare practitioners, policy-makers, patients, their advocates and carers, make well-informed decisions about health care, by preparing, updating, and promoting the accessibility of

Cochrane Reviews (Tovey, 2010), published online in the Cochrane Database of Systematic Reviews, part of The Cochrane Library. So key was Crawley's (1990) review to this endeavour, the data was incorporated into their logo (Figure 4).

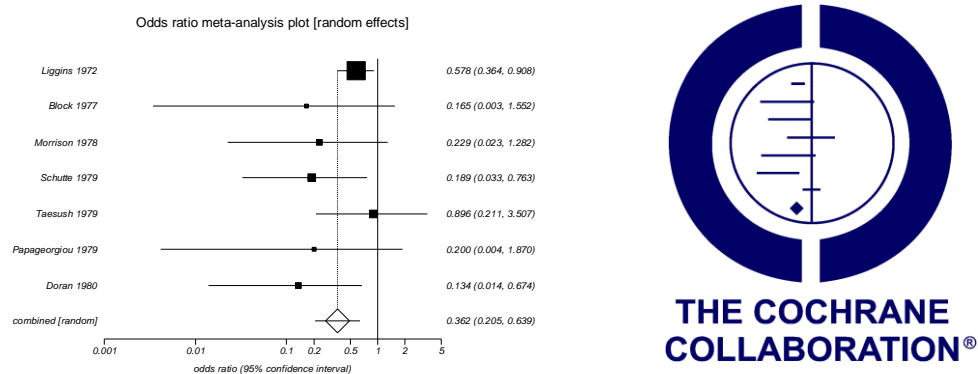


Figure 4. Meta-analysis from Crawley 1990 and corresponding data as part of the Cochrane logo

Cochrane led the formulation of the systematic approach to evidence synthesis, as categorised by systematic review (Doshi, Jones & Jefferson, 2012), to deal with the issues already highlighted by misuse of the tools of evidence-based health care (Mohar, 1999). Advocating the writing of a concise review protocol that is reviewed prior to work commences and the use of clear criteria regarding inclusion and exclusion, quality, strength of conclusions and lay summaries. Cochrane reviews are viewed as the benchmark in supporting evidence based decision making (Olsen et al., 2001). Similar organisations developed symbiotically through the last 20 years, including the Campbell collaboration focussing on education and justice (2013), as well as EPPI centre in public health and education policy (2013)

The need for and origins of evidence synthesis in health education

In the world of medical education, the issues of evidence synthesis are far more complex and challenging. For over a decade, there have been calls for medical education to become more evidence-based (Bligh, 2000; Carline, 2004; Chen, 2005). An article in the British

Medical Journal in recent years (Todres, 2007) sparked an active debate regarding the nature of quality within medical research, a key issue when synthesising evidence. The authors focussed on a lack of external funding and low quality evidence, concluding that medical education research lacks methodological rigour, compared to the accepted hierarchies of evidence in clinical medicine research.

Within clinical medicine, there is a very clear hierarchy of research methods (National Institute for clinical excellence [NICE], 2005), with higher level methods likely to contribute more to the wider 'clinical truth', often represented in the evidence pyramid (Gutiérrez Castrellón, Polanco Allué, Salazar & Lindo, 2010: p4). However, higher levels of evidence do not necessarily denote quality. For many years, checklists have been developed to identify key markers of quality or highlight areas of concern when reviewing studies such as randomised controlled trials (RCT) within the spheres of health care research (Moher, 1995). This allows not just the type of study, but its design and execution to be considered when synthesising evidence (Nuthalapasty, 2007), allowing the strength of conclusions to be tempered with this information or subgroup analysis to remove concerning research works. Entities who spearheaded evidence synthesis, such as Cochrane, have led these developments, with integration of such quality assessments in their expectations for systematic review (Higgins, 2001).

Comments regarding the poor quality of medical education research (Todres, 2007) prompted the presentation of a counter argument by a key member of the medical education research community (Dornan, 2008). This highlighted that medical education research 'cannot be viewed in such a uni-dimensional way' and eloquently summarised the evolving zeitgeist in the medical education research world that essentially suggests evidence should not be viewed in hierarchies of quality but should be selected like colours in a rich tapestry (**Gordon, Darbyshire & Baker, 2013**). This involves asking questions other than simply 'whether' interventions are effective (Prideaux & Bligh, 2002) and focussing on educational research outcomes that are likely to influence teaching practice (Prystowsky & Bordage, 2001).

Cook, Bordage & Schmidt (2008) reflected on these issues in more detail, identifying that unlike clinical medicine, educational research focuses on observation of phenomena and descriptions or tests of solutions, but often omits the middle step of model formulation, theory building or prediction. Whilst descriptions of new innovations and their assessment will always be needed, there is a requirement for a better balance of research that includes clarification studies to ask 'how' and 'why' (Albert, Hodges & Regehr, 2007)

It is important to recognise that this tapestry of research types (**Gordon, Darbyshire & Baker, 2013**) does not invalidate the issue of quality, but merely means that measures used in clinical medicine (Gutiérrez Castrellón, Polanco Allué, Salazar & Lindo, 2010) may not be appropriate to measure quality in this context (Norman, 2003). Eva (2009: p294) describes this as '*an endless oscillation between promoting the evolving empirically grounded approach and the associated criticisms of the accumulated findings*', concluding that quality in medical education research should be based on our understanding of the problems, rather than on whether or not a particular research methodology has been adopted. This means evidence synthesis in medical education must take an approach that focuses on questions other than 'whether' a particular education intervention is effective, but 'how', 'why', and 'when' education is effective (Pope, 2007).

Best Evidence Medical Education Collaborative: A critique

The Best Evidence Medical Education (BEME) collaborative was established in 1999 (Harden, Grant, Buckley & Hart), rejecting the use of anecdotal evidence in medical education and focussing on the use of evidence synthesis through systematic review. They set out to recognise the unique challenges of evidence synthesis in this field and support authors with a clear methodology. In achieving this goal, they attempted to grapple with the concept of evidence synthesis methodology to achieve this, producing often reviewed guidance pieces for researchers (Hammick, Dornan & Steinhart, 2010). These works have predominately provided insight into some of the methodological issues when establishing the process of systematic review in the context of medical education, such as sources of medical education evidence (Haig & Dozier, 2003a) and how to construct a search of these evidence sources (Haig & Dozier, 2003b). BEME has led the way in this area and these works have contributed

significantly to practice and essentially founded the process of evidence synthesis in health education, however there have been problems with the BEME movement that raise questions that have been considered and investigated throughout this thesis.

Firstly, critics have identified an undue focus on method which fails to address the underlying questions of significance that have already been identified as key. This can leave an educational systematic review presenting a coherent critique of quality, but not addressing the question of the review (Dolmans, 2003). This has been commented on as confusing the '*methods of science with the process of science*' (Berliner, 2002, p18). This focus on methods has meant that BEME output is limited, with currently just 20 published reviews 14 years after the founding of the organisation and only 10 published reviews at the time of starting this thesis. Consideration of the list of published reviews and there associated documentation (BEME, 2013) identifies a consistently large lag time between protocol and final publication, often a number of years. The recent and exponential increase in published reviews (doubling of output in the last 3 years compared to the 11 years previously) is a reflection of the refinement of these methodological issues and realignment of focus which allows greater facilitation of the review process by BEME.

Secondly, it has been recognised that BEME output has simply lacked the presentation of evidence in a manner that informs practice (Dauphinee & Wood-Dauphinee, 2004). Whilst this is concerning as the aim of BEME is to deliver such outcomes, It is possible that such conclusions in a BEME review are a true reflection of a paucity of evidence and as such can positively guide future research in an area (Albert, Hodges & Regehr, 2007). Considering the comments in the previous paragraph, it must be highlighted this is very much a capricious situation and even during this programme of works, the output from BEME has changed to better highlight the impact evidence that is uncovered may have on educators.

Thirdly, at the start of this programme of research, just one published BEME review made an explicit discussion of theory or conceptual frameworks in their introduction (Veloski, Boex, Grasberger, Evans & Wolfson, 2006) and none sought to extract explicit theory or frameworks from included papers or generate new theory from analysis of the evidence. There is a clear shift between the position at that time in 2010 and current output, with recent reviews highlighting relevant gaps in the theoretical understanding offered by the

primary research synthesised (Birden et al, 2013; Passi, Johnson, Peile, Wright, Hafferty & Johnson, 2013). There is also evidence of reviews using innovative qualitative techniques, such as realist approaches (Wong, Greenhalgh, Westhorp, Buckingham & Pawson, 2013) to generate new understanding from primary evidence. Ongoing reviews continue to show this evolution of focus with studies focussing on questions such as 'how' teaching is effective (Buckley et al., 2013) and one review specifically focussing on identification of relevant theory in a specific area of health education (Hean et al., 2013).

The potential for systematic review in health education has not been fully realised. Given calls for clarification and theory generation of primary educational research (Cook, Bordage & Schmidt, 2008), the same goal can be sought in the context of secondary evidence synthesis. Indeed, the view that theory is a product of observation and influenced by practice (Hean, Craddock & Hammick, 2012) highlights the role that an evidence synthesis piece can play in theory generation, as the complex and involved work of gathering an entire body of published educational work in a specific area means the research team have a unique insight to facilitate such objectives. Recently and after the completion of this programme of works, Bearman and Dawson (2013) have described the use of three qualitative synthesis techniques to support answering of such deeper questions. These techniques, thematic analysis, meta-ethnography and realist review, offer a set of tools to support generation of new knowledge in an area other than effectiveness. However, none of the examples cited in this piece use this techniques in the context of a complete systematic evidence synthesis, with weaknesses in the use of quantitative analysis techniques (Cook, Erwin & Triola, 2013) or the rigour of the systematic search methodology (Savin-Bader & Major, 2007)

Finally, BEME has primarily focussed on guidance and support for its Cochrane like (2013) process for systematic reviews, that supports large teams through an in-depth and robust process that achieves high quality output (BEME, 2013). However, little is offered to support smaller teams looking to complete education evidence synthesis outside of BEME, despite the existence of such support in other fields (Moher, Liberati, Tetzlaff & Altman, 2009; Campbell collaboration, 2013; EPPI Centre, 2013;). This lack of guidance leaves evidence synthesis activities outside of BEME at risk of significant heterogeneity and increases the difficulty for editors and peer reviewers in this context.

Summary

Evidence synthesis is vital to guide the evolution of healthcare knowledge and the move towards practising using the clinical truth (Burgers, Grol, Klazinga, Makela & Zaat, 2003). Medical Education has been identified of being littered with poor quality primary research (Todres, 2007). Reviews by organisations such as BEME (2003) have sought to address quality of evidence in this context and as such have identified the same issues of poor quality within primary educational research and as such highlighted such gaps in the evidence (Dauphinee & Wood-Dauphinee, 2004). However, this early uni-dimensional approach to considering quality has often been at the expense of useful outcomes (Dolmans, 2003). Educational research should consider a rich tapestry of research methods and questions (**Gordon, Darbyshire, Saifuddin & Vimalasvaran, 2013**) and this is reflected in more up to date output from BEME (2013).

Deeper questions such as ‘how’ and ‘why’ education is effective (Prideaux & Bligh, 2002), so called clarification studies that further theory and frameworks must be considered (Bearman & Dawson, 2013), but at the time of beginning this thesis could not be identified in the medical education literature. Guidance for those completing evidence synthesis of medical education evidence to answer such questions still represents a significant gap in the literature, despite the massive contribution of the BEME collaboration in essentially founding and developing the field. During this programme of study, these issues were investigated through evidence synthesis techniques employed to address the primary aims of the programme.

In particular, this researcher sought to develop and clarify methods for healthcare education evidence synthesis that can approach the synthesis of evidence compatible with those seen as clarification studies (Cook, Bordage & Schmidt, 2008) and deliver a deeper theoretical understanding of the issues at play to guide future educational innovations (Bordage, 2009). The context and focus for such investigation was particularly outside of BEME, reflecting the fact that the education systematic reviews included in this thesis were also completed outside of the BEME infrastructure. Finally, these techniques were employed to establish the effectiveness of evidence synthesis in leading educational practice within healthcare.

The role of included works

Both discussed in this section have been discussed before. However, in this section they are discussed with relevance to the fourth, fifth and sixth objectives of the thesis (Develop methods for evidence synthesis in health professional education evidence synthesis particular outside of BEME, Identify the contribution of evidence synthesis from other areas of health research and examine whether the results can guide educational design).

Gordon and Findley, (2011), Educational interventions to improve handover in health care: a systematic review

In beginning to answer the primary aim of this research programme discussed in Section two, it became apparent that assessing the level of current educational research in a sub-genre would support the development and application of appropriate conceptual frameworks for continuing research. The area selected for this initial work was handover of care (**Gordon & Findley, 2011**), a recognised key area of concern regarding patient safety (Arora, 2005). The questions being asked were not limited to effectiveness of education in this area, but also encompassed the characteristics of such education and how well it reflected appropriately identified conceptual frameworks in the field. As such, the questions being addressed were not just ‘whether’ the education is effective, but ‘how’, ‘why’ and ‘what’.

Contributions and critique of this study

A review of BEME guidance was undertaken whilst writing the protocol for this study (**Gordon & Findley, 2011**). The weaknesses of this guidance has been discussed at the beginning of this section. In this context, the lack of support to consider the research synthesis question ‘how can educational interventions to improve handover been underpinned’ was the most apparent area where this paucity of guidance existed (Prideaux & Bligh, 2002).

The BEME (2013) template for data extraction was employed in the assessment of characteristics of medical education research studies. However, no guidance was found within BEME on how to apply the statistical tools of meta-analysis more commonly

associated with Cochrane or when such tools may be appropriate. Key reviews in the field of education were also noted to be lacking such considerations (Cook et al., 2008; Ross & Loke, 2009). A more formal analysis of contemporaneous evidence synthesis works at the time was undertaken to clarify the methods that should be employed in this study.

The 2010 volume of the highest UK impact factor journals in the medical education field at the time (*Medical Education*) was reviewed. All papers categorised as review articles or stating they were reviews were obtained and analysed. This review purposeful disregarded BEME systematic reviews, given the work being completed was not done within the BEME collaborative and the limited state of the BEME published reviews at this time.

A total of eight studies were considered. Two papers offered a structured literature review (Baker, Reeves, Egan-Lee, Leslie & Silver, 2010; Nair & Webster, 2010), rather than a systematic evidence synthesis and so were not investigated further, leaving six papers (it is worth reflecting that this suggests there is still a sizeable output of systematic review in medical education published outside of BEME, with just two BEME reviews in 2010). Whilst four papers offered some mention of underlying conceptual frameworks or theoretical issues in the area as part of their background, two papers did not (Daley & Torrey, 2010; Jha, Setna, Al-Hity, Quinton & Roberts, 2010). Two papers did not discuss how they would deal with quantitative data in this context with techniques such as meta-analysis (Cook, Erwin & Triola, 2010; Daley & Torrey, 2010; Jha, Setna, Al-Hity, Quinton & Roberts, 2010; Murad, Coto-Yglesias, Varkey, Prokop & Murad, 2010). Whilst there were examples that did display the key characteristics required and in particular one that reflected on the lack of theory in the published works identified (Arora, Ashrafian, Davis, Athanasiou, Darzi & Sevdalis, 2010) and one that used thematic analysis to generate a deeper understanding of the research question (Cook, Erwin & Triola, 2010), this was not the standard and certainly there is no consistently reflected model in these high impact factor publications.

An approach to completing this study was developed that could investigate the multidimensional questions being asked in this review. The first element incorporated was consideration of appropriate conceptual frameworks. As discussed in section two, these play an essential role in identifying the nature of educational problems and in formulating solutions or designing studies (Albert, Hodges & Regehr, 2007). They help clarify and

magnify the issues at hand, being mindful that any single conceptual framework will only offer a partial view of reality (Harris, 1991). Therefore, those working without a conceptual framework or jumping quickly onto a single framework without exploring others will potentially limit their understanding of the area of investigation (Phillips, McNaught & Kennedy, 2010). Indeed, the consideration of alternate frameworks might allow multiple elements to be applied, like strands in the ever growing tapestry of knowledge and educational truth (Roland, Coats & Matheson, 2012). Different frameworks emphasise different variables and outcomes, and their inter-relatedness (Slotnick & Shershneva, 2002) and so play a key role in identifying the nature of education problems and in formulating studies to investigate them (Prideaux & Bligh, 2002). The use of frameworks in this context allows authors to be mindful of the assumptions and foundations of their work and makes the process transparent for the reader. At the time of completing this study, there were minimal educational evidence synthesis reports that considered existing theoretical elements (Arora, Ashrafian, Davis, Athanasiou, Darzi & Sevdalis, 2010) and none found in the field of medical education that looked to identify theory within studies as part of evidence synthesis.

Additionally, the content of the reported interventions were analysed in line with a thematic analysis qualitative approach (Dixon-Woods, Agarwal, Jones, Young & Sutton, 2005). This has also been more recently recognised as a method of qualitative analysis in health education evidence synthesis (Bearman & Dawson, 2013), but at the time was very innovative. Whilst the approach had been reported in this context just prior to the start of the study (Cook, Erwin & Triola, 2010), this was without the consideration of conceptual or theoretical elements. The unique innovation of combining recognition and consideration of theory with a qualitative method to synthesise evidence allowed a set of elements to be formulated into a new model for teaching handover in healthcare based on the evidence. This movement from theory identification or theory testing to theory generation is novel in this context.

When critically considering the final synthesised published work (**Gordon & Findley, 2011**), it is apparent that it examines and considers quality of evidence using a number of indices suggested by BEME, taking a multi-modal approach. It allowed existing conceptual frameworks and new theory to be synthesised in light of the evidence. The addition of this

theoretical dimension that facilitates synthesise of a new conceptual framework to guide education is a small but key step in the medical education evidence synthesis field.

There is a suggestion within the text that the use of Kirkpatrick's hierarchy (2009) as part of the reported quality criteria may act as a set of independent indices to measure quality. This scale denotes increasing difficulty of study design or complexity of educational outcomes with the environment completed, but does not denote quality, as has been confused by previous review pieces (Roland, Coats & Matheson, 2012; Ross & Yoke, 2009) and certainly does not inform the justification study questions identified as important (Cook, Bordage & Schmidt, 2008). Since publishing this work, this issue was discussed by Yardley and Dornan (2012) who strongly rejected the notion that Kirkpatrick's hierarchy could act as an arbiter of quality. In this work, it was meant merely to categorise evidence, but this should have been more explicitly stated.

Gordon, Darbyshire & Baker, (2012), Non-technical skills training to enhance patient safety: A systematic review

In planning this study, further work was needed to identify a more structured approach to evidence synthesis in medical education to build on the techniques that had been used (Gordon & Findley, 2011). A literature review using the following search strategy:- ('systematic review' OR 'meta-analysis' OR 'evidence synthesis' OR 'publication standards') AND ('checklist' OR 'reporting' OR 'statement') was undertaken in the Medline database from 1993 to present day. Papers reporting a standardised set of criteria for any form of evidence synthesis in healthcare were included. Four such publications were deemed relevant (Stroup, 2000; Moher et al, 2009; Riley, Lambert & Abo-Zaid 2010; Wong, 2013). A fifth paper was excluded as it reported the QUOROM statement (Moher, Cook, Eastwood, Olkin, Rennie & Stroup, 1999), which was a precursor from the group who went to develop the included PRISMA statement (Moher, Liberati, Tetzlaff & Altman, 2009) and they are essentially homogenous. Analysis of these checklists found a key list of consistent items occurring in all such statements (Table 1).

- Describe as a systematic review piece, with specific type mentioned
- Provide a structured summary
- Describe the rationale for the review in the context of what is already known
- Provide an explicit statement of questions being addressed
- State why this method of review was selected
- State and provide a rationale for how the searching was done
- Provide details on all the sources of information and dates searched
- Electronic database details should include full search terms for at least one database
- If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified, selected, contacted and what they contributed
- Explain how judgements were made about inclusion / exclusion
- Describe the process of data extraction and any process of contacting authors for confirmation of / or more data
- Describe and justify the method of analysis and how quality was assessed
- Give a flow diagram summarising study selection
- Provide the characteristics of all included documents
- Present the main findings in light of the reviews objectives
- Discuss strengths and limitations of the review and its findings, commenting on the strength of the evidence
- Give guidance for future research
- Provide details of funding

Table 1. Common items to reported systematic review statements/checklists

These items were deemed a bare minimum set of reporting items for any evidence synthesis and incorporated into the protocol for the evidence synthesis utilised for this study (Gordon, Darbyshire & Baker, 2012).

Contribution and critique of the study

This piece had a significant impact on all areas and aims of this programme of research, as well as the wider literature. The findings facilitated a change from theory building to testing of theoretical elements within the primary aims of the programme (section two). This study also furthered all the secondary aims of the project (objectives four – six). The methods for evidence synthesis applied previously (**Gordon & Findley, 2011**) that considered development of theoretical models and frameworks using a thematic analysis approach were developed. Much more interpretation occurred, beyond the individual study data, in line with a meta-ethnographic approach, recently identified as an appropriate tool for qualitative synthesis in this context (Dixon-Woods, Agarwal, Jones, Young & Sutton, 2005). This was used to generate new theory from primary content of the individual studies. This technique allows the move towards clarification studies in primary educational research to be addressed through corresponding clarification studies through secondary evidence synthesis (Cook, Bordage & Schmidt, 2008), a significant and novel contribution to the field (objective four). Additionally, meta-analysis was employed within this study, building on the skill and method developed in other works (**Gordon, Naidoo, Akobeng & Thomas, 2012**) and meeting objective five. Finally, the new model synthesised was presented in a manner that could facilitate future educational innovation (objective six). Further works employed this model to design and implement educational innovation (**Gordon, 2013b**)

This study made a significant and unique contribution to the field of non-technical skills education. However, this paper is also a progressive example of systematic review methodologies within medical education, as demonstrated in the editor's decision to publish it as a leading article with an accompanying critical commentary in the journal *Medical Education* that focussed on the methodological aspects of the work. The commentary (Kilminster, 2012) essentially summarised the counter arguments to the view presented in these thesis regarding quality in medical education and the role of evidence synthesis. Kilminster (2012) argued that perhaps there are limitations to the usefulness of systematic review, based on the fact that in our study (**Gordon, Darbyshire & Baker, 2012**) that over 400 manuscripts were identified in our electronic search and only 30 reviewed in

full. This was an interesting issue and one we chose to address in our response (**Gordon, Darbyshire and Baker, 2013**). The response clearly highlighted that the strength of systematic review as a form of evidence synthesis is that through constructing an appropriate and transparent search strategy, the research rejected should not be relevant. Whilst assumptions are made in this process that may limit the scope of such work, as long as these are clearly signposted, the value of the product remains.

In the past, a concern highlighted with evidence synthesis in medical education was that rejection of research deemed to be low quality can ignore useful sources of evidence (Dolmans, 2003). However, we maintain this is an issue of methodology (**Gordon, Darbyshire & Baker, 2013**) and as long as it is clear the reader how and why such decisions were made, the role of the process as a gold standard to clarify the state of the science remains. The paper also argued this clarification of assumptions in methodology is more important in the field of medical education than other areas and suggested the need for a shift from trying to answer 'whether' education is effective, to answering the 'how', 'why', 'what', 'when' and 'who' questions, that are generally far more enlightening and could be addressed through the innovative methods adopted within the review. This is in line with the position presented within this thesis.

Continuing and future study

Towards an international consensus for medical education evidence synthesis

Throughout these works there is a clear ideological alignment with leading scholars in the field regarding quality of education research (Pope, 2007; Dornan, 2008), studies have integrated methods within research that consider theory (**Gordon & Findley, 2011**) and allow generation of new theory (**Gordon, 2013c**). This novel and unique contribution to the field has clearly had an impact on the readership of the key journal in the field, igniting debate (Kilminster, 2012). It seems that there may be a role for the approach that has been developed for medical educational evidence synthesis, particularly as such methods are increasingly being reflected in new and in progress works at present (BEME, 2013). Recently and after completion of these research works, Bearman & Dawson (2013) have described key techniques that can be employed to qualitatively synthesise evidence to enhance the review questions. However, this piece and the studies it cites as examples have not till now

successfully integrated these techniques with a robust systematic review technique in a manner that can build theory (although they do offer more dimensions of considering evidence), as reported in this thesis.

BEME guidance on how to complete education systematic review (BEME, 2013) is still lacking in the area of considering theoretical analysis and theory generation and is struggling with the role of elements such as Kirkpatrick's hierarchy (Yardley & Dornan, 2012). Checklist tools are well reported in the literature, both for guidance on the completion of and reporting of research, as well as considering primary research (Moher, Schulz & Altman, 2001) and secondary evidence synthesis works (Moher, Cook, Eastwood, Olkin, Rennie & Stroup, 1999). They offer quick and clear guidance to authors planning and reporting research, as well as support to editors and peer reviews judging the quality of such work.

Reflecting on the contents of table 1, there is some consensus on the key constituents for secondary evidence synthesis amongst checklist tools that may be relevant in medical education, however far more telling is the limited scope of this list (Stroup et al., 2000; Moher et al., 2009; Riley, 2010; Wong, Greenhalgh, Westhorp, Buckingham & Pawson, 2013). By comparison, the BEME collection of papers and tools is far more comprehensive (BEME, 2013), but still lacking in key areas identified above. Ultimately, it seems there is little to guide medical education researchers towards the specific form of secondary level research that is being proposed to support and reflect the shift in primary research that is being called for in the literature (Bordage, 2009; Eva, 2009; Moher 2009; Riley, 2010; Wong, 2013).

When considering the three systematic reviews in this body of work, as well as the more recent synthesis projects (Bearman & Dawson, 2013; Hean et al., 2013), it seems that there are a number of additional criteria that are salient to medical education evidence synthesis works (Table 2).

- Describe relevant background theory or conceptual frameworks to underpin the educational question being posed
- Clarify the exact question being asked, considering If it addresses issues such as 'whether', 'why', 'who', 'what', 'when', 'for whom' and 'how' or in terms of 'clarification', 'description' or 'justification'.
- Present the characteristics of studies in a multidimensional manner
- If reporting educational interventions, report if studies gave details to allow replication and where these resources are located, as well as resources needed
- Consider quality of educational research in a multi-dimensional manner, with several indices
- Describe when and how meta-analysis will be performed
- Comment on heterogeneity from an educational, methodological and statistical perspective (where appropriate).
- Describe qualitative methods for synthesising evidence and the goal of these methods, such as thematic analysis; meta-ethnography, and realist synthesis

Table 2. Additional checklist items suggested for medical education systematic review

This list is obviously grounded in the works completed in this thesis, as well as reflecting the wider international literature (BEME, 2013; Cook, Bordage & Schmidt, 2009), but is a construct of this author. Whilst the specifics may be argued, the case for an international position statement for medical education evidence synthesis seems clear, in line with previous statements in the realms of clinical medicine, including CONSORT for primary research (Moher, Schulz & Altman, 2001) and QUOROM for secondary research (Moher, Cook, Eastwood, Olkin, Rennie & Stroup, 1999). Such a statement will guide authors when writing protocols and journal editors when assessing manuscripts. It also offers the potential to inform and raise the quality of primary research, by clarifying the criteria on which the quality of studies will be judged.

Whilst significant evidence has been discussed that raises concerns regarding the quality of medical education research in the past (Dornan, 2009; Todres, 2007) recent work would suggest that quality is still an issue (Fokkema & Teunissen, 2013; **Gordon, Darbyshire, Saifuddin & Vimalasvaran, 2013**; Verkoeijen & Tabbers, 2013), despite some guidance and a position statements (BEME, 2013). Since publishing the last review in this thesis (**Gordon, Darbyshire & Baker, 2012**) a number of new BEME reviews have been released that also begin to integrate theory generation from evidence (Birden et al, 2013; Passi, Johnson, Peile, Wright, Hafferty & Johnson, 2013). An evidence synthesis checklist and position statement developed through the expert consensus method used in similar statements previously (Moher, Cook, Eastwood, Olkin, Rennie & Stroup, 1999; Moher, Schulz & Altman, 2001) could ensure the increased use of these methods whilst ensuring homogeneity of methodology, both for BEME and non-BEME reviews.

BEME have since funded such a project to be completed by the author. This project is seeking to develop such a statement through a Delphi process, gaining international consensus and offering their backing to its dissemination on completion. This ongoing study is clearly an evolution of the works completed through this programme of study and will make a significant international contribution to the field and signal a conceptual and pragmatic jump in the medical education evidence synthesis field.

Summary of section three

Whilst the field of evidence synthesis has grown exponentially in the last 20 years, developments within the medical education world have been slow in this area (Prideaux & Bligh, 2002). There is widespread agreement that quality in this context is different to clinical medicine meaning a multi-modal method of assessment is needed (Dornan, 2008) and that evidence synthesis in this context must seek to address more than simply 'whether' interventions work. Consideration of theory (Bordage, 2009) that can support the asking of questions such as 'why' and 'how' education works can be achieved through such works (Cook, Bordage & Schmidt, 2008). Early guidance from BEME was identified as having an undue focus on methodology (Dolmans, 2003) and a lack of recognition of how to deal with these so called 'justification' studies (Cook, Bordage & Schmidt, 2008), although this is improving in more recent iterations (BEME, 2013). This has meant significant heterogeneity

in published works (Fokkema & Teunissen, 2013; **Gordon, Darbyshire, Saifuddin & Vimalasvaran, 2013**; Verkoeijen & Tabbers, 2013), similar to the problems experience by those reporting general clinical systematic reviews 15 years ago (Moher, Cook, Eastwood, Olkin, Rennie, Stroup, 1999).

Through a consideration of those existing tools and the use of methods developed through this research to integrate theory building elements into qualitative evidence synthesis techniques are now increasingly recognised in this context (Bearman & Dawson, 2013), a significant contribution has been made to the literature in this area. The current scholarly conversations and zeitgeist in medical education are reflecting these issues (**Gordon, Darbyshire & Baker, 2013**; Kilminster, 2012), with evidence of integration of these ideas in forthcoming works to be published (Birden et al., 2013; Passi, Johnson, Peile, Wright, Hafferty & Johnson, 2013). Continuing works are supporting the international development and dissemination of these concepts to support a global consensus to support high quality medical education evidence synthesis.

Section four: Discussion and Conclusions

Non-technical skills training in healthcare: The contribution of the SECTORS model

Interest in human factors within healthcare has increased exponentially over the last decade (Catchpole, 2013a), but much work to embrace this concept has been misinformed, misguided or misdirected (Bleetman, Sanusi, Dale & Bruce, 2012; Cahan et al., 2011; Ross, Rothnie, Parmalee, Masta-Gornic & Pohl, 2009; Turner, 2012). As is often the case when work is extrapolated from another field (Carroll, 1997), the tenants of such work in other technology advanced industries do not hold water in this context. This is not to say that the human factors revolution is wrong, but that change is needed (Russ, Fairbanks & Karsh, 2013).

Catchpole (2013a) calls for a greater presence of human factors in the design of clinical systems and technologies, the field to develop accreditation for professionals working in healthcare and the need to deliver training programmes in behavioural change and in system-level human factors, non-technical skills and appropriate analytical techniques. Whilst this first item is very much the realm of the psychologist, the last two need educators to embrace the issue. And in there lies the problem. Human factors and non-technical skills is vastly under discussed in the medical education literature, as reflected in the limited citations in this body of work. The values and ideals of quality in educational innovation were found to be almost completely absent in the published literature within several of the studies in this programme of works (**Gordon & Findley, 2011; Gordon, Darbyshire and Baker, 2012**).

The aim of these works was to address this gap in the literature. Through the works of this thesis, some of the key educational matters that arise when discussing new interventions have been addressed. Of particular note is the shifting of focus from effectiveness issues such as ‘whether’ education is effective and asking deeper and more useful questions (Cook, Bordage & Schmidt, 2008; **Gordon, Darbyshire & Baker, 2013**). These deeper questions that inform educators are more useful for clinical teachers and have been addressed whilst

meeting the objectives of this thesis, representing a new and important contribution to the field. :-

- Why does non-technical skills learning impact on the core skills identified? – the conceptual frameworks identified discuss theories that may explain why non-technical skills learning is needed (**Gordon & Findley, 2011**) and why education underpinned by these elements may be effective (**Gordon, Darbyshire & Baker, 2012**)
- How should such education be constructed? – grounded theory works have investigated how professionals learn non-technical skills (**Gordon, Catchpole & Baker, 2012**) and how key theoretical elements can be used to allow this to happen in a structured educational intervention (**Gordon, 2013b; Gordon 2013b**).
- When should such education be delivered? – the issues of safety and how this impacts on the timing of such education has been considered (**Gordon, 2013a**)
- Who should such education be delivered to? – the role of the multi-professional team has been investigated (**Gordon, Holt, Lythgoe, Mitchell & Hollins-Martin, 2012**) as well as considering different learning groups within the interventions produced (**Gordon, 2013b**)
- What should be delivered? – Education elements have been designed, piloted and tested, with clear reporting of pedagogy to allow replication and dissemination (**Gordon & Bose-Haider, 2012; Gordon, 2013b**)

Additionally, whilst clearly not the focus of this work, the question of effectiveness has also been considered through application of elements of the SECTORS model (**Gordon & Bose-Haider, 2012; Gordon, Holt, Lythgoe, Mitchell & Hollins-Martin, 2012**) as well as the complete model (**Gordon, 2013a**) to educational design with assessment of key outcomes. These include demonstration of effectiveness at several levels of Kirkpatrick's hierarchy (Yardley & Dornan, 2012) in several groups of learners in a number of environments, including Level 1, satisfaction with education (**Darbyshire, Gordon & Baker, 2013; Gordon, 2013a**), level 2a, change in patient safety attitudes (**Gordon & Bose-Haider, 2012; Gordon, Holt, Lythgoe, Mitchell & Hollins-Martin, 2012; Gordon, 2013a**) and level 3, change of

behaviour (**Gordon & Bose-Haider**). Clearly, much of the justification for the unique and valuable contribution of this programme of study to the wider literature has been based on the limited importance of such outcomes in informing educators (Dornan, 2008). However, when addressed in combination with the outcomes investigated, the result is a significant multi-modal package of investigation that supports readers in educational innovation in the future.

The SECTORS model is the culmination of this work and illustrates the paradigm shift in focus that is needed. This is the first piece of work that considers non-technical skills in healthcare from an educational perspective. This evidence based, conceptually underpinned, theoretically driven model for learning allows those planning such educational innovations to ensure consistency and appropriate educational design. As the field develops, the model will be refined, rejected or accepted. Whichever occurs, the synthesis of this model will support scholarly developments in this vital area of healthcare and patient safety education.

SECTORS can be applied for a number of purposes in a number of settings. SECTORS can be used at the curriculum planning stage for all health professionals to support the integration of appropriate learning outcomes within varied areas of a curriculum. As the skills it identifies are usually addressed in a number of areas, ensuring that opportunities to support acquisition of non-technical skills are identified and then taken is a key strength of the model. SECTORS also forms a framework for educators looking to design new educational components in areas pervaded by non-technical skills, such as handover or prescribing. In this context, the SECTORS model would be used to underpin teaching methods and content and so maximise the potential for key non-technical skill outcomes to be addressed. For example, in the context of medicines safety, SECTORS would support awareness of local error data that grounds itself in consequences for care. SECTORS would also support education that took a situated cognition approach, in this example through practical simulation and observation within the learners setting and modelling of behaviour change through enhanced non-technical skills. SECTORS also forms a framework for designing assessment, by identifying relevant areas of learning and so a conceptual framework to underpin the testing of acquisition of these areas of learning. Finally, SECTORS forms a foundation for further scholarly discourse (Bordage, 2009). It allows the discussion to move

to one of clarification of theory and as such supports further scholarly endeavours that may illuminate and magnify the questions at hand (Cook, Bordage & Schmidt, 2008).

Evidence synthesis in healthcare education: The state of the field

Medical education research has been viewed by many in health as a weak area in comparison to clinical medicine, with the lack of high level study methodologies denoting a lack of quality (Todres, 2007). This clearly reflects a lack of understanding of social science (Dornan, 2008), but unfortunately for different reasons there is some truth to this concern (**Gordon, Chandratilake & Baker, 2013**). For it is not the choice of methodology that is often problematic, but their poor execution or poor writing (**Gordon, Darbyshire & Baker, 2013**). This may reflect that many publishing within medical education do not have an educator or social science background and are simply keen clinical educators (**Gordon, 2013b**). This problem amplifies the need for robust methods of evidence synthesis in the field to help working educators to find 'educational truth' to support their works (BEME, 2013).

Through these works, evidence synthesis has been employed within medical education and, through supporting works, in a general clinical context (**Gordon, Naidoo, Thomas & Akobeng, 2011; Gordon, Naidoo, Thomas & Akobeng, 2012**). These works have not simply sought to adhere to or emulate existing guidance, but to move the field forward (Tabbers, 2013). In quantitative effectiveness terms, looking at the second cochrane review completed with the supporting works, the complex reviews undertaken has employed innovative statistical techniques to allow meta-analysis of otherwise heterogeneous data (**Gordon, Naidoo, Thomas & Akobeng, 2012**). When original data is not available, such techniques could be useful and this methodology, only recently reported in the statistical literature (Mant et al., 2009), can be of benefit to the wider Cochrane community.

It is within the context of medical education evidence synthesis that the most work has been completed. Integration of adherence to conceptual frameworks (Bordage, 2009) and their use to synthesis new theoretical knowledge from education content using the qualitative methodology of thematic analysis (Bearman & Dawson, 2013) was novel within evidence synthesis in education (**Gordon & Findley, 2011**). This technique mirrors calls for similar focus on theory generation in primary educational research (Cook, Bordage &

Schmidt, 2008). Further works followed this same basic methodology, but using a meta-ethnographic approach (Bearman & Dawson, 2013) to synthesis new theoretical knowledge from the literature (**Gordon, Darbyshire and Baker 2012**) and now there is evidence of other researchers applying these techniques (Birden et al., 2013; Passi, Johnson, Peile, Wright, Hafferty & Johnson, 2013). These works have sparked scholarly debate (Kilminster 2012) and discussions regarding integrating qualitative synthesis techniques into medical education systematic review (Bearman, 2013). Continuing works are seeking to integrate these techniques into a single consensus statement for medical education evidence synthesis, similar to those in other areas (Stroup et al., 2000; Moher et al., 2009; Riley, 2010; Wong, Greenhalgh, Westhorp, Buckingham & Pawson, 2013). If this can be achieved, widespread dissemination of high quality medical education evidence synthesis to support better education and outcomes can be achieved in line with the ideals of BEME (2003) and match the progress of synthesis techniques in the wider domain of evidence based healthcare can be achieved.

Methodology and limitations

Throughout this thesis, consideration of individual methodology of each study with critique has been undertaken. However, these works may also be considered as a single piece and as such, questions can be raised. In particular, when the first two primary aims of these works are considered (clarify conceptual and theoretical elements for non-technical skills education, identify relevant pedagogy for design), an alternate mode of study involving a focussed grounded theory approach in a single qualitative study may have been used. Such a study could have sought to collect large amounts of qualitative data from professionals in healthcare to determine their experiences of learning regarding non-technical skills and use this to build a theoretical model of what education may look like. Such an approach would have had several strengths. Firstly, it would have allowed energies to be concentrated to achieve a much larger data set than in some of the individual studies with triangulation of several streams of data to ensure saturation (Walsh, 2013). Secondly, as a true piece of grounded theory work (Patton, 2002), the project could have responded to the emerging data and been seen as a far more appropriate of the 'truth' of the data set (Strauss, 1998). Finally, such a project may have allowed a more focused development of core skills in grounded theory research, specifically in the realms of qualitative interviewing and analysis.

However, the benefits of this approach would have been outweighed by the disadvantages. Firstly, this is an area on which much education literature exists (Wong, Etchells, Kuper, Levinson & Shojania, 2010; **Gordon & Findley, 2011; Gordon, Darbyshire & Baker, 2012**). Whilst there are key weaknesses in that evidence base, to ignore it would have been unjustifiable. Although sporadic and heterogeneous, there were clearly emerging content themes and teaching methods. Indeed, the areas where there was a lack of concordance were found to be just as informative (**Gordon, Darbyshire & Baker, 2012**). Scholarly research using conceptual frameworks should seek to build upon proceeding work in ways that allow individual researchers to develop their own personal understanding and lead to explanatory (clarification) studies and deeper understanding that help to move the field forward (Cook, Bordarge & Schmidt, 2008). This programme of study has certainly sought to achieve this goal. Since completing these works, meta-ethnography as a technique to generate new insights from existing works has been recognised as appropriate in this

context (Bearman & Dawson, 2013), further highlighting the contribution of this technique to the field.

Secondly, a single grounded theory study for such a vast and complex area would have been open to bias, mostly from the interpretations of the author, minimised within several smaller peer reviewed study publications with multiple collaborating authors. Finally, a number of conceptual elements already existed and had been applied to elements of non-technical skills education. A grounded theory approach would have initially ignored these and as such, whilst generating new knowledge, that understanding would have been highly influenced by the unique circumstances of the research in question, limiting the extent to which findings could be generalised. In contrast, the advantage of undertaking a longitudinal multi-faceted programme of study with multiple partners, across different institutions, involved in the education of different multi-professional learners, not only minimised the risk of bias, but increased the reliability, versatility and validity of the model to different settings and education programmes.

This body of work does have a number of key limitations that need to be considered when judging the strength of the model that has been synthesised. Primarily, whilst the model reflects a considerable and varied body of work with many collaborators, this author has undertaken the majority of the work as the main contributor. Clearly, the author's views are therefore inherently reflected in the model synthesised. Additionally, whilst involving many different settings, topics and learners, all this work is situated in the North West of the UK within the NHS and publically funded higher education system. This may limit the application of the findings in other settings, but this limitation cannot be quantified. It must be noted that during the earlier works of this programme of study (**Gordon & Findley 2011**), the author has related concepts such as human factors and non-technical skills with the same flawed understanding that is pervasive within the wider conversations on this issues. Within this text it is clear that a deeper and as has been proposed more appropriate understanding of this issues must be fostered, but it is important to note that these works themselves were initially grounded in that stance. As the 'educational truth' of these works emerged, this view as rejected and as such it is not felt that this diminishes the strength of the findings. However, it may be argued that this does weaken the strength of some of the statements of conclusion within the individual works. Finally, the model synthesised has

been grounded in two key themes, handover and prescribing. It is difficult to comment on whether this limits the general use of the model.

Reflections on skill development throughout these works

This thesis presents a body of published work completed over a four year period, but with ties to a wider continuum of supporting research in evidence synthesis and patient safety education dating back seven years. Whilst the contributions to the wider field have been discussed in detail, it is appropriate to reflect on the personal scholarly development I have undertaken whilst completing these works.

Throughout the studies presented, there is clear evidence of development of key skills in qualitative research techniques from initial consideration of content as an outcome with generation of key themes (**Gordon, 2013a**) to detailed, robust research that contribute significant new knowledge through grounded theory methodology (**Gordon, Catchpole & Baker, 2013**). The development of these skills is evident in the increasing sophistication of methodological descriptions and scholarly conversations presented in these papers.

The ability to integrate theory into educational research has also been evolved through these works, with a move from consideration of theoretical elements (**Gordon & Findley, 2011**) to integration of these elements into a conceptual framework (**Gordon, Catchpole & Baker, 2013**) and finally, theory generation (**Gordon, 2013c**). This use of theory has also been integrated into evidence synthesis in a novel manner (**Gordon, Darbyshire & Baker, 2012**). Through these works and various supporting pieces, there is evidence of clear development in my scholarly execution and scholarly writing skills (**Gordon, Darbyshire & Baker, 2013; Gordon, Chandratilake & Baker, 2013; Gordon, 2013**).

The written works presented have been supported with 19 oral and poster presentations at international scientific meetings over three years (Appendix 5). This has allowed refinement of wider presentation and communication skills to reflect the enhanced scholarly skills in this thesis. Additionally, this has supported scholarly conversations that have allowed development of new working relationships and outlets for future works, such as the founding of NOMESIG (Non-technical skills in medical education special interest group).

This thesis demonstrates that this ability to converse with experts in the medical education field has also been transposed to writing within peer reviewed journals (**Gordon, Chandratilake & Baker, 2013; Gordon, 2013**). This research demonstrates the use of a

variety of research techniques and an understanding of the issues that face the wider field so as to support the development of important questions that can impact on research and educational practice. This work highlights my ability to plan, execute and output research in an appropriate peer reviewed context so as to support and lead developments in the field. Finally, these works have shown that I am able to show scholarly leadership and contribute to the wider body of scholars through works with key bodies, such as BEME and the founding of NOMESIG.

Outcomes

The following key outcomes have been achieved through this programme of works:-

- The key theoretical elements and conceptual frameworks that underpin non-technical skills education in healthcare have been identified and used to construct the SECTORS model (objective one)
- The pedagogical foundations of non-technical skills education in healthcare have been identified and applied to produce educational innovations for a number of learner groups (objective two)
- Educational effectiveness of these interventions have been assessed in a number of ways, including learner satisfaction, enhancement of knowledge, skills and attitudes and changes to behaviour within the workplace (objective three)
- Methods for medical education evidence synthesis have been developed that support identification and consideration of theory in primary evidence (objective four)
- The use of thematic analysis and meta-ethnography has been integrated with these techniques to generate new theory (objective five)
- Statistical methods have been applied to support meta-analysis in a novel manner within evidence synthesis (objective five)
- The results of such evidence synthesis have been used to generate new theory to guide educational innovation (objective six)

Recommendations and future research

Based on these outcomes and the wider findings of the studies presented the following recommendations for practice and future research can be made:-

- Curriculum planners should apply SECTORS to guide integration of appropriate non-technical skills elements within all health professional courses
- Research is needed to clarify the individual elements of non-technical skills that need to be addressed at the competency level to support curriculum planning and assessment. Such work should be related to the theoretical elements designed
- Educationalists seeking to produce non-technical skills teaching should apply SECTORS model to underpin these innovations and describe how these was achieved in a manner that can support critical analysis of the model
- Researchers reporting in the literature should describe pedagogical elements used when designing and delivering all forms of non-technical skills education to support future developments
- These activities should be used by researchers to refine, reject or confirm the appropriateness and applicability of the SECTORS model
- Guidance for evidence synthesis in medical education must be refined to include theory identification and theory generation
- A consensus statement or checklist is needed to support consistency and completeness of reporting of healthcare education evidence synthesis within the literature outside of organisations such as BEME

Taking forward this work, as part of NOMESIG, we are conducting a study to reach a consensus on competency standards for non-technical skills in medical education through a Delphi process. This study is at round two of the Delphi process. The Association for Medical Education in Europe has commissioned a team, led by myself, to write a book as part of their AMEE guide series on Non-technical skills education. In the area of evidence synthesis, BEME is supporting a project to design a reference standard for medical education systematic review reporting which will support quality assessment and act as a gold standard for those synthesising such manuscripts for dissemination in all contexts.

Conclusions

Through this programme of research, an evidence based theoretical model has been developed to understand how non-technical skills learning occurs and to facilitate instructional design to enhance patient safety and outcomes for patients. SECTORS can support curricula design, educational innovation and design of assessments. SECTORS will support future scholarly research, allowing the field to move from theory generation to theory testing and refinement.

Building on existing guidance and in response to calls for more theoretical generation in primary educational research, a complete method for health education evidence synthesis has been developed and applied. This method allows clarification of educational questions through generation of conceptual frameworks and new theory within a systematic framework and represents a significant contribution to the field. Future research is needed to assess the appropriateness and utility of this model and to further develop and extend the methods of systematic review.

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Appendix 1

Included papers

Educational interventions to improve handover in health care: a systematic review

Morris Gordon^{1,2} & Rebecca Findley²

CONTEXT Effective handover within the health care setting is vital to patient safety. Despite published literature discussing strategies to improve handover, the extent to which educational interventions have been used and how such interventions relate to the published theoretical models of handover remain unclear. These issues were investigated through a systematic review of the literature.

METHODS Any studies involving educational interventions to improve handover amongst undergraduate or postgraduate doctors or nurses were considered. A standardised search of online databases was carried out independently by both authors and consensus reached on the inclusion of studies. Data extraction and quality assessment were also completed independently, after which a content analysis of interventions was conducted and key themes extracted.

RESULTS Ten studies met the inclusion criteria. Nine studies reported outcomes demon-

strating improved attitudes or knowledge and skills, and one demonstrated transfer of skills to the workplace. Amongst the included studies, the strength of conclusions was variable. Poor reporting of interventions impeded replication. Analysis of available content revealed themes in three major areas: teamwork and leadership; professional responsibility with regard to error prevention, and information management systems. Methods used included exercises based on simulation and role-play, and group discussions or lectures focused on errors and patient safety.

CONCLUSIONS There is a paucity of research describing educational interventions to improve handover and assessing their effectiveness. The quality of published studies is generally poor. Some evidence exists to demonstrate that skills can be transferred to the workplace, but none was found to demonstrate that interventions improve patient safety.

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INTRODUCTION

Handover or hand-off is the accurate, reliable communication of task-relevant information across shift changes¹ and is vital to facilitate high-quality health care.² Its importance has increased in recent years in the UK as the introduction of the European Working Time Directive has resulted in a greater frequency of handover as a consequence of reductions in working hours.³ In the USA, where working hours are being similarly reduced, communication failure at handover has been identified as a major source of error within patient care.⁴

Previous literature has identified failings in current handover strategies^{5–8} and the potential for these to harm patients.⁹ Numerous published works discuss ways to improve handover and many of them focus on systems to manage information, such as standardised proformas^{10,11} or electronic handover systems.^{12,13} There has also been some discussion of the use of mnemonic devices to guide handover, although there is a paucity of evidence as to their effectiveness.¹⁴ Despite these innovations, research has identified dissatisfaction amongst junior staff¹⁵ with current practices as a result of the lack of policies and training.¹⁶ There have been calls for formal handover education¹⁷ and work has started to clarify competencies for training.¹⁸ In addition, handover is increasingly recognised within graduate curricula in both the UK¹⁹ and the USA.²⁰

In 2008, Arora *et al.* presented a theoretical framework using theories grounded in social sciences to explain how handover can impact on patient care.¹⁸ They discussed the possible erosion of professionalism occurring in settings of discontinuity. This can lead to staff failing to take responsibility for the care of patients in a manner that alludes to what is aptly named 'shift-work mentality', a concept which is supported by agency theory. Under this theory, the patient does not have access to the information he or she needs to make an accurate judgement on whether a doctor is behaving in his or her best interest. The 'agency problem' refers to the potential for doctors to shirk their professional responsibility in such a setting. This theory would suggest the importance of professional attitudes to safe handover. Also discussed is the management of information at handover as a source of error and how this relates to an economic theory, known as 'coordination costs'. This describes how, in increasingly complex systems, the costs (either financial or time-related) of coordination, including information management

and communication, increase. Systems are therefore needed to safely manage these potential increases.

A complete model of handover practice has previously been reported.²¹ It describes three overlapping areas of handover practice: (i) information transfer and systems for managing information; (ii) responsibility and accountability, and (iii) system elements in place to facilitate handover, such as teamwork and leadership. Recently, theories from the psychological sciences have been applied to handover communication.²² This research found that doctors often did not communicate vital information; they knew what they were trying to convey and therefore felt it was clear to everyone. This overestimation of how well they communicated made doctors less likely to verify whether the receiving doctor had understood. This concept of an egocentric heuristic, associated with handover communication, led the authors to stress the importance of focusing on communication within the team.²²

It is recognised that most junior doctors receive little or no education in handover⁶ and this contributes to weaknesses within handover systems.²³ The extent to which educational interventions are used to improve handover and how well the conceptual frameworks and models described here are reflected in these interventions remain unclear. Evidence for the effectiveness of these interventions is also unclear. We set out to determine the characteristics of educational interventions employed to enhance handover amongst health professionals and to establish the effectiveness of these interventions.

METHODS

Data collection

All interventional study designs were considered for this review. Commentary pieces, surveys, audits or review articles were not included. The target population consisted of medical and nursing staff, including undergraduates. The setting was in-patient medical establishments. Studies involving allied health professionals, who do not hand over within the acute in-patient setting, were excluded. Outcomes at any level of Kirkpatrick's adapted hierarchy²⁴ were considered for inclusion. Kirkpatrick's model describes four levels of outcome that can be assessed when studying an educational intervention. It is therefore useful to communicate the type of evidence generated when investigating an intervention. Level 1

describes outcomes associated with the reaction to an intervention, such as satisfaction. Level 2a describes attitudes and confidence, and Level 2b describes knowledge and skills. Level 3 describes outcomes associated with changed behaviour, such as the transferring of skills to the workplace. Level 4 describes patient outcomes; thus, in the context of handover, this may include patient safety data.

An educational intervention was defined as any structured educational activity. Interventions that introduced new handover systems or mnemonics without an educational component were excluded. All interventions as defined above were reported. If a study reported an intervention in limited detail or commented on improved handover without presenting evidence in support of the improvement, we attempted to contact the author for further details. Studies from all countries published in all languages were included. There was no time limit on the search, which was run in June 2010.

The following online databases were searched using a standardised search strategy (Appendix S1, online): MEDLINE; EMBASE; CINAHL (Cumulative Index to Nursing and Allied Health Literature); British Nursing Index (BNI); PsycINFO; ERIC (Educational Resource Information Centre); British Education Index (BEI), and the Cochrane Trials Database. Additionally, reference lists from included studies were searched for further relevant studies. Abstracts available online from relevant education societies, including the Association for the Study of Medical Education (ASME) and the Association for Medical Education in Europe (AMEE), were also searched.

Data analysis

Citations were reviewed independently by each of the authors. Agreement between reviewers was assessed using Cohen's kappa statistic. Potentially relevant abstracts were independently reviewed using a screening checklist (Appendix S2) and full papers obtained for any studies that appeared to meet the inclusion criteria. Disputes were resolved by consensus. The full manuscripts for all included studies were assessed independently by each of the authors. The quality of the studies was assessed using a data extraction form (Appendix S3), based on guidance available from Best Evidence Medical Education (BEME),²⁵ as well as the recommendations of Reed *et al.*²⁶ This rated studies according to each of 16 quality-based criteria. The strength of the conclusions drawn by each study was rated on a numeric scale, also in line with BEME guidance.²⁵ This is not an

assessment of overall methodological quality, but a measure of how well the conclusions made are supported by the data presented. The importance of outcomes was also assessed by relating them to Kirkpatrick's adapted hierarchy.²⁴ Disputes in these judgements were resolved by discussion between the authors until they achieved consensus. Content analysis of available or supplied interventions, coding and categorisation into themes were carried out independently by each of the authors.

RESULTS

The initial search of electronic databases identified 780 citations, of which 298 were unique. All abstracts were read by both reviewers. Agreement between reviewers on citation screening was almost perfect ($\kappa = 0.97$) and the authors agreed that 40 citations were potentially relevant. Their abstracts were reviewed using the screening checklist (Appendix S2). There were no potentially relevant abstracts from scientific meetings of ASME or AMEE. The initial screening identified a total of 19 studies for full screening.

These 19 studies were independently reviewed by each author and nine papers^{27–35} were excluded as not relevant, with no disagreement between the authors. This left 10 studies^{36–45} which met the inclusion criteria. No further potentially relevant studies were found from searching the references within the included studies. A flow diagram of the search is shown in Fig. 1. An overview of the included papers is shown in Table 1. Data were extracted independently by each of the authors, who achieved concordance on 88% of quality ratings and subsequently met to reach consensus. Consensus results of the quality assessment in each of 16 criteria are shown in Table S1.

There was significant methodological heterogeneity among the studies, as well as among the educational interventions used. Study participants included medical students, doctors, nurses and nurse specialists. The mean number of participants in a study was 38 (range: 14–72). The studies included six before-and-after studies, three action-based studies and one non-randomised controlled study. The majority of studies did not offer details of the intervention used or the resources the intervention required. All studies, apart from one,⁴⁰ had outcomes at Level 2 of Kirkpatrick's adapted hierarchy,²⁴ measuring either the modification of attitudes or perceptions (Level 2a) or, alternatively, the

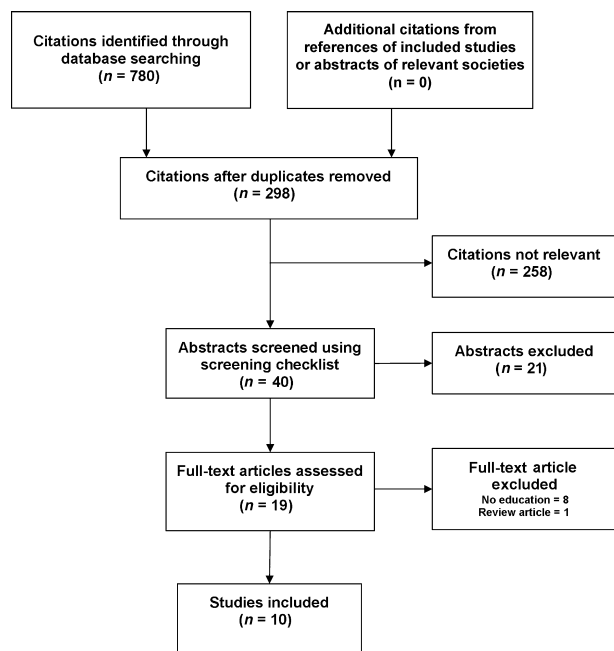


Figure 1 Flow diagram of electronic database search

modification of knowledge or skills (Level 2b). The remaining study, by Gakhar and Spencer,⁴⁰ measured the transfer of handover skills into the workplace (Level 3). The strength of conclusions as estimated using the BEME scale²⁵ was deemed to be poor in three of the studies,^{42–44} which achieved BEME scores of 2.0, representing ambiguous results that may suggest a trend. Three studies^{36,38,45} achieved BEME scores of 3 out of 5, indicating that their conclusions were most likely based on results. The strength of conclusions was judged to be good in four of the studies,^{37,39–41} which won scores of 4.0, suggesting their conclusions were clear and very likely to be accurate.

The authors of all but two studies^{39,40} were contacted and asked to give more information about the interventions used. Five of the authors responded^{37,38,42–44} by providing narratives of their teaching methods or copies of materials used that had not been included in the published manuscripts. These were used in the analysis of teaching methods and content themes. The key outcomes of the analysis are shown in Fig. 2. The main teaching methods employed were simulation or role-play, either exclusively, or as part of an overall package of measures. Common features were the use of observation, evaluation and feedback. Group lectures and online materials were also used in several of the interventions.

In line with the literature on the topic, the theme of information management became apparent within the content of the educational interventions and was

made clear by the discussion of mnemonics, checklists or technology. The second theme to emerge concerned the recognition of error caused by inadequate handover. This was usually discussed in the context of fostering a joint professional responsibility to prevent such errors, thereby enhancing patient safety. The third theme concerned team-working and communication. A number of ideas were discussed within the interventions, such as how to communicate across a power gradient. Many interventions involved senior members of staff in the training, both in order to provide models of good practice and to allow these staff to receive handover training.

DISCUSSION

This review found a general paucity of research supporting and directing the use of educational interventions to improve handover. This is in agreement with the findings of previous research.⁴⁶ Interestingly, of the 10 studies included, eight had been published in the previous 2 years. This highlights the fact that recognition of the need for good handover is gaining momentum amongst clinicians and educationalists, probably in response to worldwide moves towards decreasing doctors' working hours. It is hoped that this systematic review will serve to stimulate further research into the effectiveness of educational interventions to improve handover.

The studies in this review were generally judged to be of poor methodological quality (Table S1). Most studies gave limited information on the specifics of the intervention. Although a number of authors provided further details on request, the lack of published materials limits the scope for other researchers to build on the educational interventions presented and readers would struggle to replicate many of them. A number of the studies were also considered to have proposed conclusions that were not supported by the data they presented. Several factors contributed to this, including the aforementioned methodological weaknesses, the use of multiple system changes that confused the impact of the educational component, and the lack of any clear conclusions.

Most studies reported outcomes at Level 2 of Kirkpatrick's hierarchy; just one study reported outcomes at Level 3, signifying the transfer of skills to the workplace.⁴⁰ No study demonstrated that handover education could improve patient outcomes (Level 4). Research investigating other methods to improve handover has also failed to show this.⁴⁷ As the ultimate goal in improving handover is to enhance

Table 1 Characteristics of included studies

Author(s)	Year	Study type	Participants	Intervention	Outcome measures	Results	Conclusions	Importance of outcomes	Strength of conclusion
Berkenstadt <i>et al.</i> ³⁶	2008	Before-and-after study	25 nurses	Incorporation of simulation-based handover into a full-day teamwork and communication workshop	Improvement in preconfigured quality checklist scores of observed handover	Statistically significant increase in handover of information after the intervention	Simulation-based training is able to improve handover and patient safety	Level 2b	3/5
Chu <i>et al.</i> ³⁷	2009	Before-and-after study	72 interns	Seniors give sessions on handover and feedback to interns receiving handovers on their first night on call Lectures on handover once per month All part of overall handover strategy	Survey assessing perceptions of knowledge, attitudes and ability to transfer patient care Perceptions of effectiveness of handover process	Statistically significant increase in perceptions of ability to hand over patients, make contingency plans or perform read backs	The structured handover programme improved the participating interns' perceptions of their knowledge of the handover process and their ability to transfer care effectively The programme was well received	Level 2a	4/5
Clark <i>et al.</i> ³⁸	2009	Before-and-after study	65 nurses and visiting medical officers	Assertive communication skills workshop as part of overall handover improvement project	Improvement in confidence and opinions of staff on a questionnaire post-implementation	80% of staff stated they were more confident at handover post-implementation and 68% said handover had improved	This early evidence supports the use of specific communication training as it improves nursing confidence in handover	Level 2a	3/5
Farnan <i>et al.</i> ³⁹	2010	Before-and-after study	32 Year 4 medical students	90-minute workshop on handover, electronic access to materials on handover One week later, a 2-hour standardised handover experience (OSHE) Creation of handover CEX tool for assessment	Pre- and post-workshop surveys by students assessing preparedness for handover Satisfaction of faculty staff with the assessment instrument, the handover CEX Participant scores for written and verbal handover performance	Evaluation of pre- and post-workshop survey data revealed a statistically significant improvement in preparedness for performing effective handover (27% pre- versus 67% post reporting 'well prepared' or 'very well prepared'; $p < 0.009$) Students also expressed unanimously positive comments on the experience	This brief, standardised handover training exercise improved students' confidence and was rated highly by trained observers Future work focuses on formal validation of the handover CEX instrument	Level 2a	4/5
Gakhar & Spencer ⁴⁰	2010	Before-and-after study	15 doctors (residents)	30-minute lecture followed by 30-minute small-group practice session with feedback Used Yale SIGN-OUT mnemonic ⁴⁵	Pre- and post-training observation of verbal sign-out, completion of written sign-out and confirmation of accuracy of written handout	Statistically significant improvement in all outcomes, except accuracy of written allergy information	The curriculum was well received by interns and helped them develop skills required by the ACGME, including competencies in communication, practice-based learning and systems-based practice	Level 3	4/5
Horwitz <i>et al.</i> ⁴¹	2007	Action-based study	32 participants: 14 interns, 14 students, 6 other	Curriculum design process followed by a large-group interactive discussion and then small-group sessions for 20 minutes with practice, feedback and evaluation Accompanied by a number of other online and printed resources Use of SIGN-OUT mnemonic	Likert scale ratings for the course and retrospective pre- and post- ratings of comfort in giving and receiving handover	Perceived comfort at providing sign-out increased significantly (3.27 ± 1.0 before versus 3.94 ± 0.90 after wards; $p < 0.001$)	The oral sign-out curriculum was well received by participants Further study is necessary to determine the long-term impact of the curriculum	Level 2a	4/5
Klamen ⁴²	2009	Action-based study	69 medical students	Simulated handover experience in small groups, as well as video and website accompanying materials	Assessment of students' opinions of intervention and score on 10-item handover checklist	Mean score of 81.5% on checklist Positive comments on intervention with mean score of 4.1/5	The simulated in-patient unit was an effective and efficient environment in which to teach students about handovers in a busy, demanding in-patient unit setting	Level 2b	2/5

Table 1 (Continued)

Author(s)	Year	Study type	Participants	Intervention	Outcome measures	Results	Conclusions	Importance of outcomes	Strength of conclusion
Lyons <i>et al.</i> ⁴³	2010	Non-randomised controlled study	Doctors on neurology critical care unit (total not specified)	Single educational session drawing on a literature review, local audit and consultants' views Introduction of a handover proforma and a change of location for handover	Timing and clinical content of handovers evaluated pre- and post-intervention A later group of non-trained doctors used as a control group These factors were correlated with patients' clinical scores	Significant difference in content at baseline versus post-intervention	Early specific training is vital for quality clinical handover	Level 2b	2/5
Malter & Weinschel ⁴⁴	2010	Before-and-after study	17 doctors in gastroenterology residency training (8 fellows, 9 faculty members)	Core lectures on handover to convey background information on the subject of handovers, to review focus group results, and to educate on the use of SBAR (situation, background, assessment, recommendation)	Self-assessment rating of site and personal handover	Improvement in median self handover scores for fellows from 1–2 to 4	No clear conclusions Discussions suggests that this programme could improve communication and patient care	Level 2a	2/5
Nestel <i>et al.</i> ⁴⁵	2005	Action-based study	14 nurse specialists	2-hour teaching intervention on handover presentation skills using principles of adult learning	Intervention evaluated by participants in terms of learning outcomes achieved and perceived value	Between 8 and 11 participants completely achieved learning outcomes All thought the session was valuable	No clear conclusions made Results presented suggest positive attitudes amongst participants towards the intervention	Level 2a	3/5

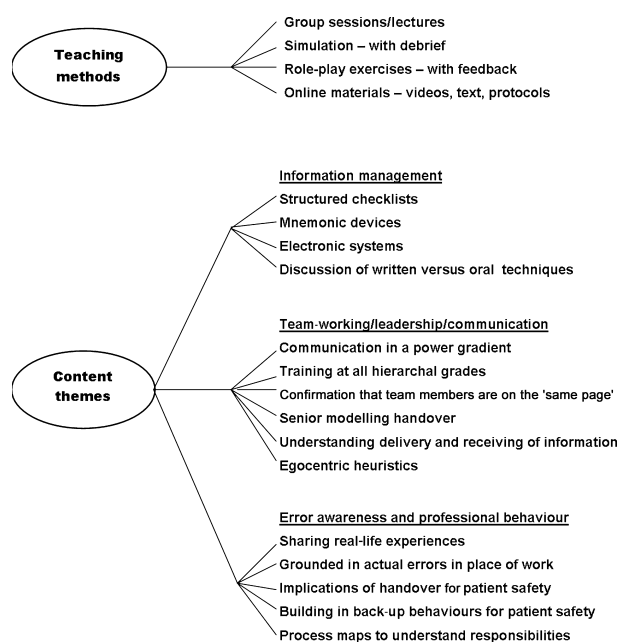


Figure 2 Summary of content themes and teaching methods reported in the included studies

patient safety, this deficiency in evidence must be recognised and future work designed to rectify the situation.

There are currently no internationally recognised competencies and outcomes for handover education,

which may have contributed to the heterogeneity amongst the educational interventions used in the studies reviewed here. Despite this, there were a number of recurring teaching methods. Simulation or role-play were employed by a number of the studies^{36,39–42,45} and previous research¹⁷ has found that doctors feel these are useful in developing handover skills. These studies employed debriefing and feedback, which have been shown to improve performance after simulation teaching.⁴⁸

A number of key content themes were identified; these can be related to the previously described theories concerning handover. The first content theme of information management clearly relates to the theory of 'coordination costs'¹⁸ and refers to the systems needed to manage increasingly complex handovers. The second content theme of error relates to the previously described agency theory.¹⁸ The interventions discussed error in the context of fostering joint professional responsibility. This challenges the 'shift work' mentality and therefore may improve patient safety. The final theme of communication and team-working relates to the theory of egocentric heuristics,²² which was discussed within a lecture used in one of the interventions.³⁹ These content areas clearly align with the previously discussed model of handover.²¹ This would seem to be an appropriate model, with a theoretical basis, for designing education to enhance handover skills,

supported by the limited evidence available in the literature.

The use of these teaching methods and content themes is paralleled by work in other fields. The National Aeronautics and Space Administration (NASA) determined that many crashes were caused by failures in interpersonal communication, decision making and leadership.⁴⁹ A teamwork and simulation-based intervention to improve safety, designated 'crew resource management' (CRM) training, was developed. It focuses on behaviour in teams and encourages the individual to speak up if something is not being done appropriately. This is intended to combat the sort of bystander apathy that can occur in groups, as described in social science theories concerning diffusion of responsibility.⁵⁰ It also embraces the importance of learning from error to prevent recurrence.⁵¹ Training in CRM has already been adapted in health care, most notably by anaesthetists.⁵² Catchpole *et al.*⁵³ recently interviewed Formula One (F1) racing teams and found similar attitudes to handover reflecting the same three broad content themes. This triangulation with other fields supports the utility of the handover model²¹ for guiding future educational design in health care.

This systematic review has several limitations. Although this selection was not limited by language or date, it included only papers reporting interventions with doctors or nurses in the in-patient setting. A decision was made to limit the inclusion criteria in this way as handover itself is not a single well-defined task, but is a rather heterogeneous activity that takes place in many aspects of health care and therefore can take many different forms. The screening process excluded a small number of studies which reported educational interventions aimed at improving handover in health care in other allied groups, such as when patients were moving from one primary care establishment to another or arriving by ambulance for care. These described different models of handover and thus different topics for education. A further review looking at handover in all areas of health care may wish to include these. This review has followed its remit of assessing educational interventions to improve handover, but there are many other forms of intervention that are also intended to do so. Readers may wish to research these alternative methods. Most studies gave only limited details of the interventions used and, although some authors offered extra data, the analysis of content themes and teaching methods is limited by this lack of detail. It must also be noted that this review has only included

research of an interventional nature. Although we have touched upon a number of other streams of work in this discussion, we did not undertake a thorough review of the wider literature on the topic and this should be considered in any assessment of our conclusions. All of the studies included in the review reported positive results of their educational interventions and therefore the possibility of publication bias must be considered. Certainly, this lack of negative results inhibits any comments as to the relative impact of different learner characteristics on the success of such interventions. Finally, none of the studies attempted to assess the long-term retention of the outcomes measured and this further limits the conviction with which we can conclude that such interventions are effective.

We would suggest that further work is needed to clarify the competencies required by health care staff to make effective handovers. Such work should take a multidisciplinary view of health care handover and cover the issues of communication across disciplines and the power gradient. Further assessment and refinement of the utility of the model for guiding handover education discussed in this review should also be attempted. We would also suggest that further work is needed to develop interventions to improve handover skills. The use of methods that parallel CRM and F1 race team training may be considered. Reports of such interventions should give sufficient details to allow replication. Whichever investigative technique is chosen when assessing such interventions should be robustly utilised and well described on publication. Finally, consideration should be given to the possibility of assessing whether such interventions can impact on patient outcomes.

CONCLUSIONS

There is a paucity of research investigating educational interventions to improve handover amongst medical and nursing staff, although this field is growing rapidly. The studies reported suggest that educational interventions can improve handover, but small sample sizes, the lack of research into long-term retention and the possibility of publication bias limit the significance of this conclusion. The methodological quality of reported studies is generally poor. There is limited evidence demonstrating the transfer of skills to the workplace and no evidence that these interventions improve patient outcomes. Further work is needed to establish clear competencies for handover training. In addition, further

research is required to produce more robust evidence on the effectiveness of educational handover interventions and their ability to facilitate the transfer of skills to the workplace, the ultimate aim of which is to improve patient safety.

Contributors: MG conceived and designed the project, carried out the literature search, data extraction and analysis and served as lead writer on the manuscript. RF commented on drafts of the protocol and manuscript and contributed to the literature search, data extraction and analysis. Both authors approved the final manuscript for submission.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article. Available at: <http://online.library.wiley.com/doi/10.1111/j.1365-2923.2011.04049.x/supinfo>

Table S1. Quality assessment of included studies (consensus ratings).

Appendix S1. Search strategy.

Appendix S2. Abstract screening checklist.

Appendix S3. Data extraction form.

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Training on handover of patient care within UK medical schools

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Background: Much evidence exists to demonstrate that poor handover can directly impact patient safety. There have been calls for formal education on handover, but evidence to guide intervention design and implementation is limited. It is unclear how undergraduate medical schools are tackling this issue and what barrier or facilitators exist to handover education. We set out to determine curriculum objectives, teaching and assessment methods, as well as institutional attitudes towards handover within UK medical schools.

Methods: A descriptive, non-experimental, cross-sectional study design was used. A locally developed online questionnaire survey was sent to all UK Medical Schools, after piloting. Descriptive statistics were calculated for closed-ended responses, and free text responses were analysed using a grounded theory approach, with constant comparison taking place through several stages of analysis.

Results: Fifty percent of UK medical schools took part in the study. Nine schools (56%) reported having curriculum outcomes for handover. Significant variations in the teaching and assessments employed were found. Qualitative analysis yielded four key themes: the importance of handover as an education issue, when to educate on handover, the need for further provision of teaching and the need for validated assessment tools to support handover education.

Conclusions: Whilst undergraduate medical schools recognised handover as an important education issue, they do not feel they should have the ultimate responsibility for training in this area and as such are responding in varying ways. Undergraduate medical educators should seek to reach consensus as to the extent of provision they will offer. Weaknesses in the literature regarding how to design such education have exacerbated the problem, but the contemporaneous and growing published evidence base should be employed by educators to address this issue.

Keywords: *handover; handoff; patient safety; non-technical skills; undergraduate medical education*

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Background

Handover or handoff can be defined as the passing of responsibility and information, both in varying quantities, between shifts or locations. Handover has been identified as a vulnerable period in the care process during which information may be lost, distorted, or misinterpreted (1–3), and this can directly impact patient safety (4, 5). Recent global moves to reduce working hours amongst medical staff, along with reconfigurations in services have increased the frequency and complexity of handover (6). There is much published work discussing ways to improve handover, mostly focussing on systems to manage information, such as standardised proformas (7, 8) or electronic handover systems (9, 10), although there is a corresponding paucity of evidence as to their effectiveness (6).

There have been calls for formal education on handover (11) and work has started to clarify competencies for training (12). In addition, handover is increasingly being recognised within graduate curriculum, with examples in the United Kingdom (13) and the United States (14). The published research on handover has tended to not be highly concerned with education (15), with only 10% of handover improvement projects being categorised as involving teaching or training. This author recently completed a systematic review of educational interventions to improve handover (16) that found a paucity of research investigating this issue, although this field is growing rapidly. Limited evidence was found to demonstrate that skills could be transferred into the workplace and no evidence was found that could improve patient outcomes. More importantly and as is often the case with

evidence synthesis in medical education, a lack of published work describing the theoretical underpinning or pedagogical foundations of interventions was discovered. Educators are left with the problem of enhancing provision with limited evidence to guide on how to do so, even if evidence suggests that such education can be effective.

Given this lack of evidence and the clear need for handover education in some form, undergraduate medical education institutions are also being expected to train and assess elements of handover of care. However, the current state of this training within medical schools, the type of education being offered and how assessments are being made, remain unclear.

We set out to determine the current state of handover training within undergraduate medical schools in the United Kingdom and institutional attitudes to identify any common facilitators or barriers to handover education.

Methods

A descriptive, non-experimental, cross-sectional study design was used. An online questionnaire survey was employed. The Questionnaire was developed locally for this study and piloted before its delivery by email using the online service 'SurveyMonkey'. It consisted of mainly closed questions, with some open-ended questions to gather qualitative data. Key educational personnel within each school in the United Kingdom were contacted and a single respondent was identified to take part. Therefore, the whole population sample of UK medical schools was invited to participate.

Descriptive statistics for closed-ended responses were compiled and analysed. Free text responses were analysed using a grounded theory approach (17). Anonymous responses were compiled and coded for key items. The analysis proceeded through three stages, consisting of open, axial and selective coding, with constant comparisons taking place throughout each phase (18). Each stage provided categories that could be used to explore the themes of the data and further inform the next stage of analysis.

Results

Response rate

A total of 19 out of the 32 UK medical schools invited to participate responded (14 from England, three from Scotland and one each from Northern Ireland and Wales). Of these, three schools declined to take part, with two reporting that school policy dictated they could not complete such studies and one school asking for local ethical approval. An ethics application was made, but no response was received at 12 weeks and so this was abandoned. This left a sample of 16 (50%) UK medical schools, with each country in the United Kingdom represented.

Curriculum

Nine schools (56%) reported having curriculum aims, objectives or outcomes regarding the ability for graduates to handover, whilst the remaining schools had none. It was reported that handover was addressed from semester 1 in one school, but within the final semester of the course in the remaining schools. Several respondents mentioned patient safety as the driver for including handover in the curriculum.

Teaching and assessment methods

As half of the schools did not recognise handover within their curriculum, there was no provision. Amongst the remaining schools, there was considerable variation in methods. This has been summarised in Table 1.

Institutional view on handover education

Thirteen schools (81%) felt that handover needs specific training and that it is an important educational issue. Fourteen schools (88%) agreed that they would like to see more published educational research on handover. However, 81% did not agree that handover is an important issue for undergraduate education.

Table 1. Teaching and assessment methods reported amongst the 16 undergraduate medical schools studied

Teaching methods	No. of institutions	Assessment	No. of institutions
Observation during training	16	Objective structured clinical exam	5
Communication skill courses	6	Ward-based direct assessment	4
Case-based discussions	5	Communication skills exam	2
Reflective exercises	3	Reflective exercises	1
Lectures	3	Written assignments	1
e-Learning	3	Online assessment	1
Problem-based learning	2	Review of logbook	1
Ward simulation exercise	1	Ward simulation exercise	1

Free text responses and themes

There were 223 items recorded in the open phase of coding. As analysis proceeded through the axial phase of coding, a number of themes were synthesised into a theme map (Fig. 1). At the selective level of analysis, this led to the four key themes below:

- (1) *Handover as a key educational issue:* Responders overwhelmingly agreed that handover is an increasingly important issue, identifying the drivers already mentioned. In particular, patient safety was the unifying area of alignment.
- (2) *When to educate on handover:* The majority of institutions felt that handover should be an educational objective for early graduate or 'on the job' training and that it did not sit well in a busy undergraduate programme.
- (3) *Need for further development of teaching:* Despite the views above, most schools felt they should be developing more interventions and were doing so.
- (4) *Requirement for formal assessment tools:* A lack of validated assessment tools was a key concern expressed, although most schools were currently assessing handover through existing methods.

Discussion

This is the first study to examine education in the area of handover over a large sample of institutions. The key finding is ambivalence amongst UK undergraduate

schools regarding this issue. They strongly agree that handover education is important and are compelled to develop teaching in this area, but they also strongly expressed the view that this is an issue that should be dealt with within postgraduate training. As a result of these conflicting views, schools are responding in varying ways, with significant difference in the provision being offered. Half of the schools are essentially not addressing handover education at present. The other half is using a range of teaching and assessment methods, again with no consensus. It is worth noting that no institution reported alignment with any conceptual frameworks or theoretical models when discussing handover training and this is probably the only unifying finding of this study. This most probably reflects weaknesses in the literature already identified, but clearly is a concern as the effectiveness of any provision made will be impacted by this lack of appropriate theoretical alignment or underpinning.

The view that handover education should occur in the postgraduate training is at odds with an identified model (16), which views handover not as a free standing issue, but built on expertise in a range of generic skills (16). These three overlapping areas are: (1) information transfer and systems of managing information; (2) responsibility and accountability; (3) elements in place to facilitate handover within the healthcare environment, such as teamwork and leadership. This skill set frames handover education as both a technical and non-technical skill (19). As such, these skills should be acquired from the very start

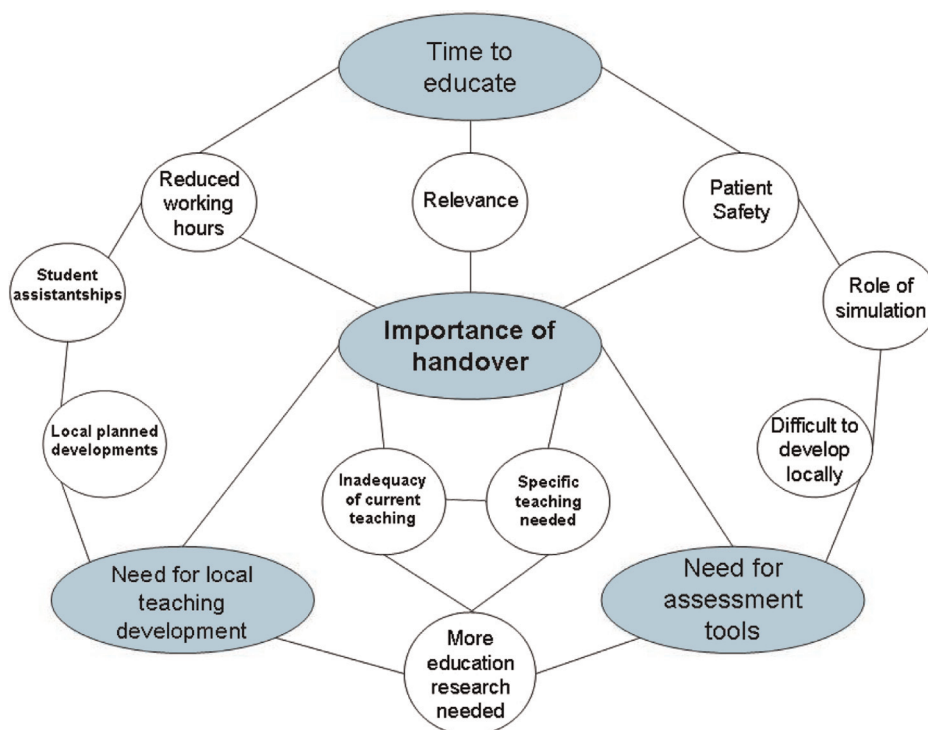


Fig. 1. Map of key themes at the axial level of data analysis.

of undergraduate training. It may be appropriate to address the specific issue of handover information management systems within the postgraduate setting, but skills in team working, communication and professionalism are key areas that should be addressed before graduation, both in the context of handover education, as well as part of the generic non-technical skill set all graduates require. Work using the handover educational model in this way (20) to design undergraduate teaching has begun and suggests its application is appropriate and pedagogically sound.

Therefore, the key barrier to development of handover education does not seem to be the lack of literature or evidence on the issue, but a lack of consensus amongst undergraduate medical institutions as to the extent of provision they must offer. Whilst it is outside of the scope of this work to suggest what form that provision should take, it is clear that the lack of consensus is impacting students, who almost certainly do not have a uniform set of skills. It seems reasonable to suspect this problem is not unique to the United Kingdom and is likely to reflect a global issue surrounding a relatively new issue in medical education.

The current concern regarding a lack of formalised and validated tools for handover education is a valid one and must be addressed. Clearly, this is difficult as there is not an even consensus regarding competencies in this area (12), although recently the first tool for assessing handover has been reported in the literature (21). This tool is based on the mini-clinical encounter exercise work based assessment and whilst not formally validated, offers an interesting development to educators.

In addition, the issue of effectiveness of developments in handover education must also be considered. Even though this is the focus of most existing literature, it has been poorly answered. This outcome is limited to those demonstrating changes in attitudes or knowledge and skills, with minimal demonstrating changes in behaviour. Whilst the goal of handover education is clearly focussed on improving patient safety, there is no evidence that handover education, evidence based or otherwise, is able to actually improve the safety of patients (22). Any future work aimed at designing, implementing and assessing undergraduate handover education must attempt to address this issue.

There are some key limitations to these findings that must be considered, mostly regarding risk of bias. This study was based in the United Kingdom only and whilst a large sample was included, there is the possibility of a bias amongst interested respondents. In addition, acceptability bias amongst respondents may also limit the usefulness of some of these findings. Finally, the qualitative data analysis could be influenced by the single author's views and personal biases.

Conclusions

Whilst undergraduate medical schools recognised handover as an important education issue, they do not feel that they should have the ultimate responsibility for training in this area and as such are responding in varying ways. Undergraduate medical educators should seek to reach consensus as to the extent of provision they will offer. Weaknesses in the literature regarding how to design such education have exacerbated the problem, but the contemporaneous and growing published evidence base should be employed by educators to address this issue.

Conflict of interest and funding

The author has not received any funding or benefits from industry or elsewhere to conduct this study.

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Teaching handover of care to medical students

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Handover is a key activity in acute health care

SUMMARY

Background: Handover is a key activity in acute health care, with patient safety implications if it is not performed well. This is becoming more important with shorter working hours and therefore a greater number of handovers. Despite this there is a paucity of evidence to guide education to enhance practice. A teaching session for senior medical students on handover of care was devised, delivered and evaluated, with the aim of producing a theoretically sound intervention that is acceptable to students and

can be delivered with limited resources.

Context: Teaching sessions to improve the handover of care have been described before, but the descriptions lacked the detail to allow a reader to deliver the session as intended.

Innovation: We designed and delivered a 1-hour session on handover for senior medical students. This was based on models of handover practice and education, and was based on broader patient safety education principles. Student satisfaction was high and students rated their

knowledge as having improved. No funding and minimal resources were used to develop and deliver the teaching session.

Implications: A pedagogically sound teaching session, based on best-evidence theories for modelling handover practice, is presented. The perceived ability to handover has also been extremely high after the intervention. Other educators can use this intervention as a starting point for designing interventions within their own setting, and to allow future research to investigate the effectiveness of such interventions.

INTRODUCTION

As a result of falling working hours in many countries, the number of shift changes, and therefore handovers, has increased. Handover is a vulnerable period during which information may be lost, distorted or misinterpreted,¹ and patients may be harmed as a result.

Most junior doctors have had no formal training in handover,² and they feel underprepared for it.³ Despite this fact, newly qualified doctors are expected to perform this task immediately upon starting work. A recent systematic review examined the evidence on educational interventions to improve handover,⁴ and concluded that there is a small but growing research base and that educational intervention can improve handover, but that gaps remain, including: a lack of long-term retention studies; limited evidence of transfer of skills to the workplace; and absence of evidence about patient outcomes.

The starkest finding was the lack of detail about the interventions used. This prevents practitioners from replicating interventions.

The authors present an educational intervention for improved handover designed for medical students in clinical practice. This intervention is described with clear pedagogy and is based on current theoretical models.

METHODS

Setting

Medical students on hospital placement identified an initial need for the session. Clinical examinations had recently included a station that tested handover of care, and this had caused anxiety amongst the students who felt unprepared for this task. A session was designed that



Responsibility and accountability are key problems in a shift-based system

would address students' concerns and attend to the patient safety issues identified.

The session runs for an hour. This length was chosen because of timetabling restraints, but seemed adequate. Following participant feedback several revisions were made to the structure of the session.

Design and theoretical underpinning

The intervention has been structured using Gagne's nine events of instruction. A model of handover practice guided the content. These areas of practice are:

- information transfer and managing information;
- responsibility and accountability;
- system elements in place to facilitate handover.⁵

A systematic review applied educational theories to each of these areas to offer practical guidance based on designing teaching interventions for handover.⁴ Table 1 summarises this.

The transfer of information is often taught through the use of role-play and scenarios that practise different communication skills.

Responsibility and accountability are key problems in a shift-based system. Published educational interventions tend to use discussions of personal experience of error to enhance professional responsibility in learners.⁴

System elements to facilitate handover relates to an economic theory, known as 'coordination costs'. Systems are needed to safely manage this increasing cost and reduce the risk of error. This can include handover mnemonics, pro formas and computer systems.

A map of the session in relation to the three pillars of handover education and Gagne's nine events is presented in Table 2.

TEACHING INTERVENTION

The tutor guide, student handout covering the key elements of handover, the scenarios and a video outlining the session are available by contacting the corresponding author.

Preparation

A tutor guide was offered to the facilitators before the session. A room with adequate space, equipment to play the video and copies of all role-play scenarios was all that was required.

The session was designed to run with between six and eight

Table 1. Three pillars of handover education

Handover practice element	Related theory	Implications for education
Information transfer	Egocentric heuristic: doctors often do not communicate vital information at handover. It was not that they didn't know what to communicate, but rather that they overestimated their own communication skills. This egocentric heuristic led them to be less likely to verify whether the receiving doctor fully understood the situation. ⁶	Communication skills training to encourage improved checking of information transferred and understanding
Responsibility and accountability	Agency theory: patients do not have access to the information needed to make an accurate judgment regarding whether a doctor is behaving in their best interest. The 'agency problem' is the potential for doctors to shirk professional responsibility. This outlines the importance of professional attitudes to safe handover. ⁷	Discussion of consequences of poor handover to enhance professional responsibility
Systems to facilitate handover	Coordination cost: cost, either in terms of time or finance, of coordination increases in increasingly complex systems, including the costs of information management and communication	Education on mnemonic devices, handover checklists and systems to ensure safe practice

Table 2. Session map related to Gagne's nine events and the pillars of handover education

Session map	Gagne's nine events	Pillars of handover education
Introduction		
Presenting a difficult handover	1 – gains attention	Responsibility and accountability
Learning objectives	2 – describes the goal; learning objectives	
Group discussion		
Explore learners' own experiences	3 – stimulate the recall of prior knowledge	All three pillars
Facilitated discussion	4 – present material to be learned	
Role-plays		
Introduced	5 – provide guidance for learning	Information transfer
Practise	6 – elicit performance	
Peer and facilitator feedback	7 – provide informative feedback	
	8 – assess performance test	
Second group discussion		
Focus on practicalities and structure	3 and 4	Systems to facilitate handover
Second role-play	5, 6, 7 and 8	Information transfer
Video	1, 2, 3 and 4	Information transfer
		Systems to facilitate handover
		Some responsibility and accountability
Multi-disciplinary team role play	6, 7 and 8	All three pillars
Closure		
Attend and reflect on a handover	9 – enhance retention and transfer	All three pillars preferably

students, although it has been run successfully with between two and 13 students.

Introduction

The facilitator explained the session and learning objectives. The session aim is to help students to perform handover safely and effectively once they graduate. The learning objectives derived from this aim are:

- to understand the patient safety aspects of handover (knowledge);
- to perform a handover both individually and as part of a team (skill);

- to fully appreciate the impact of handover on patient care and team functioning (professionalism).

Personal examples of difficult handover scenarios were used to engage learners and to begin to increase their awareness of sources of error. This led into the initial discussion.

Group discussion

Group discussion aimed to explore the learner's own observations of clinical handover. An open, circular, seating arrangement was used, with the tutor included as part of the group, helping to give members of the group equality

and allowing eye contact between group members.⁸

Personal experience has shown that these discussions tended to cover the major practice elements (Table 1). The facilitator encouraged the learners to give examples of their own clinical experience, thereby grounding the rest of the session in pre-existing knowledge. By encouraging the learners to reflect on their own experience, the facilitator aimed to encourage a discussion of what a good handover is, recognising that agreement on this does not exist and that it will be situation dependent. The impact of poor handover on patient care was a recurring theme.

Personal examples of difficult handover scenarios were used to engage learners

Box 1. Example of role-play scenario

Handover Tutorial Scenario 1 – Participant A

Background

You are a surgical F1* handing over following a night shift. You have one patient to handover to this ward's F1, then have to do the same for three other wards. You are on again tonight so want to do this quickly so that you can get some much-needed sleep.

Patient

Jane Smith

D.O.B. 28/01/1939

Patient no. – PN00112233

Location – Ward H3, bay 3, bed 2

This patient was admitted 3 days ago with absolute constipation; she is known to have bowel cancer with lung and brain metastases. Two days ago the on-call surgeon placed a stent to relieve the obstruction, and she has since passed stool. She also has type-II diabetes, high blood pressure and is on treatment for high cholesterol.

At 3 AM she became short of breath. She was pyrexial, 38.2 C, and had a high respiratory rate and heart rate. She had crackles and reduced air entry on the left, and was productive of green sputum. You were unable to obtain an X-ray, but started treatment assuming hospital-acquired pneumonia. She received antibiotics and oxygen. A sputum sample was sent for analysis.

The rest of the patients on this ward did not require your attention last night.

Handover Tutorial Scenario 1 – Participant B

Scenario

You are the surgical F1 receiving the handover from the night team. You have a patient to prep for theatre and a pile of jobs to do already, so want to do this quickly.

You know that one of your patients was unwell last night, but little else.

*(F1 is a newly qualified doctor in the UK)

Role-play

A series of scenarios were provided for the learners to role-play in pairs (or threes). This engaged the learners and provides a safe environment to question their own practice. Allowing repeated attempts helps the learners to improve, and to recognise this improvement. Both peer and facilitator feedback was vital for this. An example of the role-plays used is provided in Box 1.

After two role-plays the group re-formed for another discussion. The group discussed their experience and then focused on the practicalities of handover. The idea of structure to handover is introduced, and a handout is provided based on a Royal College of Physicians of London document.⁹ The handout is not a 'one size fits all', and the students were encouraged to develop a structure that fits them and the situation. Further role-plays were then run.

Video

A DVD produced by Salisbury Hospital for their 'hospital at night' training demonstrates examples of excellent and awful team-based handover.¹⁰ This was

The session [also] introduced principles of teamwork and hierarchical communication

useful as a prompt for further discussion, and led into the final role-play.

Multi-disciplinary role-play

The final scenario was based around the local day-to-night medicine on-call handover. The learners each played a different member of the team. As well as bringing the other elements of the session together it introduced principles of teamwork and hierarchical communication. This also related the learning to the students' own practice, aiming to encourage the transfer of skills to the workplace.

Closure

After the final role-play the session ended. Students were advised to attend a handover on their current placement, and if possible take part. They were encouraged to think critically about the structure and functioning of the handover, and what they can do at work to ensure that handovers are safe and effective.

RESULTS

The initial cohort of students who participated in the session provided feedback as to the strengths and weaknesses of the session. This was used in attempts to improve the session.

A total of 44 students took part in seven sessions. Student feedback was analysed in a quantitative fashion, with a Likert-type scale (1, strongly disagree; 10, strongly agree), addressing the students' satisfaction with the session. This relates to level 1 of Kirkpatrick's hierarchy,¹¹ and suggests that students were satisfied with the learning experience. The mean, median and range for each of these areas are found in Table 3.

Students also agreed that their knowledge on handover of care had improved, with a mean score of 9.1 and a range of 7–10.

Table 3. Mean, median and range of scores, on a Likert scale, from student feedback

	Mean	Median	Range
Clear objectives	8.9	9	6–10
Logical sequence	9.0	9	6–10
Adequate time	9.1	9	7–10
Relevant	9.4	10	7–10
Interesting	8.7	9	6–10
Understandable	9.0	9	5–10
Useful	9.2	10	7–10
Interactive	9.4	10	7–10
Stimulating	9.0	9	7–10
Recommend	9.1	9	7–10

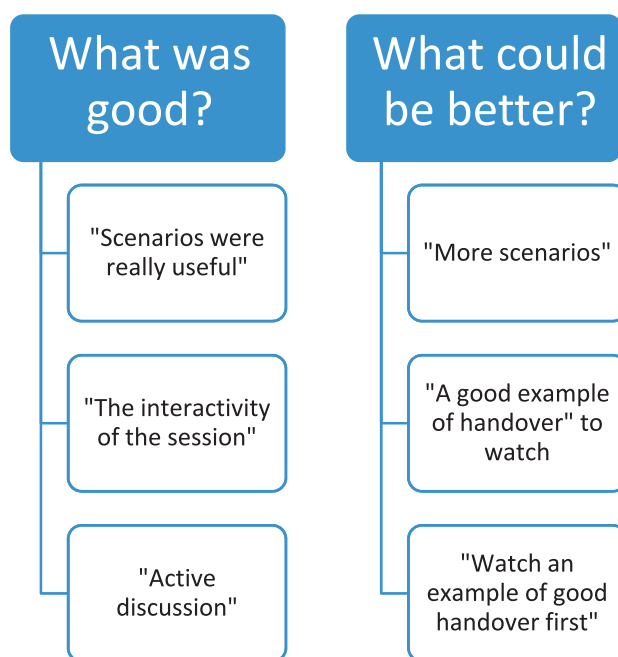
Qualitative data from free-text responses were also collected, which helped to develop the session. A selection of responses is shown in Figure 1.

DISCUSSION

Education to improve handover is needed, and we have attempted to address some of the deficiencies in previously published handover education research.⁴ Interest in handover education in undergraduate medical training is increasing, but there is still no

agreement as to whether this is the most opportune time to gain a skill that is so grounded in the clinical environment.¹² Despite this, the feedback from our participants was clear that they found a need for such training, and that the intervention itself met their learning needs.

We have described the design, theoretical foundations and details of the intervention to allow replication. It was designed and delivered with limited resources and no external funding. It can



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Figure 1. Examples of qualitative feedback used to develop the session

therefore be delivered in most health care education settings. Access to facilities to print the scenarios is important, but they can then be reused. The video is useful but not essential. To show it to a small group all that is needed is a laptop with loud enough speakers.

This research has several limitations. No pre-session analysis of the students' knowledge or attitudes was performed. The Likert-type data collection is prone to acquiescence bias, and this has not been controlled for. These factors limit the reliability of the effectiveness assessment data collected.

Future studies could aim to demonstrate the effectiveness of this and similar interventions by measuring handover skills both before and after the intervention. To develop the intervention, the session could be combined with teaching around medical error to enhance its use as a patient safety education tool. Integrating other topics such as prioritisation, a working ward round and prescribing, perhaps using more involved and sophisticated simulation, could also be a way of moving forward.

CONCLUSION

This intervention has been designed with a pedagogically

sound structure, and was based on the best-evidence theories for modelling handover practice. The feedback from participants has been extremely positive, and participants' perceived ability to handover has also been high post intervention. Other educators can use this session as a starting point for designing interventions within their own setting, with future research investigating the effectiveness of such interventions.

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Integrating other topics could also be a way of moving forward

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Human factors perspective on the prescribing behavior of recent medical graduates: implications for educators

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Background: Junior doctors are at high risk of involvement in medication errors. Educational interventions to enhance human factors and specifically nontechnical skills in health care are increasingly reported, but there is no work in the context of prescribing improvement to guide such education. We set out to determine the elements that influence prescribing from a human factors perspective by recent medical graduates and use this to guide education in this area.

Methods: A total of 206 recent medical graduates of the North Western Foundation School were asked to describe their views on safety practices and behaviors. Free text data regarding prescribing behaviors were collected 1, 2, and 4 months after starting their posts. A 94.1% response rate was achieved. Qualitative analysis of data was completed using the constant comparison method. Five initial categories were developed, and the researchers subsequently developed thematic indices according to their understanding of the emerging content of the data. Further data were collected through group interviews 8–9 months into the placement to ensure thematic saturation.

Results: Six themes were established at the axial coding level, ie, contributors to inappropriate prescribing, contributors to appropriate prescribing, professional responsibility, prescribing error, current practices, and methods for improvement of prescribing. Utilizing appropriate theoretical elements, we describe how recent medical graduates employ situational and error awareness to guide risk assessment.

Conclusion: We have modeled the human factors of prescribing behavior by recent medical graduates. As these factors are related to a number of recognized elements of nontechnical skills training within health care, educators should consider design elements from such existing interventions to support prescribing improvement programs. Future research should seek to assess the effectiveness of prescribing focused nontechnical skills training.

Keywords: medication error, patient safety, nontechnical skills

Introduction

Prescribing errors are amongst the commonest of adverse events in health care,^{1–3} with junior doctors often noted to be at high risk of making such errors.^{4–7} A large UK study suggests that recent graduate error rates are comparable with those made by other prescribers,⁵ but found that they are responsible for 75% of all inpatient prescriptions, hence increasing the overall incidence of errors amongst this cohort. Recent graduates lack contextual prescribing knowledge⁵ and have expressed dissatisfaction with their training,⁷ suggesting that poor knowledge could be a factor. Improved education has been a mainstay of techniques to combat medication errors. Whilst there has been some published work investigating educational tools to improve

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prescribing knowledge and skills, the overall evidence base guiding interventional design is limited,⁸ with minimal work demonstrating the effectiveness of such interventions in reducing errors affecting patients.

It is recognized that prescribing errors are not solely caused by deficits in knowledge or clinical skills, but are often multifactorial with several active failures and error-provoking conditions acting together.⁹ In 2000, the UK Department of Health published a report outlining strategies to reduce risk from preventable errors in health care caused by human factors.¹⁰ Guidance on how to achieve this goal was mostly focused on system-based improvement strategies, which has led to changes, such as electronic prescribing, computerized order entry systems, and an enhanced role of clinical pharmacy services.¹¹ However, errors still occur with alarming frequency.¹²

Extensive work in high-stakes industries as early as the 1970s demonstrated that reducing error is not just about the right technical skills or systems-based human factor avoidance techniques, but addressing the nontechnical (cognitive and interpersonal) skills of staff that may also contribute to error.¹³ There have been successful attempts to design education to improve nontechnical skills within other high-risk sectors¹⁴ and there is a small but growing evidence base to direct nontechnical skills education to enhance safety within health care.¹⁵ Despite the complexities of introducing such relatively novel forms of education and the clear potential for applications to reduce medication errors, there is no published work investigating their design or use. Such forms of education would not replace other methods of reducing medication error, but support improvement as part of a package of measures, which may include knowledge-based education sessions and organizational system based error reduction strategies.

These are a number of published works that guide understanding of how technical and nontechnical factors may impact prescribing. Previously, a perceived “blame culture” surrounding prescribing has been reported, which may actually promote nontechnical errors.¹⁶ Denial of personal roles and responsibilities as a barrier to safe prescribing has also been found.¹⁷ In the context of other patient safety issues, increasing general error awareness to enhance practice has been proposed,^{18,19} and this has been used in prescribing improvement with some success.²⁰ Finally, a computer-based prescribing error model of writing prescriptions has previously been designed²¹ based on control theory, a psychological theory of human performance which explains skilled behaviors, giving insight into how prescribing decisions are made.

All these elements form a conceptual framework that can allow us to understand the relationship between people and systems of work, known as the human factors perspective,²² within the context of prescribing education. Whilst non-technical skills and systems factors in surgery have been carefully studied,²³ there is a lack of clarity as to how these different elements interact to affect prescribing. Human factors models can assist in achieving that analytical balance between person and system. We set out to investigate the internal and external factors which impact on recent graduate prescribing, understand their responses to these factors, and by considering the conceptual elements discussed, use this to model safe prescribing behavior from a human factors and nontechnical skills perspective to support educational design in this area.

Materials and methods

Data collection

Participants were newly qualified doctors who had volunteered for a randomized controlled trial of an e-learning intervention to improve prescribing, with full methodological details previously published.²⁴ This research had ethical and research and development approval from the University of Dundee. This study was carried out prospectively, in parallel and independently to the randomized controlled trial to answer its distinct research question.

All doctors within the Foundation school were invited to take part, with exclusions including those who had previously worked in prescribing roles, those who had limitations on their prescribing, or those who had come from a background in the pharmaceutical industry. The study began one month into Foundation training, with 161 in Foundation year 1 (FY1) and 45 in Foundation year 2 (FY2). The participants were randomized to receive a knowledge-based e-learning intervention or no intervention. Participants completed prescribing assessment, attitude, and confidence questionnaires online pre-intervention and 4 and 12 weeks post-intervention as part of the trial. In addition, at each of these data collection points, participants were also asked to report details of their views on prescribing safety, practices, and behaviors at that time. This request was as a free text response, which was also returned online. Reminders were sent to nonresponders at 1 and 2 weeks, respectively.

For triangulation and confirmation of saturation of these data, at the conclusion, participants from both study groups were invited to attend semistructured interviews. A total of 20 participants responded, which consisted of a representative mix of participant demographics. These interviews were

completed by two of the authors after the last assessment and again focused on prescribing safety. A thematic index was developed to code the data. Five initial categories were developed, based on the conceptual frameworks already discussed before the study began (Table 1) and prior to analysis of the free text data. A total of five questions were devised for the interview schedule, based on each of the areas within this framework. Eleven participants were randomly selected for interview before it was deemed that saturation had been achieved, with no new themes emerging.

Data analysis

Whilst our initial thematic index (Table 1) formed a starting point for analysis, we avoided making a priori hypotheses and conclusions, in keeping with a grounded theory approach.²⁵ Free text responses were held pseudonymously using study IDs. Following collection and processing, the data were coded using Nvivo (QSR International Pty Ltd, Doncaster, Australia).

The initial thematic indices were developed, with the addition of emerging thematic categories according to interpretation of the content of the data. The analysis proceeded through three stages, consisting of open, axial, and selective coding, with constant comparison taking place throughout each phase.²⁶ Each stage provided categories that could be used to explore the themes of the data. After the baseline data were analyzed, the post-intervention data for the control and intervention groups were initially analyzed separately. The group interviews were completed and transcribed externally with pseudonyms for anonymity and these data were also coded into the thematic framework to ensure theoretical saturation had been reached. Delineation between human and system was facilitated using the SEIPS (Systems Engineering Initiative for Patient Safety) model.²²

Results

A total of 205 participants were recruited, with 106 participants randomized to the control group and 99 to the intervention group, with demographics such as gender, age, and previous degrees equally distributed between groups.²⁴

Table 1 Initial categories for data coding, based on the proposed conceptual framework

- Perception of current prescribing abilities
- Barriers to prescribing
- Solutions to these barriers
- Facilitators to appropriate prescribing
- Blame culture surrounding prescribing

A total of 388 of a possible 412 potential text responses were received (94.1%). Figure 1 shows the open and axial themes. In the open coding stage, 27 categories were developed from the initial thematic indices. The next stage of the analysis established six comprehensive themes, ie, contributors to inappropriate prescribing, contributors to appropriate prescribing, professional responsibility, prescribing error, improving prescribing, and current practices. Analysis of the two study groups post intervention revealed no divergence in the data, so the data sets will be discussed together.

The first two themes were the focus of many responses, essentially mirroring each other, with the participants suggesting solutions to each of the problems they identified. Seeking information sources was widely cited, with 244 of 1242 items coded into this category. The use of the British national formulary, pocket prescribing books, local guidelines, and national policies were all mentioned. Some cited positive role models behavior, while others cited inexperience or concerns with the possibility of error. There was an increase in the reported use of prescribing resources over time (Table 2). This does not appear to be influenced by whether participants had received the extra knowledge and skills training offered as part of the trial, but rather seemed to be a direct response by the recent graduates to their experiences:

“I think that I am increasingly cautious with my prescriptions. I double check everything but the more I prescribe, the more I am aware of complications that may occur.”

Table 3 gives details of responses for each of the categories within these first two themes reported in line with the SIEPS model for understanding the structures, processes, and outcomes in health care from a patient safety perspective.²²

The next theme, professional responsibilities, describes how recent graduates viewed their ability to prescribe not as a right or duty, but as a task they complete as a professional, accepting the associated risks and hence responsibilities. In the initial baseline data set, the weight of this responsibility led to apprehension:

“It is you signing it, so ultimately you are responsible for that prescription if anything goes wrong.”

“I feel I am scared and am conscious that I am newly qualified so don’t want to harm any patients by my mistakes with my prescribing.”

In the subsequent data sets, this theme surfaced in how the prescribers responded to those around them. In particular, there were 19 coded items which all occurred at the final data

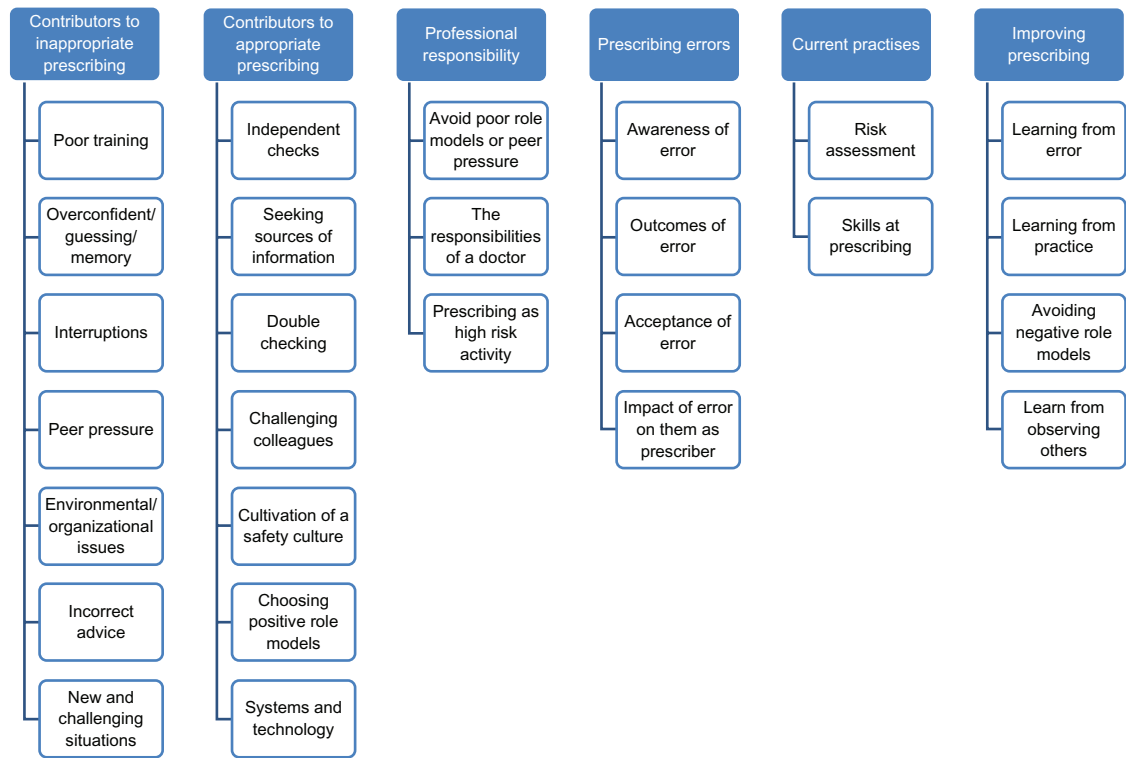


Figure 1 Open and axial coding themes.

collection point that related to peer pressure from medical or nursing colleagues to prescribe:

“I might not do what the nurses want me to do, ie, prescribe that particular drug and they’ll get quite angry with me.”

“When you want to question, they’d just say ‘what do you mean? Just get on with it.’”

In this way, professionalism in the context of prescribing was linked to the next theme, prescribing errors. The recent graduates are clearly aware of the many factors leading to error and how to start negating these, as discussed in the first two thematic areas. This awareness of error was a key theme, but many participants commented on their own experience of error, how it affected them, and frequently discussed the potential outcomes of error:

“The most serious consequences can happen, they can be fatal.”

Table 2 Use of external sources of prescribing information, number of open coded responses from free text data at baseline, and final data collection point

	Baseline	12 weeks
Total	54 (33.3%)	101 (62.3%)
Control group	30 (34.9%)	57 (62.7%)
Intervention	24 (31.6%)	44 (57.2%)

“You ultimately are legally responsible. We can also get into a lot of trouble with the GMC!”

While it was expected that fear of blame would be a barrier to speaking up, in fact the reverse was true:

“I’ve seen quite a lot of drug errors and people have said ‘Oh you know there was an F 1 who did this’ but no one’s ever said they were stupid, they’ve just said this is an error.”

The next theme was current practices. This comprised two aspects: firstly, that generally trainees felt prepared to prescribe, but were cautious in doing so, and, secondly, risk assessment. This related to a number of the categories, discussing how error changed behavior and methods to improve prescribing, often to negate the risks they identified. Some specific examples included:

“To prescribe safely, I must look things up, which prohibits me prescribing quickly, for example during a ward round, so maybe there is a risk of things not being prescribed as I have to list things to go back and prescribe later.”

“I often choose a drug I am familiar with rather than a new one, to reduce risk.”

“I try to treat prescribing like a procedure, with preparation phase involving checking the correct patient, indication and any allergies. I always use a calculator to do even the

Table 3 Open coded responses and excerpts for two axial coding themes: contributions to inadequate and adequate prescribing, organized in line with the SIEPS model²²

Systems component	Category	Coded items (n)	Excerpt
People	Confidence/guessing/memory	30	"The seniors are confident in what they are doing. Or at least they think they are and they think they're right."
	Peer pressure	19	"I've had it where I was told to prescribe this and they'll tell me the dose and times but I still go and ... because someone else told me what to do, and they might be more senior than me but it's my signature on it so ... He gave me a funny look, like a dirty look as if I'm not trusting them!"
	Challenging colleagues	3	"I think they can be quite understanding, because my consultant told me to prescribe amiodarone once for a patient, and I said 'OK' and then I thought about it and I thought 'no, I'm not happy.' And I rang him back and I said 'I'm not prescribing it,' and he said 'OK, give him a beta-blocker!'"
Tasks	Incorrect advice	13	"Recently, I was asked to prescribe zopiclone 7.5 mg by a nurse. I never prescribed this drug before, so I checked and I prescribed 3.75 (as advised by the BNF)."
	Choosing positive role models	43	"In particular I have found it useful talking to more experienced nurses who have worked in my specialty for a long time and are familiar with the common drugs used on the ward."
	Independent checks	21	"Having other people look at your prescription chart ... I regularly ask my ward pharmacist for advice."
Technology and tools	Double checking	30	"I worry if I have not checked my prescriptions and it's easier for me and safer for patients if I just double check."
	Seeking sources of prescribing information	244	"I have become more aware that I should use reliable, identifiable sources when dealing with unfamiliar medications such as the BNF or BNF online. This means that a verified dosing regimen can be used."
	Systems and technology	10	"They have different colored drug charts, which I quite like. Like that because you can see instantly if someone's got an allergy or not based on the color of the drug chart in front of you. It does make you think when you're about to prescribe something 'hang on it's yellow.'"
Environment	Interruptions	20	"There's an ECG in your face and somebody behind you waiting to ask you something and you just lose track of what you're doing ..."
	Workspace	11	"Having two drug cards and quite often one disappears and you might not know that there's another one and that means you're not aware that they are receiving different drug."
	New and challenging situations	8	"It's usually in an emergency setting that you have to give them, and you're not happy, because you've not used it that many times before."
Organization	Training	10	"Our university didn't place much emphasis on prescribing, until the very last few weeks of our course, so it's very much something that I've had to teach myself."
	Cultivation of safety culture	7	"I've seen quite a lot of drug errors and people have said 'Oh you know there was an F I who did this' but no one's ever said they were stupid, they've just said this is an error, I've never seen anyone being blamed."

Abbreviations: fl, foundation doctor year 1; BNF, British National Formulary; ECG, electrocardiograph.

simplest drug calculations. I am very aware that prescribing is one of the riskiest things doctors do.”

Risk assessment seemed to determine when and to what extent they would prescribe safely. Occasionally, the outcome of this risk assessment would lead them to prescribe in a suboptimal way:

“When asked to prescribe something by a senior without checking, it would depend on the person and depend on the drug, if you knew it was a sort of dangerous drug, I’d double check it.”

“I think junior doctors can easily panic and assume it’s more important to get something done fast so they can get on with all their other jobs than it is to do something safely.”

“If I don’t know a drug I look it up. The exception to this is if I am rewriting a drug card and I need to be quick. If I know it has been checked by a pharmacist I don’t look it up if I haven’t got time.”

The final theme was improving prescribing. Error is clearly identified as a source of learning. This occurs on a personal level, with errors constantly shaping behavior, but also in peer groups, with several participants mentioning root cause analysis as a method employed within the workplace:

“In our hospital we learn in teaching, somebody will bring up something that’s happened, they’ve mismanaged the patient, and its lessons learned at the end.”

“With a facilitator from ITU and somebody volunteers to present a case and then the facilitator breaks everyone up into groups and each person gets a different thing to look at, like the human errors ... and you sit and discuss them at the end with the facilitators.”

The importance of learning from experience was emphasized:

“Prescribing is best learnt actually doing it and having to look up doses yourself. Also helps if you have to prescribe the same drug for lots of patients – helps drum it in.”

“I take every opportunity to rewrite and check drug charts in order to increase practice prescribing.”

This experience often involved examples of poor practice and actively avoiding these negative role models.

In the final selective coding level of analysis, these themes were bound by the authors in a nontechnical skills model of recent graduate prescribing behavior (Figure 2), which was influenced by our conceptual framework, but grounded in the data analyzed. This model initially denotes the prescriber receiving input to improve prescribing from the sources identified (learning from error, practice, and observation). These then go on to influence the prescriber in three main areas. The first is awareness of error in prescribing, both as presented in teaching and experienced in their own practice. The second is situational awareness, around the contributors to error they encounter

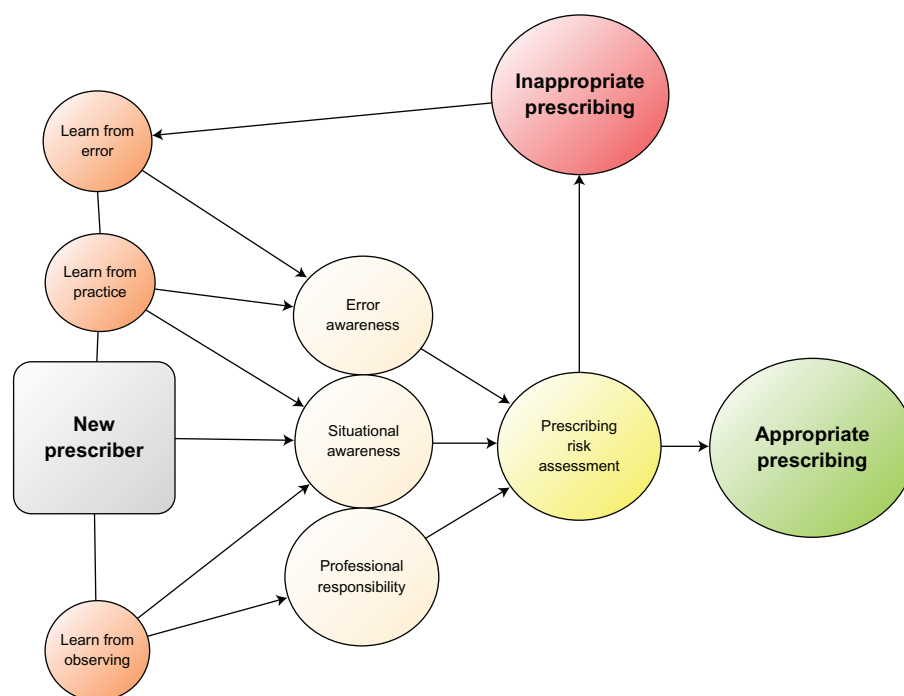


Figure 2 Human factors model of safe prescribing behavior by recent medical graduates.

and how these may be tackled. The final area is professional responsibility to prescribe. This is also heavily influenced by their role as a trained professional, but in particular by observing poor role models, peer pressure to prescribe irresponsibly, and, finally, from an increasing awareness of risk. These areas are represented as tightly bound, because one clearly influences the other, with heightened professional responsibility improving situational awareness and improved knowledge of error influencing professional responsibility. Finally, these elements all encourage risk assessment which should facilitate good prescribing.

Discussion

Within these data, there were clear behavior shifts over time, with increasing referencing for information, double-checking, and use of technology to support prescribing. Participants explained that whilst they felt competent to prescribe on graduation, they began to feel that other practices are increasingly needed to support safer prescribing. It seems that over time, the participants learned not just to practice the clinical skills they had acquired, but to understand that their performance and safe prescribing was enhanced by their nontechnical (cognitive and social) skills situated within the systems context in which they were working. Sometimes there was a gap between those systems and skills which lead to risks; sometimes it was those systems of work or the good application of teamwork and cognitive skills that led to improved care and safety. This is clearly in line with a human factors view that would predict how practitioners learn to work safely within a complex sociotechnical system.²⁷

Previous reports have suggested an organizational culture of blame, prescriber's unwillingness to accept responsibility for error,¹⁷ and a culture of lack of safety amongst recent graduates.⁵ However, we found little concern with blame surrounding prescribing errors and indeed a culture of acceptance at an institutional level, again aligning with a human factors perspective of such activities. This reinforces the value of exploring activity at the sharp end of care, before generating solutions "top down" which might otherwise be based on limited or erroneous assumptions.

Our participants clearly exhibited heightened awareness of error, from their own experience and observations. They often reflected on negative behaviors, how they may lead to error and on changes to their own practice. There was substantial consideration of contributors to poor prescribing, for which clear solutions to each were suggested. Whilst positive prescribing role models were seen to enhance practice, the trainees did not seem to be adversely effected by

negative behaviors. Rather, in an extension of the internal process already described, they used these experiences to shape their own practice further. From a number of comments from the participants, it seems that negative examples of prescribing enhanced their sense of professional responsibility and improved their prescribing risk assessments.

The model synthesized (Figure 2) shows how recent medical graduates use these different elements to inform their personal assessment of prescribing risk. Whilst this usually produces appropriate prescribing, if errors are made or observed, behavior-determining processes are enhanced, leading to a more informed and inherently safer risk assessment, following the principles identified in our conceptual frameworks. Thus, a substantial part of the work of new practitioners had been to adapt behavior to create safety, and there may be an opportunity to assist this process.

Our participants clearly learn the tenets of safe prescribing through an explorative and iterative process of behavioral modification. Experience and, in particular, experience of poor prescribing, drives this process. Interestingly, the perspective was inwardly directed, with no mention of a desire to effect change in colleagues, their environment, or systems. Thus, the new practitioners learned to adapt to the environment in which they found themselves without substantial sharing of their learning or a uniformly well structured theoretical understanding. Certainly, many behaviors seemed positive, but there should remain a concern that the outward "systems" perspective was becoming lost, and that more generally, the lessons that were being learned were not shared or universal. Thus, each was developing his or her own way of working. Clearly, there might be value in structured education to ensure uniform safety and nontechnical skill acquisition. Further, because experience of actual error is key to this process, education that can allow such nontechnical skills to be acquired without error occurring is clearly of benefit to patients.

Therefore, we would propose that educators wishing to train in any aspect of prescribing should pay attention to the key principles of this model. Several areas of this model are already parts of educational techniques to enhance patient safety.¹⁵ Although crew resource management may form a good basis for development, most current publications describing crew resource management in health care focus on "whether" it is effective, and although nontechnical skills training has been carefully defined in some areas,²³ how it should be delivered and the mechanisms of learning have been poorly investigated.¹⁵ This lack of theoretical underpinning or evidence-based construction offers little of use

to educators. Moreover, the assumption that this learning is not taking place is erroneous; clearly it is, and is impacting behavior in a significant way. This study may be the first to demonstrate this, and we need to take care not to fall into the trap of offering prescribing training that does not fit easily with and complement this workplace learning. Such superimposition of “sharp end” knowledge and skills from other industries that may not consider the context of learning in health care has perhaps been the biggest disincentive for crew resource management and nontechnical skills training, and is reflected in high costs, mixed benefits, and heterogeneity of courses that have been described.¹⁵

Our model offers a simple structure that will aid in the better translation of safety skills training into a prescribing environment and could be used to guide the design of interventions for improvement and ultimately support better outcomes for patients. Whilst this may lead to stand alone interventions, these findings can be used to enhance all prescribing education by carefully considering the relationship between humans and systems.

This study has several limitations. The method of data analysis we have used is clearly open to interpretation bias on the part of the researchers, with our own preconceived ideas shaping the analysis. Every effort has been made to minimize such bias, in line with accepted methodology.²⁴ Although it covers a wide range of hospitals, specialties, genders, and ages, this was a volunteer sample, with the possibility that this may be a source of bias. In particular, it is possible that the participants may have been involved in more errors and be more disposed to improvement of prescribing at enrolment. Social acceptability bias is also possible, with respondents censoring opinions they felt would be unacceptable. Given these limitations, further study is needed to confirm the features of our proposed model and, in particular, its utility for educators planning nontechnical educational interventions for prescribing skills. Further, given that there is minimal evidence to suggest that nontechnical skills training in health care can change behavior or outcomes for patients, attention should be paid to these areas when investigating educational packages.

Conclusion

We have studied and modeled prescribing behaviors of recent medical graduates from a nontechnical skills perspective to demonstrate how several factors influence a constant process of prescribing risk assessment. Given that these factors are related to a number of recognized elements of nontechnical skills training within health care, educators should consider

design elements from these interventions to support prescribing improvement programs, although future work is needed to assess the application of our findings in other settings and to assess the role of prescribing focused nontechnical skills training in general.

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Disclosure

The authors report no conflicts of interest in this work.

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Non-technical skills training to enhance patient safety: a systematic review

Morris Gordon,^{1,2} Daniel Darbyshire³ & Paul Baker⁴

CONTEXT Many quality improvement education programmes have been introduced over the last decade with the purpose of enhancing patient safety. The importance of non-technical skills training is becoming increasingly prominent, but the extent to which educational interventions have been used and the theoretical underpinnings of such interventions remain unclear. These issues were investigated through a systematic review of the literature.

METHODS Any studies involving an educational intervention to improve non-technical skills amongst undergraduate or postgraduate staff in an acute health care environment were considered. A standardised search of online databases was carried out independently by two authors and consensus reached on the inclusion of studies. Data extraction and multimodal quality assessment were completed independently, followed by a content analysis of interventions and the extraction of key themes.

RESULTS A total of 22 studies met the inclusion criteria. Measured outcomes were variable,

as was the strength of conclusions. Theoretical underpinning of interventions was not described in any studies. Content analysis revealed reasonable consistency with the emergence of five key themes: error; communication; teamwork and leadership; systems, and situational awareness. Teaching was often multidisciplinary and methods used included simulation and role-play exercises, and observation.

CONCLUSIONS The methodological quality of published studies is reasonable, although the reporting of specific interventions is poor. Although a recognised model to support the design of patient safety education is lacking, a number of theories have been applied to guide educators in future instructional design. Further published work should clearly describe interventions and their theoretical underpinnings, and should aim to further explore which specific aspects of interventions are effective and why. Such research should also try to assess whether such interventions can impact patient outcomes.

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INTRODUCTION

For millennia doctors have begun their careers by making a pledge that starts with a declaration of the principle to 'do no harm'. Despite these words, it has often been acceptable to believe that harm to patients is unavoidable and to rationalise that the majority of patients do not suffer from such events. Work by the Harvard Medical Practice¹ tried to quantify the incidence of such errors, particularly those that are preventable. This led to the publication of the Institute of Medicine's report *To Err is Human*, in 1999,² which shocked public sensibilities and, by dint of the resulting furore, prompted immediate action amongst the highest levels of health care establishments and policymakers across the world. This momentum impacted all areas of health care and gained prominence in all health institutions. In 2000, the UK Department of Health responded with the report *An Organisation with a Memory*.³ This focused safety improvement strategies on systems to manage risk arising from tasks, environments or organisations, rather than from human errors, which represent the last and probably the least manageable part of the causal sequence leading to the occurrence of a preventable adverse event. Although many such interventions now exist, contemporaneous data suggest that preventable errors still occur and therefore other error reduction strategies are needed.

Extensive work in high-stakes industries⁴ has demonstrated that improving safety is not just about enhancing knowledge or skills, but also concerns the addressing of human factors and poor performance of non-technical skills that can lead to errors.⁵ These two areas are related because human factors pertain to everything in the working environment that can impact patient care, such as guidelines, equipment, systems and an understanding of how human behaviour affects these. Non-technical skills are the cognitive and interpersonal skills that complement an individual's clinical knowledge and facilitate the effective delivery of safe care (although there is a lack of consensus on such definitions in the literature). In the 1970s, the National Aeronautics and Space Administration (NASA) investigated non-technical skills to understand airline crashes. NASA designed programmes to modify behaviour through psychologically grounded education, such as crew resource management (CRM) training. This training focuses on behaviour in teams and embraces the importance of learning from error to prevent recurrence.⁶ This type of education has been transferred into health

care, most notably in anaesthesiology,⁷ and has been shown to reduce error.⁸

Improving patient safety is increasingly mentioned in the context of training, such as in the UK General Medical Council's publication *Tomorrow's Doctors*,⁹ although no guidance is given on how such aims might be achieved. Further educational innovation in this area is currently limited by three main barriers: a lack of clarity in the different methods of patient safety improvement; poor understanding about what makes an effective intervention in each area, and a lack of clarity in the theoretical underpinnings of such instructional design. Education around hand-over of care, a key patient safety issue, has been investigated.¹⁰ Several key themes were applied to an existing model of handover¹¹ that related to a number of non-technical skills and appropriate theory proposed to help guide further educational design. These theoretical elements may support understanding in the context of general non-technical skills-related patient safety education.

As well as systematic reviews of specific patient safety issues, such as handover¹⁰ or prescribing,¹² a systematic review of quality improvement and patient safety curricula was recently published.¹³ This found increases in knowledge associated with patient safety education, but had several limitations. Its scope was limited to medical staff and included only a selection of electronic databases and a limited timeframe. It also suffered from a lack of clarity in its definition of patient safety and quality improvement curricula and placed little focus on non-technical skills and human factors in either its search strategy or criteria for the inclusion of studies. Finally, it made no attempt to assess the theoretical orientation of interventions. Recently, guidance based on undergraduate training in patient safety was published, but this also failed to present any theoretical underpinnings for the curricula,¹⁴ despite work suggesting that educators wish clarity in this area.¹⁵ We therefore set out to review the evidence regarding educational interventions to enhance patient safety using a non-technical skills training approach, with the aim of exploring the effectiveness and theoretical underpinnings of such interventions.

METHODS

Our objectives for evidence synthesis were not aligned with a particular epistemological stance and thus we did not take a strict positivist or constructionist approach.¹⁶ Rather, we followed a pluralistic

Table 1 Characteristics of the studies included in this review

Author	Year, location	Study type	Participants	Intervention
Blegen <i>et al.</i> ³³	2009, USA	Before and after	Multidisciplinary: medical and non-medical	4-hour session Didactic presentation from aviation expert on communication/teamworking, followed by small-group practise Other interventions concurrently took place
Blum <i>et al.</i> ³⁴	2004, USA	Action-based	148 anaesthetists	1-day training session Initial scenario, followed by crisis RM-based facilitated discussion and review of video recording of initial scenario Several further scenarios, one involving a medical error
Cox <i>et al.</i> ³⁵	2009, USA	Action-based	Multidisciplinary teams of students	Students were given cases describing a medical error Working in small teams over 4 weeks, students simulated an RCA and began using performance improvement tools At completion, they presented their work to fellow students
Ellis & Jenkins ³⁶	2011, UK	Before and after	152 multidisciplinary trainees from several acute care areas	Overview of human factors, followed by teamworking exercises Clinical scenarios based on real clinical incidents
France <i>et al.</i> ³⁷	2005, USA	Action-based	182 individuals in multidisciplinary teams	1-day intervention delivered by crew RM experts from the military or aviation, consisting of lectures and role-playing simulated scenarios
Hall <i>et al.</i> ³⁸	2010, USA	Action-based non-RCT	146 Year 3 medical students	First 1-hour session reviewed skill-based patient safety tools, RCA and Reason's Swiss cheese model ⁶⁰ Second session: students described actual events and analysed them
Haller <i>et al.</i> ³⁹	2008, Switzerland	Action-based	239 multidisciplinary obstetric staff	2-day interprofessional seminar Video, followed by discussion of error, lectures aimed at improving knowledge Role-play aimed at highlighting expectations and misunderstandings
Jankouskas ⁴⁰	2010, USA	RCT	496 medical students	Control intervention: basic life support training Intervention: 30 minute crisis RM training on the team process variables of teamworking, task management, situation awareness, and interprofessional attitude, with pre- and post-intervention videotaped practise scenarios
Kyrkjebø <i>et al.</i> ⁴¹	2006, Norway	Action-based	12 medical and nursing students, nursing postgraduates	Interactive lecture on crisis RM theory Video ending just before patient injury as a trigger for discussions on how to interrupt the causal chain Simulation training with scenarios related to the videos, followed by reflections
Lindamood <i>et al.</i> ⁴²	2011, USA	Action-based	128 multidisciplinary staff of neonatal unit	4-hour course in high-fidelity simulation suite including game play, didactic presentation on principles of crisis RM including video review, NICU-specific high-fidelity simulated clinical scenarios and post-simulation video-based debriefing
Mann <i>et al.</i> ⁴³	2006, USA	Action-based	Entire obstetric staff	4-hour curriculum covering team meetings (what questions to ask), situational awareness, communication and handover and mutual support Additional organisation shifts in safety culture occurred
Marshall & Manus ⁴⁴	2007, USA	Action-based	688 theatre staff	Workshops were delivered through a combination of information, demonstration and practice-based methods to present teamwork material Interactive break-out session that focused on the development of SBAR briefings
McKeon <i>et al.</i> ⁴⁵	2009, USA	Action-based	Five nurses on clinical leadership programme	2-day aviation check airman crew RM and human factors training at FEDEX and 1-day intensive health care team training in adaptation and coordination, as well as self-correction

Outcome measures	Results	Conclusions	Level of outcomes	Strength of conclusions
Agency for Healthcare Research and Quality Hospital Survey on Patient Safety Culture	Five of 11 safety culture subscales showed significant improvement Nurses perceived a stronger safety culture than doctors or pharmacists	The intervention seems to have improved the safety culture on these medical units	Level 2a	3/5
Surveys measuring acceptance, utility and need for recurrent training immediately post-course	The highly rated course was well received Half the trainees reported improvement in their crisis RM non-technical skills at a critical event following the course	These data provide indirect evidence supporting the contention that this type of training should be more widely promoted, although more definitive measures of improved outcomes are needed	Level 1 Level 3	3/5
Survey focusing on six subscales: human fallibility; disclosure; teamwork/communication; error reporting; systems of care, and curricular time spent with other professionals	At pre-test, there were significant professional group differences in all six subscales At completion, differences in four subscales were resolved with the exception of human fallibility ($p < 0.001$) and curricular time spent together ($p < 0.001$)	The curriculum was successful in resolving most professional group differences covering important principles related to patient safety, quality of care and teamwork	Level 2a Level 2b	2/5
Evaluation questionnaire, SAQ and follow-up interview	Attendees reported very positive responses to the evaluation questions No change in SAQ	HuFaST empowers frontline staff to assume responsibility for patient safety	Level 1 Level 2a	1/5
End-of-course feedback and crew RM human factors attitude survey	Positive reaction to participation Improved human factors attitudes	The training had a positive effect on attitudes towards the roles of coordination, communication, leadership in creating and maintaining effective teams	Level 1 Level 2a	4/5
Patient safety attitudes and self-reported safety skills survey Student-submitted reports compared with contemporaneous reports from the patient safety reporting system	Statistically higher comfort levels with identifying the cause of an error than in student control group ($p < 0.05$) Proposed safety interventions more robust than those suggested by others regarding similar events ($p < 0.0001$)	Increased student comfort in safety event analysis Students documented stronger resolution robustness scores, suggesting similar training should be offered to patient safety reporters	Level 2a Level 2b	4/5
Satisfaction questionnaire	Most participants valued the experience and rated their satisfaction as very high	The simulated in-patient unit was an effective and efficient environment in which to teach students about handovers in a busy, demanding in-patient unit setting	Level 1 Level 2b	2/5
Anaesthetists' non-technical skills system, error rates, response time	The teams trained in crisis RM and basic life support skills demonstrated an increase in team process as measured by teamworking, task management, and situation awareness They did not demonstrate improved team effectiveness, difference in response time or number of medical errors	The educational programme was an effective method for promoting team process	Level 2b	4/5
Focus group with structured interviews to evaluate the session	Students were satisfied with the programme Change in attitudes on role of teams and importance in teamworking	This is a valuable tool for challenging ways of looking at other professions in interactions involving patient safety	Level 1 Level 2a	3/5
Course evaluation	Over 98% of participants either strongly agreed or agreed that the curriculum was applicable and realistic and improved their comfort with crisis RM skills	No clear conclusions made	Level 1	1/5
AOI	The AOI score for high-risk premature births improved 47%, term deliveries 14%	Teamwork training is an important tool in the prevention of medical errors and can improve patient safety	Level 4b	2/5
Hospital survey on patient safety culture	Improved attitudes reported towards safety, communication, error awareness and reported behaviour change	Overall improvements in achieving increased levels of patient safety awareness and trends towards improvement in the quality of team-based behaviours and performance	Level 2a Level 3	3/5
20-item MCQ test measuring safety-oriented teamwork communication knowledge, guided debriefing and course evaluation	Test scores validated competency in safety-oriented, teamwork communication Learning objectives were met	The course teaches nurses how to improve patient safety at the front line of care	Level 2a Level 2b	1/5

Table 1 (Continued)

Author	Year, location	Study type	Participants	Intervention
McCulloch <i>et al.</i> ⁴⁶	2009, UK	Before and after	Theatre staff observed in 103 procedures	9-hour classroom non-technical skills course based on aviation crew RM was offered to all staff, followed by 3 months of twice-weekly coaching from crew RM experts
Papastrat & Wallace ⁴⁷	2003, USA	Action-based	35 undergraduate nursing students	Using a PBL approach, students were exposed to medication administration and errors Using the frameworks of failure mode analysis and human error mode and effects analysis, students devised solutions to prevent errors and facilitate error reporting
Pratt <i>et al.</i> ⁴⁸	2007, USA	Before and after	220 multidisciplinary obstetric staff	4-hour course covering four different modules: communication; situational monitoring; mutual support, and leadership Several other changes were also made
Rudy <i>et al.</i> ⁴⁹	2007, USA	Action-based	149 staff in multidisciplinary groups	2-hour session including didactic content addressing the background principles of crisis RM, demonstration of crisis interventions, trainee participation interactions in managing a crisis event, and critical analysis and self-reflection of performance using video debriefing
Thompson <i>et al.</i> ⁵⁰	2008, USA	Action-based	2 full year cohorts of Year 1 medical students	10-hour patient safety elective spanning 5 weeks Modules included science of safety, investigating a defect, measuring safety and teamwork culture, teamwork and communication Methods included lecture, discussion, reading, simulated experience, PBL, video review
Wakefield <i>et al.</i> ^{51,52}	2008, 2009, UK	Before and after	38 multidisciplinary clinical and non-clinical staff	3-day face-to-face training in RCA supported by a six-module e-learning resource
Halbach & Sullivan ⁵³	2005, USA	Before and after	572 Year 3 medical students over 4 years	4-hour curriculum with three parts: an introductory lecture/discussion lasting 1 hour to 12–24 students by family doctors; brief required readings, and a videotaped simulation of discussing an error with an SP Students received verbal and written feedback
Madigosky <i>et al.</i> ⁵⁴	2006, USA	Before and after	92 Year 2 medical students	10.5 hours over the curriculum covering five main themes: patient safety overview; error reporting; system versus human approach; safety tools, and ethics/disclosure
Patey <i>et al.</i> ⁵⁵	2007, UK	Before and after	110 final-year medical students	5 hours in two sessions held 3 days apart Session 1: nature of error Swiss cheese model; video illustrating an adverse event, and student identification of active and latent errors Discussion of learning from other industries Session 2: led discussion on the importance of recognising personal limitations, seeking help and effective communication

AOI = Adverse Outcome Index; IPL = interprofessional learning; MCQ = multiple-choice question; NICU = neonatal intensive care unit; NOTECHS = Oxford Non-Technical Skills; PBL = problem-based learning; RCA = root-cause analysis; RCT = randomised controlled trial; RM = resource management; SAQ = Safety Attitudes Questionnaire; SBAR = Situation, Background, Assessment, Recommendation; SP = standardised patient

Outcome measures	Results	Conclusions	Level of outcomes	Strength of conclusions
Attitudes were measured using the SAQ Teamwork was scored using the NOTECHS method Technical errors and non-operative procedural errors (NOPEs) were recorded	Non-technical skills and attitudes improved after training (NOTECHS increase 37.0–38.7 [$t = 22.35$, $p = 0.021$], SAQ teamwork climate increase 64.1–69.2, [$t = 22.95$, $p = 0.007$]) Technical errors and NOPEs declined	Non-technical skills training improved technical performance in theatre, but the effects varied among teams	Level 2a Level 2b Level 3 Level 4	4/5
Qualitative feedback regarding the session and reflective comments by tutors	This course encouraged students to think, explore communication and teamworking skills 80% said they would wish to use a similar PBL-based approach for this course in the future, rather than a traditional approach	A PBL approach can encourage active learner participation, provide clinically relevant material, and create renewed enthusiasm for classroom learning	Level 1	4/5
SAQ, AOI and weighted adverse outcome score	A significant decrease in severity of adverse events and malpractice claims and improved attitudes were seen	Crisis RM concepts can be taught to a large number of staff and behaviours transferred to the workplace	Level 2a Level 4	3/5
A survey was designed to assess perceived positive changes in behaviour following crisis RM training and how crisis RM principles might have been applied by participants in clinical and personal-life situations	83% had managed a crisis since the course and 68% indicated better practice performance during emergencies 38% applied crisis RM to personal crisis experiences	Crisis RM training leads to perceived improvements in performance during critical events Ongoing crisis RM training can heighten awareness of the potential for health care mishaps during emergencies and improve patient safety	Level 2b Level 3	3/5
Groups received a recent sentimental event and were asked to apply their knowledge of systems theory to an RCA of their assigned case Student evaluations were collected and tutor observations made throughout the course	Students evaluated the course positively Attitudes shifted with greater awareness of the negative and positive impact of system factors on patient outcomes Students were able to identify the correct system factor causes for errors in scenarios	The course was well received by students and highly effective in changing their attitudes about medical harm and patient safety	Level 1 Level 2a Level 2b	4/5
Semi-structured focus group interviews pre- and post-intervention Individual interviews post-intervention	During the interviews and focus group discussions diverse experiences and expectations about the e-learning element of the programme were identified	Varied views on blended learning were seen IPL may encourage practice change Participants indicated that IPL and inter-professional working had the capacity to precipitate change	Level 1 Level 2a Level 2b Level 4a	2/5
Before and after participating in the curriculum, students were asked to complete questionnaires on self-awareness about patient communication and safety Curriculum evaluations and follow-up surveys were also distributed	Participants reported that they strongly agreed or agreed that the SP and feedback exercise was a useful learning experience Statistically significant increases in the self-reported awareness of students' strengths and weaknesses in communicating medical errors to patients and increased confidence	These findings suggest that awareness about patient safety and medical error can be increased and sustained through the use of an experiential curriculum Students rated this as a valuable experience	Level 1 Level 2a Level 2b	4/5
Students completed a knowledge, skills and attitudes questionnaire before the curriculum, after the final learning experience, and 1 year later At 1 year, students also responded to items about their use of the curriculum, error reporting, and disclosure experiences	There was improved knowledge, skills and attitude after the course, but the majority of these improvements were not sustained at 1 year	Results show that a patient safety and medical fallibility curriculum can affect the knowledge, comfort with skills, and attitudes of Year 2 medical students	Level 1 Level 2a Level 2b Level 3	4/5
Questionnaire to measure students' self-rated knowledge, attitudes and behaviour in relation to patient safety and medical error Formative questionnaire on the teaching process and how it could be improved	Some knowledge items significantly improved 1 year post-intervention High levels of satisfaction with the course were reported	Knowledge and perceived personal control over safety had improved Students rated the teaching process highly and found the module valuable	Level 1 Level 2a Level 2b	4/5

model, not using a single arbiter for quality assessment¹⁷ and including a mixture of evidence types. This study was not submitted for ethical approval as it did not directly involve participants of any type.

Data collection

Inclusion criteria embraced all study designs targeting medical, nursing and allied professional staff, including undergraduates, in any acute health care environment. Outcomes at any level of Kirkpatrick's adapted hierarchy,¹⁸ describing four levels of educational outcome that can be assessed, were considered. Although Kirkpatrick's model can be used as a critical appraisal tool, the present authors agree with Yardley and Dornan¹⁶ that this risks excluding valid data. Rather, Kirkpatrick's hierarchy was used as a classification tool to communicate the type of outcome that had been generated, of which multiple levels are possible within a single study.

Educational interventions were included if they were concerned with non-technical skills training to address outcomes in key safety issues identified from current statistics.¹⁹ An educational intervention was defined as any structured educational activity. If a study reported an intervention in limited detail or commented on improved safety without presenting evidence to support its claims, an attempt was made to contact the author(s) for further details. The search did not apply any exclusion criteria relating to date of publication, country of study or language of publication. Exclusion criteria ruled out any studies based in areas outside acute health care, studies describing systems-based interventions for enhancing safety without a specific educational intervention, and studies describing educational interventions that were focused on developing technical skills, rather than non-technical skills, to enhance safety (as are often seen in simulation interventions).

The following online databases were searched to June 2011 using a standardised search strategy (Appendix S1, online): MEDLINE; EMBASE; Cumulative Index to Nursing and Allied Health Literature (CINAHL); British Nursing Index (BNI); PsycINFO; Educational Resource Information Centre (ERIC); British Education Index (BEI), and the Cochrane Trials Database. Additionally, reference lists from included studies were searched for further relevant studies. Abstracts available online from relevant education societies, including the Association for the Study of Medical Education (ASME) and the Association for Medical Education in Europe (AMEE), were also searched. Abstracts were included if the authors

were able to offer further details that allowed a quality assessment and were excluded if such data were not available.

Data analysis

Citations were reviewed independently by MG and DD. Potentially relevant abstracts were independently reviewed and full papers obtained for any studies that appeared to meet the inclusion criteria. A manuscript screening tool was designed and used (Appendix S2) to support this process. Disputes were resolved by consensus. The full manuscripts for all included studies were assessed independently by both MG and DD. The quality of the studies was assessed using a data extraction form (Appendix S3), based on guidance available from Best Evidence Medical Education (BEME),²⁰ as well as the recommendations of Reed *et al.*²¹ Outcomes were also classified in line with Kirkpatrick's adapted hierarchy,¹⁸ in line with BEME guidance.²⁰ Disputes in these judgements were resolved by reaching consensus. Thematic analysis, utilising NVivo Version 9.0 (QSR International Pty Ltd, Doncaster, Vic, Australia), of the descriptions of the interventions was performed independently by MG and DD. This was again followed by a meeting to gain consensus. When appropriate data were available, meta-analysis was performed using REVMAN Version 5.1 (Nordic Cochrane Centre, Cochrane Collaboration, Copenhagen, Denmark).

RESULTS

Initial searching identified 437 citations, of which 432 were unique. All citations were read by MG and DD. Two potentially relevant abstracts from scientific meetings of ASME and AMEE were identified, but details to allow further screening were available for only one of these. Agreement between the two reviewers on citation screening was almost perfect (kappa statistic: 0.99) and consensus decreed that 55 citations were potentially relevant. Abstracts were reviewed using the screening checklist (Appendix S2). A total of 31 studies were identified for full screening.

These 31 papers were independently reviewed and 11 studies^{22–32} were excluded as not relevant, with no disagreement between the authors. This left 20 papers^{33–52} that met the inclusion criteria. Four potentially relevant papers were obtained by hand-searching of references and three of these were included,^{53–55} giving a total of 23 included articles. One study was reported in two papers^{51,52} and will be

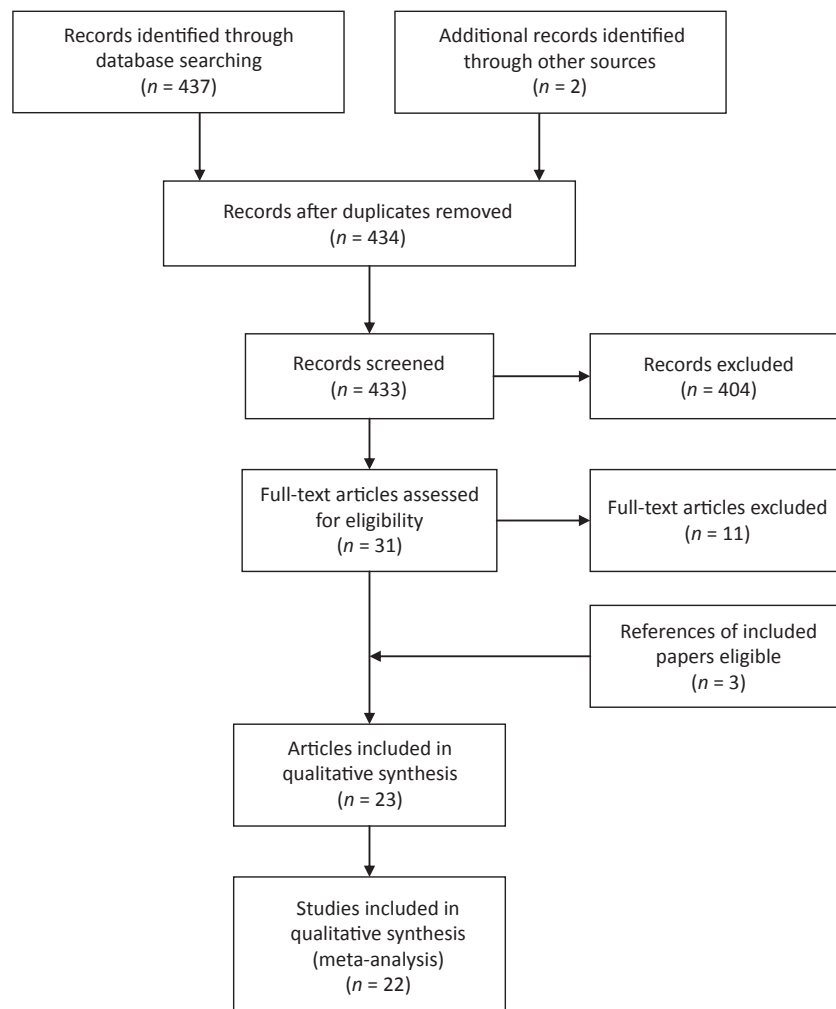


Figure 1 Flow diagram illustrating the search strategy

analysed as a single study; therefore 22 studies are included in this review. A flow diagram of the search is shown in Fig. 1. An overview of the included papers is shown in Table 1. Data were extracted independently by MG and DD, who achieved concordance in 89% of quality ratings and then met to reach consensus. Consensus results of the quality assessment in each of 16 criteria are shown in Appendix S4.

There was significant methodological heterogeneity among studies. Over half of the studies (13 of 22) described interventions delivered to multidisciplinary teams. The mean number of participants was 212 (range: five to 688). The majority of studies did not offer details of the intervention used (13 of 22). No study presented detail on the theoretical orientation of the intervention. Six studies described a direct alignment with the principles of CRM, although there was significant variation in their definitions and descriptions of CRM education. The strength of

conclusions estimated by using the BEME scale²⁰ was deemed to be poor in seven of the studies, which achieved scores of 1 (suggesting that results are not significant)^{36,42,45} or 2 (suggesting that results are ambiguous and may suggest a trend).^{35,39,43,51,52} Six studies^{33,34,41,44,48,49} were given scores of 3 on the BEME scale, indicating that their conclusions were most likely based on results. The remaining nine studies achieved scores of 4 for the strength of their conclusions,^{37,38,40,46,47,50,53–55} which suggests the conclusions are clear and very likely to be true.

There was variation in the focus of outcomes amongst the studies, with representation of all levels of Kirkpatrick's adapted hierarchy²⁷ (Table 1). However, there was also significant variation in the methods used by individual studies to measure outcomes, which reduced the scope for meta-analysis. Attitudes towards patient safety represented the most investigated outcome measure, but, amongst the 15

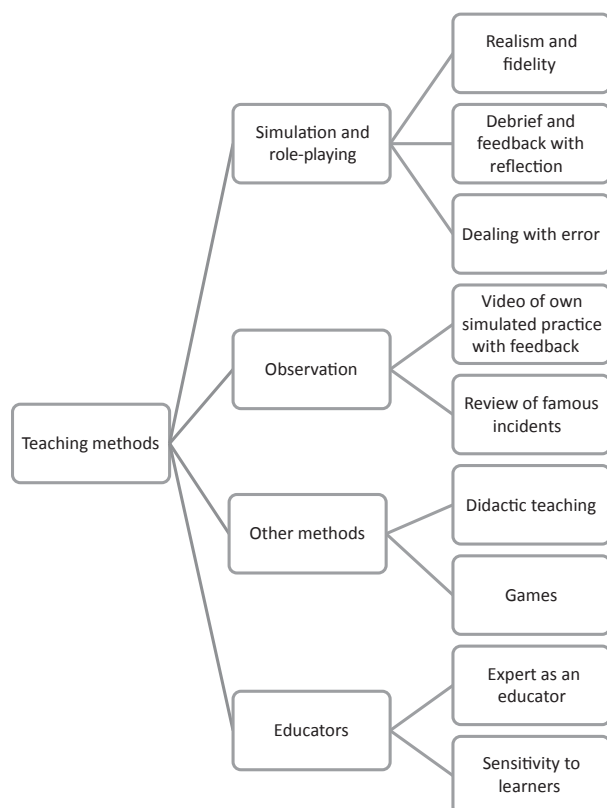


Figure 2 Analysis of teaching methods

studies that used this outcome, 11 different survey-based measures were employed. One previously validated instrument,⁵⁶ the Safety Attitudes Questionnaire (SAQ), was used in three studies,^{36,46,48} in two of which the authors provided data to allow meta-analysis.^{36,46} Meta-analysis of teamwork domain data revealed no statistically significant difference between pre- and post-intervention scores (standard mean difference 0.00, 95% confidence interval – 0.13 to 0.13).

The authors of papers that reported insufficient detail on the interventions they described were contacted. Four groups of authors responded,^{33,35,39,46} providing additional information that was used in the analysis of teaching methods and content themes. The key outcomes of the analysis are shown in Figs 2 and 3. The main teaching methods were simulation or role-play. Key attributes discussed were the importance of debriefing, feedback, the impact of 'fidelity' of simulation, and the use of simulation as a method to introduce error without harming patients. Other teaching methods were the use of didactic material and the use of computer-based and practical games on safety. The importance of expertise amongst educators was cited, although this expertise

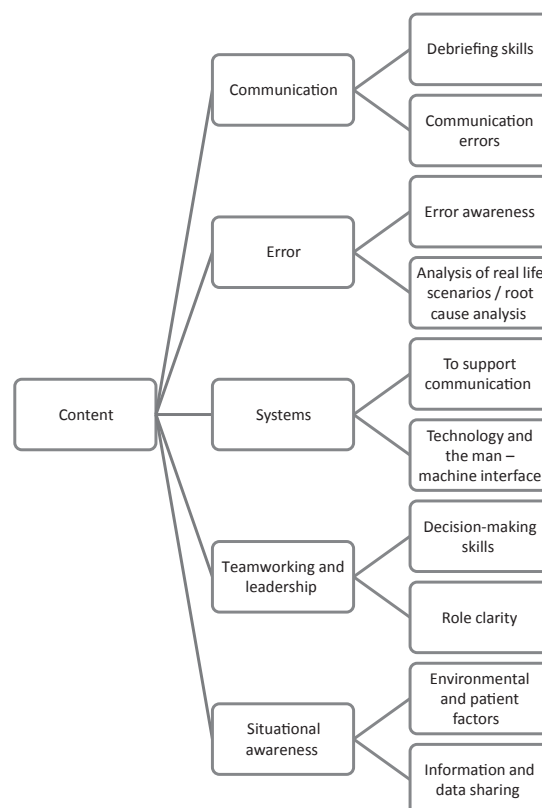


Figure 3 Analysis of content themes

was often clinical or human factors-based, rather than derived from skills in education.

Several key themes emerged from the content of the educational interventions. The first theme of communication referred to the importance of bringing debriefing skills into the workplace and ensuring effective communication with patients when errors occur. The second theme referred to error and represented the core of most teaching programmes, which included content to improve error awareness, often using critical incident analysis. Such material was usually presented with the aim of improving professionals' understanding of their roles in error, thereby enhancing their sense of responsibility for the reduction of error. The third theme referred to the role of systems, both as a method of error reduction and as a source of error, often focusing on the human-machine interface. The fourth theme referred to teamworking and leadership, particularly in terms of decision making as a team and clarity of roles. This theme focused on shared mental models, as well as on empowering participants to challenge appropriately to enhance safety. The final theme was situational awareness and the use of this awareness to identify potential risks and take action to prevent error.

DISCUSSION

This review found a body of research that can support and direct the design and use of non-technical skills education to improve patient safety. There was disparity amongst the characteristics of the studies included in this review, which showed stark differences in their research methodologies, but significant concordance in educational subject matter and teaching methods. Key to a large number of studies was a multidisciplinary approach that mirrors real-life working within health care. Additionally, the roles of observation and simulation as teaching methods were also well reported and this parallels findings in our previous review on handover education.¹⁰

The studies were generally judged to be of reasonable methodological quality (Appendix S3); those studies judged to be of poorer quality most commonly offered paucity of detail about the intervention, investigated limited outcomes or drew conclusions that were not supported by the data presented. Outcomes at all levels of Kirkpatrick's hierarchy were investigated and significant heterogeneity amongst specific outcome measures was identified. This range of outcomes has limited the extent to which effectiveness can be judged using meta-analysis. The single analysis found no significant difference, but this used unpublished subgroup data in one outcome domain and therefore does not support strong conclusions.

Most studies focused on educational outcomes rather than process and it is worth noting that few studies investigated higher-level outcomes. This does not lower the quality of evidence or limit the data contained within such studies, but does reflect a lack of outcomes that support the translation of knowledge, skills and attitudes into behaviour change and reductions in adverse events. Paradoxically, such investigation will not support future educational design, but may be key in affecting policy and as such must be considered as a focus for future investigation.

No study gave details of the theory on which educators based their educational designs, although there was a clear concordance in content themes and teaching methods. This may be explained by the almost universal acknowledgement of the principles of CRM training as an inspiration, if not a direct guide, to design. There was considerable confusion surrounding what constitutes CRM training and its educational underpinnings. Therefore, the lack of a theoretical model to guide non-technical skills-based

patient safety training appears to be a reflection of the same deficiency within CRM training. Although they are rooted in psychological concepts, CRM techniques seem to be lacking from the perspective of education theory. The application of appropriate theory would inform future design in both of these associated training areas. Based on the present review, a number of candidate theories can be applied.

Each of the content themes identified can be related to existing theoretical constructs, some of which mirror those identified in our previous review of education to enhance handover of care.¹⁰ The first theme of communication relates to the psychological theory of egocentric heuristics,⁵⁷ which describes how staff greatly overestimate how much of what they say has been understood or retained. Therefore, the use of methods that encourage reflection on communication may be helpful. The second theme of error relates to agency theory.⁵⁸ This describes the potential that exists for the shirking of professional responsibility because patients do not have access to information that can be used to judge health professionals. The interventions discussed error in the context of fostering joint professional responsibility and teamworking. This challenges a 'shift work' mentality and therefore may improve patient safety.

The third theme, of information management, relates to the theory of 'coordination costs',⁵⁸ which describes how systems are needed to manage increasingly complex health care organisations to maintain safety. The fourth theme, of teamworking, can be related to social science theories concerning the diffusion of responsibility⁵⁹ and supports techniques that combat bystander apathy. The final theme, of situational awareness, relates to Reason's three-bucket model.⁶⁰ This model views the risk for error in any given situation in terms of three buckets pertaining to the professional, the task and the environment, respectively. By considering the potential for error in each, staff can use this system to consider the inherent risk in a given situation. The application of these theoretical elements supports and guides teaching in each of the five content areas, as well as deepening understanding that may lead to further theoretical developments in this area.

This systematic review has several limitations. The search strategy was aimed at capturing non-technical skills training interventions to enhance safety, but, as discussed, there is much confusion surrounding these terms and how they are applied. Although the search was revised several times and piloted to check the

balance of its precision and utility, this inherent lack of clarity and the resulting subjectivity in researcher judgements may have led to the omission of some studies. Readers must also consider that education is just one method of instigating improvements in patient safety and the quality improvement programmes mentioned have been shown to reduce adverse events in certain circumstances. The considerable heterogeneity amongst the methods used in the studies included in this review has also limited the scope for further analysis in relation to a number of important areas, such as the characteristics of learners or educators. All of the studies included in the review reported positive results and thus the possibility of publication bias must be considered. Finally, few studies attempted to assess long-term retention and this further limits the strength with which it can be concluded that such interventions are effective.

Further work is needed to investigate how non-technical skills training can enhance patient safety. This work should build on the principles identified and educators should adequately describe their interventions and the theories underpinning their study designs. Educators may wish to use the five content themes and their associated theoretical elements to support such developments. Whichever investigative technique is chosen to assess such an intervention should be robustly utilised and well described on publication. Finally, the possibility of assessing whether such interventions can impact on patient outcomes should be considered.

CONCLUSIONS

There is a contemporaneous body of research on educational interventions that relate to training in non-technical skills and are aimed at enhancing patient safety. There is significant variation in the outcome measures used in this research, which limits the strength of conclusions on the effectiveness of these interventions. However, most studies reported positive outcomes and the general methodological quality of studies was reasonable, which suggests they have educational utility. There was significant uniformity in the content of interventions, which referred to five key areas: error; communication; teamwork and leadership; systems, and situational awareness. Although a recognised model to support the design of patient safety education is lacking, this uniformity in content allows for the application of a number of theories that may guide educators in future instructional design.

Contributors: MG conceived the project, drafted the protocol, led the study, contributed to the literature search and to the collection and analysis of data, and drafted the manuscript. DD contributed to the revision of the study protocol, the literature search, and the extraction and qualitative analysis of data. PB contributed to the conception of the project, the planning of the review, the revision of the study protocol, the design of the literature search and the various forms associated with the search and extraction. All authors contributed to the critical revision of the paper and approved the final manuscript for publication.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Appendix S1. Search strategy..

Appendix S2. Manuscript screening tool.

Appendix S3. Data extraction form.

Appendix S4. Quality assessment of included studies (consensus ratings).

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A novel system of prescribing feedback to reduce errors: A pilot study

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Abstract. *Background:* Prescribing errors are one of the most common adverse events in healthcare. Previous research in patient safety has highlighted the importance of error awareness education to enhance professional attitudes and reduce errors. Systems of contemporaneous prescribing feedback previous researched are limited by shift working.

Objectives: We introduced a departmental prescribing feedback system to address this limitation.

Methods: We used a Before and After study design. The setting was a single inpatient paediatric unit and 26 Paediatric medical staff participated. Baseline assessment of prescribing errors and safety attitudes took place, followed by 3 weekly reassessments over a 3 month period. After each assessment, a feedback poster was displayed and emailed to staff, giving general and anonymous personalised feedback.

Results: 205 medication orders representing 3,280 opportunities for error were examined. There was a statistically significant reduction in the error rate ($P < 0.0001$) between baseline (8.8%, 69 out of 784 possibilities for error) and completion at 3 months (1.8%, 12 out of 656 possibilities for error). There was an improvement in patient safety attitudes, but this was not statistically significant.

Conclusions: This pilot project has demonstrated an error feedback system can reduce errors. This technique could be easily adopted and introduced, warranting further research.

Keywords: Patient safety, error, prescribing

1. Background

In a seminal report, it was estimated that prescribing errors kill 7000 patients a year in the USA [1]. Improvement programmes focussing on system based approaches to enhance safety have been well investigated, but there is limited work to demonstrate that this translates into improved prescribing and enhanced outcomes [2]. This is because whilst poor knowledge and skills contribute, adverse events are multifactorial, with several active failures and error-provoking human factors involved [3]. In the context of prescribing, it is not surprising that there is a paucity of evidence to demonstrate that education focussed on knowledge and skills, without addressing human factors, can impact outcomes for patients [4].

Human factors engineering is a branch of work from psychology that is often misunderstood and seen as synonymous with systems based improvement strategies. Extensive work in high stakes industries as early as the 1970s demonstrated that improving safety is not just about the right technical skills or

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systems, but addressing human factors (non-technical skills) amongst professionals that lead to error [5]. The airline industry found that many crashes were due to failures of interpersonal communication, decision making and leadership amongst the crew [6]. Programs that recognised these human factors were designed to modify behaviour and this led to crew resource management training. As such work is focused on the worker at the 'sharp end of errors', this sort of training would seem to be a useful compliment to existing system based patient safety improvement strategies.

Existing published educational interventions on patient safety are sparse at best [7], but the role of error awareness to enhance professional attitudes and to reduce human error is a cornerstone of most published work. Error awareness has been proposed as a key element of education for another patient safety issue, shift handover [8]. In this context, the 'agency problem' is discussed, where doctors evade their professional responsibility [9] in settings of discontinuity or where the ability of patients to accurately assess the professionals performance in a task is limited. This would seem particularly relevant in the context of prescribing.

We recently reported improvements in prescribing skills using an e-learning prescribing package and this did have elements that discussed error and its identification [10]. Previous work has investigated how a ward round based 'check and correct' system to provide error feedback can be implemented [11]. The educational strength of such a system is that by bringing discussions of error into the workplace, it is in line with a situated cognition model of education, where learning is seen in terms of student's increasingly effective ability in different scenarios rather than in terms of an accumulation of knowledge [12].

Given that prescribing errors are not just caused by a lack of skill, but also by human factors that lead to doctors using prescribing skills incorrectly in practice, such methods of learning around the topic of error awareness are an extremely promising strategy to enhance safety. However, check and correct is limited due to the workload associated with the system, difficulties in getting feedback to the appropriate individuals who works shifts and the fact that the whole cohort of medical staff do not benefit from each piece of feedback. Our objective was to design, implement and assess a system that can address these limitations.

We introduced a process of intermittent and repeated prescribing feedback to enhance error awareness in an inpatient setting and to measure its impact on rates of prescribing errors and patient safety attitudes.

2. Methods

2.1. Study design

A before and after study design was used. This study was a service development project and so ethical approval was not required. The local research and audit department approved the study.

2.2. Setting

The study took place in a district general paediatric inpatient department. There were 26 paediatric staff covering a full shift rota. Seven of these staff members were working in paediatrics as part of a rotation, but had 3 months experience within the department at baseline. All staff was sent the trust prescribing guidelines at baseline, as well as a unique study ID. A pharmacist visits the ward on a daily basis to check prescriptions and this activity was not changed during the study period.

Table 1
Technical errors assessed

Patient demographics	Name
	Weight
	Date of birth
	Hospital number
	Consultant
	Allergy status
	Location
Order details	Name appropriate (generics used in line with trust policy)
	Units correct and abbreviations appropriate
	Route noted and abbreviated correctly
	Dose practical and measurable
	Frequency correct, as required drugs maximum administrations in 24 hours noted
	Drug signed for and bleep number given
General	Order in block capitals
	Legible
	Tidy (no damage to chart from wear, water, etc.)

2.3. Intervention

A baseline assessment of a whole ward sample of inpatient prescription charts were reviewed against the trust prescribing policy. Each medication order was assessed in 16 areas of technical error (Table 1), with any breaches noted. These areas of error are adapted from the previously described check and correct system [11]. Additionally, the actual dose itself and relevant calculations were checked using appropriate prescribing reference texts. If they occurred, clinical errors were also recorded (previously defined as errors that are likely to cause incorrect treatment or actual harm [13]). Each order could have more than one error. Errors were not recorded if they had been corrected by the prescriber immediately, but were recorded if they had been corrected by other staff.

At the end of this assessment, a feedback poster was placed prominently within the staff areas of the department and emailed to all participants. Over a 3 month period between April and June 2011, 3 weekly re-assessments were carried out, each followed by the distribution of an up to date feedback poster. Initially this contained basic information and acted to gain attention (Fig. 1), but in subsequent audit cycles these were updated to include anonymous individual feedback using participants ID number, if patterns of error were observed within these individuals.

2.4. Outcome measures

The primary outcome measure was the rate of technical prescribing errors, defined as an incorrect, missing or unclear item in each of the 16 areas assessed (Table 1). A pro forma, based on this list, was used to screen each order during each ward assessment by MG. A pilot assessment was completed and this allowed, through author discussion, consensus on errors to be reached. During this pilot, inter-observer reliability checks were made between MG and a second paediatrician to confirm the appropriate and consistent use of the assessment tool.

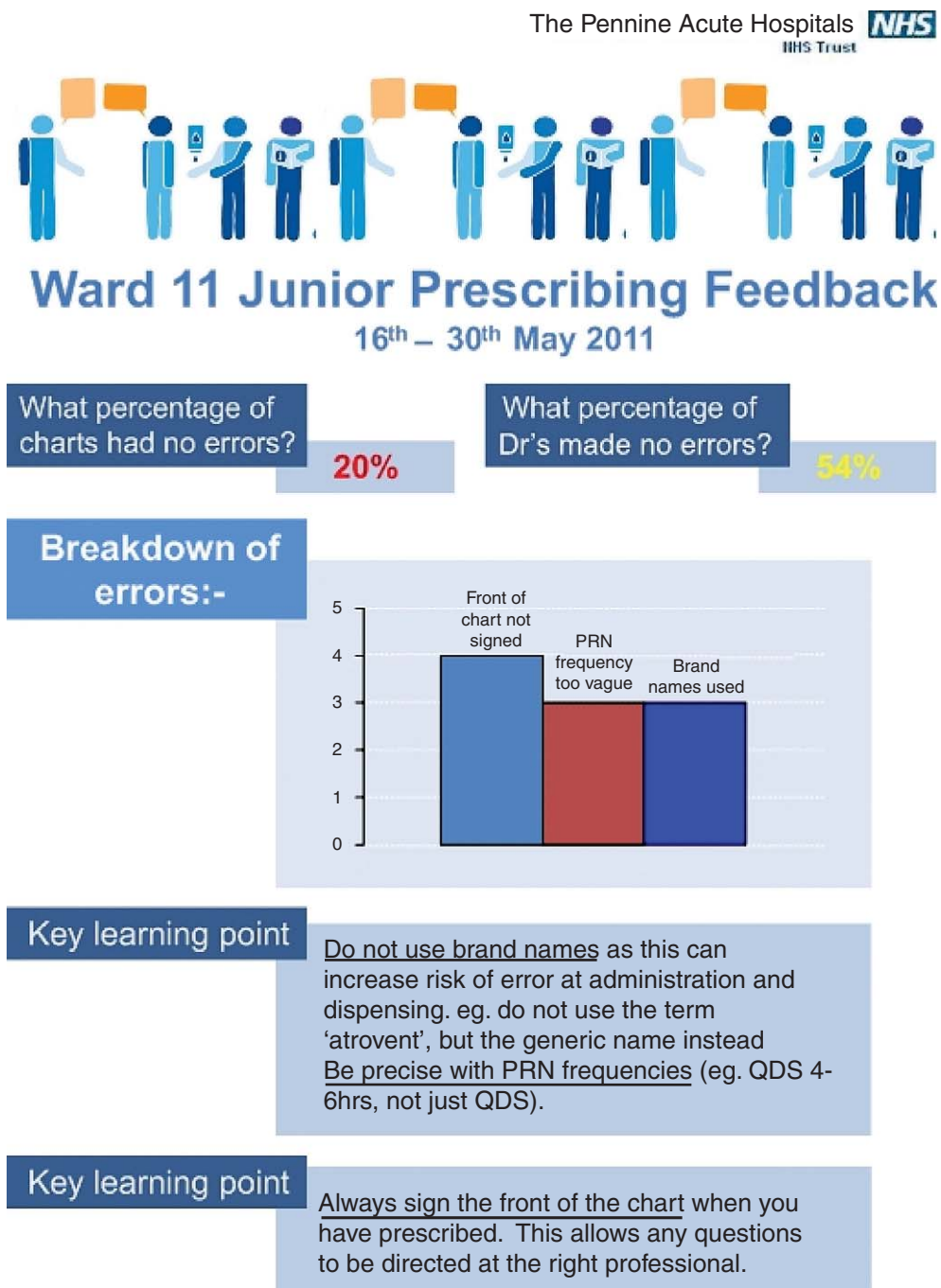


Fig. 1. Example feedback poster.

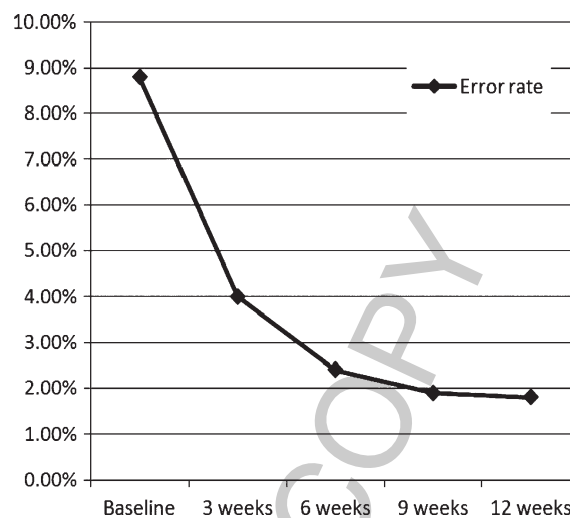


Fig. 2. Error rates during the study.

The secondary outcome measures were the rates of clinical error and the patient safety attitudes of participants, measured using a modified APSQ-II survey [14]. This 37 item questionnaire has been validated in the undergraduate setting, although it has not previously been used in postgraduate trainees. It was modified to change mentions of undergraduate experience to postgraduate, but otherwise left unchanged. This was sent and returned by email and was anonymous. At completion of the 3 month study period, participants were once again asked to complete the modified APSQ-II.

2.5. Data analysis

The error rates were calculated as a percentage of all opportunities for error within each assessment. These were compared at baseline and completion using a two tailed chi-square test. Mean APSQ-II scores were compared with a wilcoxon rank signed test. Data was analysed in Statsdirect (version 2.7.8, StatsDirect Ltd, UK).

3. Results

During the assessments, we examined 74 charts containing 205 medication orders and representing 3,280 opportunities for error. Each assessment took approximately 30 minutes on the ward and 30 minutes to analyse. The percentage of trainee who prescribing contained errors showed a statistically significant drop from 75.9% to 25.9% ($P=0.007$) [15]. There was a statistically significant reduction in the overall error rate ($P<0.0001$) between baseline (8.8%, 69 out of 784 possibilities for error) and completion at 3 months (1.8%, 12 out of 656 possibilities for error). Table 2 presents the error rate data throughout the study and this has been summarised in Fig. 2.

There was only one clinical error during the study period (a drug allergy was not recorded, but was corrected by a pharmacist), so no analysis of this dataset was possible. This was in agreement with routine pharmacy screening of the same sample. At baseline, the mean APSQ-II score amongst participants was

Table 2
Error rate data during the study

Assessment	Errors observed	Total error opportunities	Error rate %
Baseline	69	784	8.80
3 weeks	27	672	4.00
6 weeks	14	592	2.40
9 weeks	11	526	1.90
12 weeks	12	656	1.80

124.6 and post intervention the mean was 129.7, suggesting improved patient safety attitudes, although this result was not statistically significant.

4. Discussion

The error feedback system led to a statistically significant reduction in technical prescribing errors. A trend was seen towards improved patient safety attitudes, although this was not statistically significant. This system allows staff to have intermittent and repeated feedback on problem areas within the department, as well as allowing them to monitor their own practice. It situates error based learning within the workplace and allows the individual, as well as the team to receive educational benefit from each error that occurs, however significant. This is so difficult to achieve in a full shift based system, but key for patient safety, suggesting the utility of such a method to enhance prescribing.

This intervention was in low fidelity and extremely easy to introduce. There were no set up costs and therefore such an intervention could be implemented immediately within almost all settings. With the support of the pharmacy department, data from the routine pharmacist's activities could be harnessed, with only additional time needed to synthesise the data. In areas with high rates of error, it could be argued that this would be an efficient method, particularly given the time savings they would make when fewer errors are encountered. Large scale multi-centre studies investigating errors have been supported by pharmacists collecting data in this way [16], suggesting this presents a viable and sustainable improvement model, particularly given the costs associated with technology based medication error reduction strategies.

Despite the promising nature of these results, this study does have a number of limitations. Given that this was a pilot project, its small sample size limits the strength of our results. Also, as this was a single centre before and after non-controlled study, this further limits the strength of our findings. Errors were measured using a process based approach. Whilst this is a well recognised method in the prescribing improvement literature and does allow statistically significant findings in small studies, it has been criticised as an approach for focussing on minor errors that are unlikely to cause harm [17], with studies focussing on harm to patients seen as preferable. The secondary outcome regarding attitudes may have indeed been limited by sample size and this may be addressed by a further large scale study. Finally, it was not possible to measure the effect of such an intervention on outcomes for patients. As this is the aim of all safety initiatives, this would be highly relevant to investigate in the future.

Future research should seek to examine the viability and effectiveness of this system if introduced in a more widespread fashion, particularly in terms of patient outcomes and cost benefit. Such a system could be used to address all stages where medication errors occur, including administration and therefore involve the multidisciplinary team.

6. Conclusions

This small pilot project has demonstrated the potential utility of an error feedback system to enhance error awareness and improve prescribing. This technique is low fidelity in design and warrants further research. Such work should use larger samples, consider multiple sites and a randomised controlled design, as well as measuring outcomes for patients and considering cost effectiveness when compared to other methods of error reduction.

Ethical approval

Not sought.

Competing interests

None to declare.

Funding

None.

Author contributions

Morris Gordon planned and carried out the study, analysed the data and let the write up. Bratati Bose-Haider conceived the idea, supporting planning and carrying out of the study, as well as contributing to the write up.

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SHORT REPORT

Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals

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Educators in healthcare face significant challenges trying to improve interprofessional teamworking skills, with a lack of clarity on how to teach and evaluate such skills. Previously, the team objective structured clinical encounter (TOSCE) has been reported as a teaching and assessment tool, but it has been used primarily in homogenous groups of undergraduates. An interprofessional team of educators set out to evaluate the TOSCE as a teaching intervention amongst a large interprofessional group of postgraduate nurses and midwives. After the TOSCE, 83% of participants reported that they were more aware of potential weaknesses in teamworking and 60% felt more able to work in a team. Mean Likert scale ratings were 4/5 for usefulness, enjoyment and relevance. The TOSCE is a feasible tool for teamwork skill assessment in the demanding postgraduate interprofessional setting and requires further investigation to ascertain its potential for formative and summative assessment of skills.

Keywords: Action research, interprofessional learning, teamwork

INTRODUCTION

Interprofessional teamwork is a key to the successful delivery of healthcare, as well as being a crucial element to ensuring patient safety (e.g. Gordon, Darbyshire, & Baker, 2012). There is growing evidence that education directed at interprofessional groups can have positive outcomes for teamworking and for patients (e.g. Reeves et al., 2008). As such, interprofessional learning (IPL) is now key in many curricula. Research has highlighted weakness in existing teaching methods and the need for validated teamwork assessment tools (Brown & Waite, 2002). McMaster University and the University of Ottawa recently developed such a tool – the team objective structured clinical encounter (TOSCE) –

based on the medical objective structured clinical evaluation (OSCE) (Harden & Gleason, 1979) and interprofessional assessment literature (Simmons et al., 2011).

BACKGROUND

A TOSCE brings together a healthcare team for a simulated clinical meeting. This involves the review of trigger materials, with participants taking on different roles and developing a common plan. An assessor observes this interaction using a validated assessment tool and offers feedback. Unlike an OSCE, the scenario-based encounters have been designed to act as a learning experience offering formative feedback, as well as being validated for summative assessment. The TOSCE approach is theoretically grounded, maximizing learning potential. It sharpens student's proficiency through rehearsing responsibilities and challenges role stereotypes. TOSCE diminishes negative hierarchical influence by increasing patient advocacy and challenges bystander apathy described in social science theories concerning diffusion of responsibility.

Published work on feasibility, acceptability (Marshall et al., 2008), validity and reliability has all been positive (McMaster, 2012). However, this research has been in the undergraduate setting with predominantly medical students. This clearly ignores the very style of working that the tool is encouraging and does not follow a situated cognition view of learning, with students taking on roles that do not relate to their professional identity. In addition, as this work was in primary care, using isolated groups, it is difficult to comment on feasibility within a postgraduate training environment, where there are often large groups of students to be trained during limited release from work.

An interprofessional team of healthcare educators set out to pilot the use of TOSCE as an IPL teaching tool to support teamworking skill development and assessment in a group of postgraduate health professionals and assess its acceptability and effectiveness.

METHODS

TOSCE participants were a single group of postgraduate neonatal nurses ($n = 15$) and midwives ($n = 30$) on a part-time postgraduate course. Three educators were required to deliver the 3-hour teaching session. Initially, students were given a brief introduction and shown a video of a famous airline disaster, designed to stimulate a discussion surrounding errors from teamworking. This was followed by a short presentation on how failures contribute to non-technical skill errors, based on previously developed materials (Gordon et al., 2012).

Participants were then allocated pro rata into appropriately mixed teams of seven to eight learners. Three of these teams, each with one staff observer, completed a TOSCE simultaneously. Each team member was provided with information to share in the meeting appropriate to their normal role. The content was on child safeguarding, an existing course requirement and used existing materials from a national society (NSPCC, 2001). A short video (NSPCC, 2001) that introduced the case vignette¹ was shown, and subsequently the team was given 20 minutes to conduct their meeting. After a 20-minute break, which allowed the observers to collate their results, discuss student performance and fill in personal feedback forms, the team was given 20 minutes of feedback (McMaster, 2012). In total, each TOSCE lasted approximately 1 hour. At this point, the groups swapped and the remaining three teams completed their TOSCE.

This was an action-based, before and after research design. Prior to the session, students completed the T-TAQ teamwork attitudes questionnaire (Baker, Amodeo, Krokos, Slonim, & Herrera, 2010). Post-TOSCE, they completed a further evaluation form consisting of closed, Likert and free text responses and another T-TAQ questionnaire. Descriptive summary data based on closed-ended and Likert-style questions were calculated. Comparison of pre- and post-intervention T-TAQ assessment scores was completed with a Wilcoxon signed-rank test.

RESULTS

Key closed-ended results are summarized in Table I. Mean Likert scale ratings were 4/5 for usefulness, enjoyment and

relevance. Teamworking attitudes improved, measured using the T-TAQ instrument (pre-mean 127, post-mean 131), although this was not statistically significant.

Verbal debrief of staff participants revealed great enthusiasm for delivering TOSCE as a teaching method. However, some concerns were raised about the size of the groups, suggesting that group numbers should be limited to five or six participants, as it was perceived that this would make observations and feedback easier and allow greater time for participants to have a meaningful role.

DISCUSSION

In this instance, TOSCE was successfully incorporated into a session on teamworking skills for postgraduates and delivered to a large group of students within the limitations of their schedules. This is a key development, as previous work has used small groups of students on placement where time is more flexible. In addition, the session was accepted as a valuable teaching method by a group of experienced healthcare professionals, with apparent positive changes in their levels of confidence in teamworking, as well as an indication of improved attitudes.

Whilst the TOSCE tool has already been extensively evaluated, this study represents a significant innovation, proving that the tool can be used as an actual IPL learning intervention, rather than to simulate such an encounter. In this context, TOSCE was found to be an acceptable, feasible and effective method (at least in terms of enhancing perceived skills), for bridging the gap between teamworking curriculum outcomes and skill improvement. As previous work highlights the role of teamworking in enhancing safety as well as quality (Gordon et al., 2012), the TOSCE tool offers a useful option to educators of all the healthcare professions and appears to be practically deliverable without significant investment.

As this is a pilot study, clearly the strength of these findings is limited. In particular, the sample size was small and the evaluation was post-intervention, with no baseline for comparison. In addition, the T-TAQ survey did not reveal statistically significant results, and it is difficult to gauge if this is related to the tool itself or the sample size. Given the potential uses of the TOSCE tool for continuing professional development, as well as for revalidation or assessment of professionals, further research is required. Furthermore, efforts should aim to assess the utility of the tool to enhance behavior within the workplace and over the long term, as well as its impact on outcomes for patients. Moreover, work is needed to assess validity as a summative assessment tool in this proposed setting.

In summary, the TOSCE appears to be a feasible tool for teamwork training within a postgraduate IPL environment. In this study, it was well received and improved perceived skills in teamworking. However, further work is required to explore its more sustained use, with an aim to assess impact on patient care through a more robust investigation.

Table I. Closed-ended questions completed post-TOSCE encounter.

Question	Yes, n (%)	No, n (%)
More aware of potential weaknesses in teamworking	37 (83%)	8 (17%)
More conscious of own abilities	31 (70%)	14 (30%)
More able to challenge poor behavior from colleagues	29 (65%)	16 (35%)
Greater ability to work in a team	27 (60%)	18 (40%)

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

NOTES

¹Furthermore, information concerning the case vignette can be found at www.betterprescribing.com/tosceappendix1.doc.

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The broader role

Non-technical skills training to enhance patient safety

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There are few reports of educational interventions that focus on non-technical skills to address human factor sources of error

SUMMARY

Background: Patient safety is an increasingly recognised issue in health care. Systems-based and organisational methods of quality improvement, as well as education focusing on key clinical areas, are common, but there are few reports of educational interventions that focus on non-technical skills to address human factor sources of error. A flexible model for non-technical skills training for health care professionals has been designed based on the best available evidence,

and with sound theoretical foundations.

Context: Educational sessions to improve non-technical skills in health care have been described before. The descriptions lack the details to allow educators to replicate and innovate further.

Innovation: A non-technical skills training course that can be delivered as either a half- or full-day intervention has been designed and delivered to a number of mixed groups of undergraduate medical students and doctors in postgraduate training. Participant

satisfaction has been high and patient safety attitudes have improved post-intervention.

Implications: This non-technical skills educational intervention has been built on a sound evidence base, and is described so as to facilitate replication and dissemination. With the key themes laid out, clinical educators will be able to build interventions focused on numerous clinical issues that pay attention to human factor contributors to safety.

INTRODUCTION

The scale of the patient safety problem entered the public and professional consciousness in 1999, with the Institute of Medicine's report *To Err is Human*.¹ In 2000, the UK Department of Health responded with a report outlining the need for a systems-based human factor approach to help manage risk in health care.² This was in line with thinking from a leading psychologist in the field who proposed the now ubiquitous Swiss cheese model of error.³ This model views human error as inevitable, and suggests that interventions should focus on barriers to prevent such human error causing harm. Despite strategies including audit, risk management, organisational safety culture change and new technology, errors still occur with alarming frequency.⁴

Non-technical skills describe the personal attributes of a professional that contribute to error. As such, they are not directly addressed in a systematic approach to human factor safety improvement. Extensive work in high-stakes industries as early as the 1970s demonstrated that improving safety must also address the non-technical skills that lead to human error.⁵ The airline industry recognised that many crashes were the result of failures in these non-technical skills, including interpersonal communication, decision making and leadership.⁶ Teaching programmes were designed to enhance skills, and are now used globally, but published works translating such methods into health care are sparse at best.^{7,8}

CONTEXT

A systematic review of non-technical skill patient safety education found that although a number of interventions have been used, based on the aforementioned airline crew resource

management, a key problem is a lack of descriptions of the interventions and their theoretical underpinning.⁷ As such, there is little published work that clinical teachers could replicate or use to guide their own design in this key area. Even the WHO patient safety curriculum fails to offer clarity in its theoretical discussions and pedagogical guidance on non-technical skills training.⁹

The systematic review of non-technical skills interventions in health care also reports a qualitative analysis of existing published interventions.⁷ This identifies key content and teaching methods that should be used to construct an effective non-technical skills training course for health care professionals, with appropriate theoretical underpinning. This has been used to design such an intervention, and is presented to allow local non-technical skills patient safety educational innovation, as well as the replication of this intervention.

INNOVATION

Theoretical underpinning

Several themes were used to construct the course (Figure 1), each underpinned by key theoretical constructs. The theme of systems and technology is related to an economic theory of coordination costs. This describes how increasingly complex organisations are subject to ever-increasing costs (either financial or time) in order to achieve effective management. This requires systems to ensure safety, particularly at the human–system interface. Error awareness is related to agency theory. This social science theory describes how in settings of discontinuity, such as is often found in task-based working, the professional begins to think of 'the patient' rather than 'my patient'. When this occurs, there is a potential to shirk professional responsibility, causing human error. It has been proposed that highlighting sources of error in a way that is relevant to the task or

Non-technical skills ... are not directly addressed in a systematic approach to human factor safety improvement



Figure 1. Thematic areas and examples of techniques for enhanced safety

This activity reinforces the view that human error is not inevitable

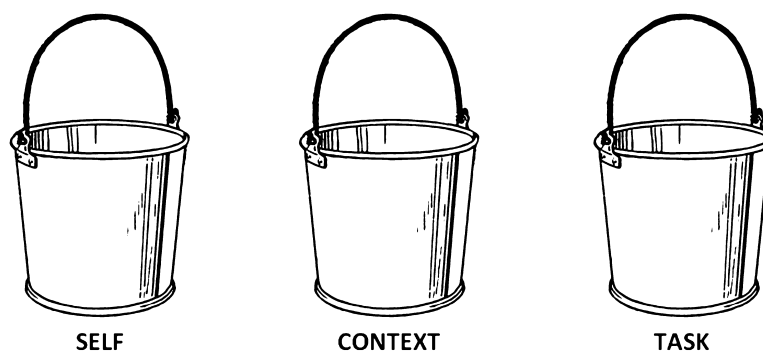


Figure 2. The three-buckets model for risk assessment. Adapted by permission from BMJ Publishing Group Limited. Quality and Safety in Health Care. *Reason J.* 2004;13:suppl 2 ii28–ii33

environment of professionals can challenge the 'agency problem'.¹⁰

A psychological theory of egocentric heuristics describes how those giving information greatly overestimate their ability to do so, and highlights the key role of communication in safety. Additionally, social science theories concerning diffusion of responsibility, which can lead to dysfunctional collaborative working, highlight the role of methods to support team working. Finally, concepts such as the three-bucket model support the role of risk assessment in decision making.¹¹ This theory views the risk in any situation from the professional's perspective, and asks them to consider how full each of their buckets is (Figure 2). The buckets describe the risks associated with the 'task', the 'context' and the 'self'. By considering this when taking on any new activity, professionals can learn to actively risk-assess and gain situational awareness in order to enhance safety.

Course participants

This course has been run with between 12 and 16 participants, consisting of a mixture of undergraduates, recent medical graduates and specialty trainees. It has been run as a full- or half-day course, with the same overall structure.

Required resources

The course has been designed with minimal requirements, and can be run in a room equipped

with a PC with a projector or large monitor. The course has been run with one facilitator.

Teaching intervention

Figure 1 shows the concepts and techniques that are taught in relation to each of the theoretically relevant themes identified for the course. The learning outcomes for the day are presented in Box 1, and the structure of a 1-day course is shown in Table 1, with a description of each of the activities.

Human factors as a source of error

Five-minute videos depicting major adverse events outside of health care (i.s. air, space and sea) were presented. In small groups, participants consider what caused the error, how could it be prevented, and how this relates to health care. This prompts a group discussion surrounding non-technical skill human errors in health care, usually grounded in personal experience, in each of the course theme areas. The session finishes with a short

lecture discussing human factors and non-technical skills in health care.

Non-technical skill critical incident analysis

Anonymous participant incidents are analysed in small groups. Using a framework they consider the non-technical skill and human factor system errors that occurred in each case, and how these could have been averted from the professional's perspective, by considering decisions at 'switch points'. This activity reinforces the view that human error is not inevitable, and that enhancing their non-technical skills not only positively impacts their own behaviour, but also that of their colleagues, who may benefit from enhanced situational awareness.

Enhancing safety

Short lectures with supporting handouts on each of the theme areas are delivered, covering a number of crew resource management improvement techniques (Figure 1). Participants complete exercises including the preparation of a team briefing for an emergency incident, the handover of care using a system such as SBAR (situation, background, assessment and recommendation) and analysis of cases using the three-bucket model for risk assessment.

Discussing error with patients

A short discussion is facilitated regarding difficulties in giving

Box 1. Learning outcomes for the non-technical skills patient safety course

- Gain insight into the role of non-technical skills in human factor causes of major adverse events outside health care.
- Discuss how such non-technical skills contribute to error within your own workplace.
- Review key skills to enhance safety practice through improved non-technical skills in each of the identified problem areas.
- Apply these non-technical skills in practical exercises related to key patient-safety issues, including prescribing, emergency planning and handover of care.

Participants reported that they felt more capable at spotting sources of human error after the session

Table 1. Course structure and relevant themes

Time*	Session	Content and teaching techniques	Theme
09:30	Introduction	Icebreaker, aims, objectives	
09:45	Human factors as a source of error	Video scenarios from outside health care, group work, short lecture	Error awareness, situational awareness and risk assessment
11:00	Break and refreshments		
11:15	Critical incident analysis and pro-active risk analysis	Small group analysis of anonymous participant cases	Error awareness, situational awareness and risk assessment – situated cognition
12:00	Techniques to enhance safety practice	Communication, teamworking, practise scenarios using techniques	Communication, teamworking
12:45	Lunch		
13:30	Techniques to enhance safety practice (continued)	Situational awareness, systems and technology, practise scenarios using techniques	Systems, situational awareness
14:30	Discussing error with patients	Short review and practise in pairs	Communication
15:00	Break and refreshments		
15:15	Group scenarios	Each group to attempt applying techniques in two scenarios: handover; preparing for an emergency	Simulation – situated cognition
16:00	Debrief and summary		

*Using 24 hour clock format.

feedback to patients when human errors occur, and the role of an open culture for adverse events in health care. Participants complete a role-play discussing a medication error. An example scenario is shown in Box 2.

Large group exercises

Simulated team meetings are run in two large groups. The first group conduct a large handover meeting. The second group prepare for a difficult obstetric emergency. Participants are expected to integrate the different skill elements to facilitate safe practice and exhibit an enhanced ability to assess situational error-provoking factors and address the risk that these pose to safety. Several participants act as observers and make notes in

each of the skill areas to feedback to their peers.

Evaluation

The local research and development department were contacted, and confirmed that they classified this as educational evaluation. As such, they did not require any formal ethical approval for anonymous data to be collected.

The course has been run on several occasions, with adaptations to the specific audience as needed. Feedback has been positive from participants of all backgrounds and levels of experience. Likert ratings for content, relevance, interactivity and enjoyment were positive (with mean ratings of 9/10 for

all areas). All (100%) participants reported that they felt more capable at spotting sources of human error after the session. Free-text responses identified the varied range of activities used and interactive styles of the course as positive. For future courses, it was suggested that some further pre-course material would be helpful to better frame the day and prepare the participants.

For one of the most recent half-day courses, the Attitudes to Patient Safety Questionnaire-II patient safety questionnaire was completed before and after the intervention. Patient safety attitudes improved significantly post intervention (with mean scores of

Box 2. Example scenario for participants to complete in groups of three

Communicating about an adverse event scenario

Instructions for doctor

Setting – paediatric intensive care unit (PICU)

Time – 23:00

You have been asked to speak to a patient's parent. Baby Thomas is currently ventilated for severe septicaemia with respiratory failure. He required a bolus of saline earlier in the day.

At handover, the nurses found a bag of IV metronidazole next to his bed. He is not on this medication, but when they aspirated, it became apparent that the volume missing is equal to the bolus given, and the consultant has presumed that as this bag looks similar to a bag of saline a bolus of metronidazole amounting to a 10-fold overdose has been given. Toxbase has been consulted and the medication is generally safe in overdose.

Your task is to explain this incident to the parent.

Instructions for parent

When this case is discussed with you, try and stay in character and act as you may do in real life, asking appropriate questions.

Instructions for observers

There are several key elements to look for within this scenario:

- Apologise (not personally, but for the whole team)
- Explain what happened
- Discuss any risks
- Describe actions
- Discuss incident reporting and analysis of this data
- Offer complaints procedure
- Ask if they have any questions
- Explain again and apologise again

134 before and 142 after; $p = 0.026$).

IMPLICATIONS

There have been numerous reports of educational interventions to enhance patient safety.⁷ Additionally, many clinical educators will have witnessed or been part of local innovation in this area. However, this report has set out to innovate by describing an intervention focused on the often-confused area of non-technical skills improvement. Although many of the elements are not revolutionary, it is hoped that the integration of these themes into a single package, with relevant theoretical underpinning, will

allow readers to introduce similar courses locally.

Many of the themes used within the course could form the basis of education on specific safety issues, such as prescribing, handover of care and resuscitation training. Although the focus of such education will often be on specific knowledge and skills, the addition of content that could enhance non-technical skills should become routine, as indeed all health care training can be patient safety training.

In considering the work presented, a number of limitations must be taken into account. Although the intervention has

been run a number of times in different settings, it has been facilitated by the author on all occasions. How easily such interventions can be replicated, how well materials can be disseminated for local instruction and whether these issues impact the intervention, remain unclear. Additionally, evaluation has mainly focused on qualitative comments and satisfaction outcomes. Finally, the full course has only been delivered to doctors so far, and so it is difficult to comment on its use for the wider health care team, despite its generic design.

Further work should consider the possibility of investigating different outcomes. Whichever investigative technique is chosen when assessing such outcomes, it should be robustly used and well described on publication. Additionally, the use of this course for other professionals or in multi-professional teams should be investigated. Finally, consideration should be made as to the possibility of assessing whether such interventions can impact on patient outcomes and rates of adverse events.

CONCLUSION

This non-technical skill educational intervention has been built on a sound evidence base, and has been described in order to facilitate replication and dissemination. With the key themes laid out, clinical educators will be able to build interventions focused on numerous clinical issues that pay attention to human factor contributors to safety. Future research should look to consider outcomes such as workplace behaviour change and patient adverse events, as well as refining or amending the conceptual elements presented.

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Clinical educators will be able to build interventions that pay attention to human factor contributors to safety

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Hypothesis

Building a theoretically grounded model to support the design of effective non-technical skills training in healthcare: The SECTORS model

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ABSTRACT

Patient safety is an increasingly prominent issue in healthcare. Despite much work investigating human factors system based approaches to reduce avoidable errors, there has been minimal work investigating education in this area. Education to enhance non-technical skills and support behaviour that reduces human factor sources of error is in its infancy. Published works describing interventions are heterogeneous in content and teaching methods, as well as limited in their underpinning or pedagogy. There is no well-recognised model or framework to guide educators in designing such interventions, which further compounds the problem. In this manuscript, the SECTORS model is proposed, a theoretically-grounded framework to aid understanding of how learning in non-technical skills occurs within healthcare. SECTORS combines three key elements: - The generic Knowledge and skills in core areas that contribute to and support learning in non-technical skills (Systems and technology use, Error awareness, Communication, Teamworking), a situated cognition approach to formal and experiential learning that develops these skills (Observation and simulation) and developments in analytical skills that can integrate these and support decision making (Risk assessment and Situational awareness). Further work is now needed to investigate the appropriateness of this model and its utility and effectiveness in supporting design of such education.

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INTRODUCTION

Attitudes to errors in health care began to change towards the later end of the 20th century with a string of high profile incidents reported in the media. The Institute of Medicine's (IOM's) 1999 report *To Err is Human: Building a Safer Health System* in the US [1] was pivotal in organising this movement. This report shocked the public and galvanised politicians by suggesting that medical errors were causing up to 98,000 deaths per year in the US alone. The infamous comparison to a 'Jumbo Jet of patients dying every single day from medical errors' caused a furore that prompted immediate action across the globe.

In 2000, the UK Department of Health published a

report outlining strategies to reduce risk from preventable errors in healthcare [2], mirroring similar international moves. Guidance on how to achieve this goal was mostly focussed on system based human factor improvement strategies, in line with thinking from Reason, who proposed the now ubiquitous Swiss cheese model of error [3]. This model proposes that as human error is inevitable, organisational or system based strategies are the best ways to enhance safety and deal with the human factors causing errors. Despite resulting programmes of risk assessment, incident analysis, national quality improvement campaigns,

audit and clinical governance, errors still occur with alarming frequency [4].

Extensive work in high stakes industries as early as the 1970s demonstrated that reducing error is not just about the right technical skills or system based human factor risk reduction strategies, but addressing the non-technical skills of staff that may lead to error [5]. These two areas are related, with human factors concerned with everything in the working environment that can impact patient care, such as guidelines, equipment, systems and an understanding of how human behaviour affects these. Non-technical skills are the cognitive and interpersonal skills that individual must possess to effectively deliver safe care within this environment.

The local and national improvement programmes already described have mainly focussed on human factor system based risk reduction, with education to enhance non-technical skills less common. Clearly these are not mutually exclusive and such forms of education would not replace other methods of error reduction, but support improvement as part of a package of measures. There have been successful attempts to design education to improve non-technical skills within other sectors [6]. This work was spearheaded by the National Aeronautics and Space Administration (NASA), commissioned by and in response to major disasters in aviation. They determined that many crashes were due to failures of interpersonal communication, decision making and leadership [5]. Programs were designed to modify behaviour, such as crew resource management (CRM) training to address these issues.

There have also been numerous attempts in the last decade to mimic such design within healthcare. However, despite a growing body of published work in the area, there is still a major flaw in the accumulated literature [7]. As is often the case in any education issue in healthcare, the focus of published research has been on 'whether' such interventions work, rather 'how', 'why', 'what' and for 'who' such interventions work. As such, the published body of work amounts to a heterogeneous collection of reports that at best offer a modest guide for design and present little in the way of convincing evidence of effectiveness. Additionally, there is not a single report that offers any form of theoretical underpinning [7] or conceptual framework for their work [8] and therefore, this body of work is collectively flawed.

The author has conducted a programme of research that has been unified by a single underlying question: how can effective non-technical skills training be produced to enhance patient safety? To answer that question, it has become clear that an understanding of how non-technical skills learning can occur within healthcare is

needed. This paper will propose a model to aid such understanding and suggest its application within medical education.

METHODS

A programme of works has supported the answering of the authors overriding research question, all of which have been independent with their own specific research aims. These have included evidence synthesis using systematic review [7,9], qualitative research to understand the issues in further depth and test candidate elements [10,11] and piloting of educational interventions produced using this theory [12,13]. A number of these works have involved collaboration with other researchers and together with the existing literature on the topic, have been used to support synthesis of the final model by the author.

Throughout the development of the model, conceptual frameworks have been used. Conceptual frameworks play an essential role in identifying the nature of education problems and in formulating solutions or designing studies [8]. Even if they do not describe them, educators and researchers employ conceptual frameworks, in the form of models, theories or best practices, to guide educational research. Conceptual frameworks help to shed illuminate and magnify the issues at hand [14]. The use of frameworks has allowed the author to be mindful of assumptions and foundations of this development, as well as allowing this process to be transparent for the reader.

RESULTS

SECTORS describes the three areas that facilitate learning of non-technical skills in healthcare. The first sector describes the generic Knowledge and skills in core areas that contribute to and support learning in non-technical skills, the second sector the approach to formal and experiential learning that develops these skills and the final sector the developments in analytical skills that can integrate these elements and support decision making. Most importantly, SECTORS shows how these elements are linked in a cyclical manner, with the outcomes of practice further enforcing non-technical skills education and education informing practice, all underpinned by experience of adverse events. The model is shown in figure 1.

Systems and technology

Systems and technology based programmes are the most reported method of patient safety improvement [15,16] and form the cornerstone of much education in the area [7,9], supported by an economic theory, known as "coordination costs". This describes how in increasingly complex systems, the cost (either financial

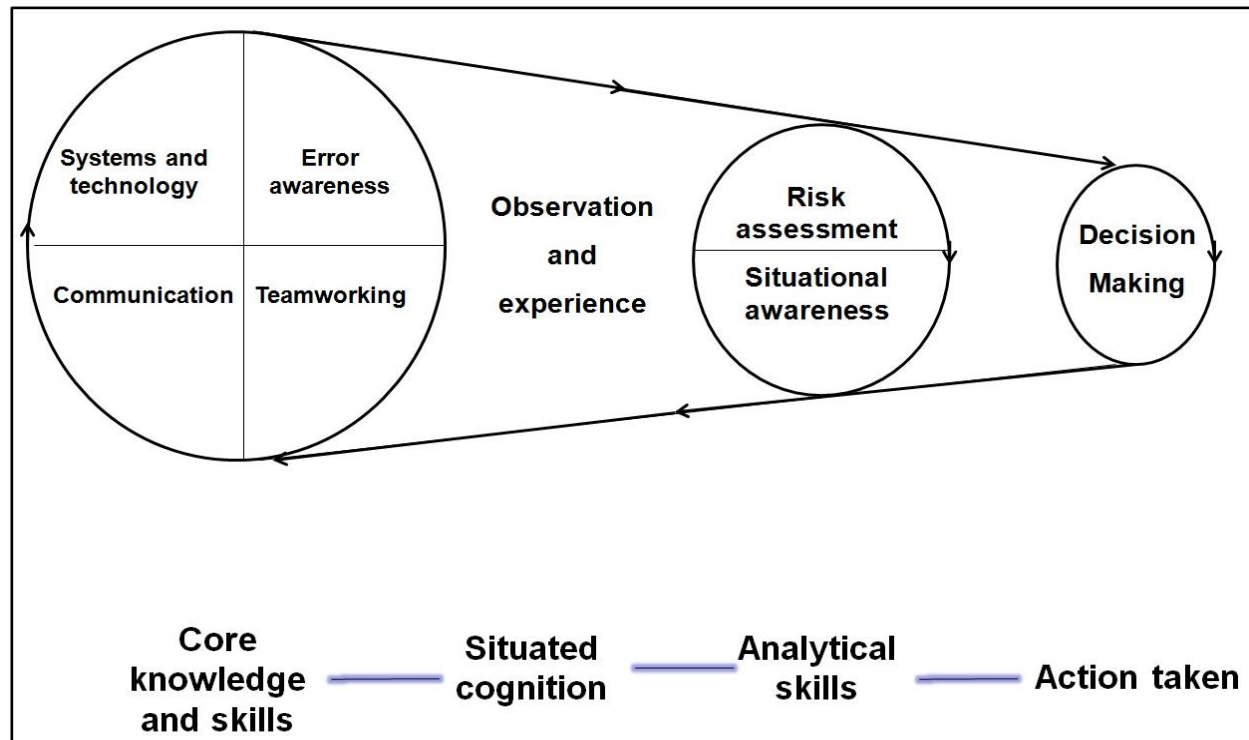


Figure 1. The SECTORS model for patient safety education

or time related) of coordination, including information management and communication, increases. Systems are therefore needed to safely manage this potentially increasing cost. A System can also act as a schema, a concept from psychology and cognitive science that describe an organized pattern of thought or behavior. They offer a framework representing some aspect of the world, or a system of organizing and perceiving new information. As a person's own schemata may be unwavering in the sight of new contradictory information (disconfirmation bias), an external shcemata offered by guidelines or protocols may reinforce more complete and safe way of working and reduce risk of error. From the learner's perspective, systems are seen in two ways. Experienced and senior members of staff may see systems as stifling innovation and eroding trust, so instead often choose to adhere to unwritten rules rigidly [17]. In recent graduates, the reverse is true and the use of systems to support safe practice is rapidly adopted, with an understanding that such procedures are necessary and helpful adjuncts to practice that is developed through experience in the clinical environment [18]. From either perspective, systems are viewed as the foundation to safety and as such are a key element of learning within non-technical skills. They offer schemata to organize thinking and manage the 'coordination costs' of increasingly complex healthcare systems.

Error awareness

Awareness of error, both within and outside healthcare is another cornerstone of existing educational interventions [7,9]. Poor awareness of error can lead to risk taking behaviour and in effect an erosion of professionalism, with tasks completed without consideration of the patient themselves. This sort of 'shift-work mentality' is supported by agency theory. Under this theory, patients do not have access to the information needed to make an accurate judgement regarding if a doctor is behaving in their best interest. The 'agency problem' is the potential for doctors to shirk their professional responsibility in such a setting. This is a problem that has been brought to the forefront in recent years as doctors across the globe are increasingly working in shift patterns that are similar to their nursing colleagues. In response to this, handover of care has become a more prominent issue for educators [19]. As well as the erosion of professionalism that can occur with shift working, there is reduced error wisdom caused by a lack of awareness of one's own errors as a result of discontinuous working. Error wisdom can lead to mental preparedness, independent of practical skills [20] and this has been shown to improve performance in healthcare [21].

For the learner, awareness of error is key to direct non-technical skills learning and is the primary element in almost all existing published healthcare interventions, as well as those outside healthcare [7]. Error awareness directs behaviour, informs analytical skills and supports decision making. The author has demonstrated that error awareness, independent of any other educational intervention, can enhance practice [10]. Within healthcare, generic understanding of broad error categories can be mixed with specific analysis of more relevant and local error issues [12], a development from the relatively constricted cockpit environment in which such education was born.

Communication and Teamworking

These elements are described together as they are symbiotically linked. A number of theories underpin a conceptual framework of understanding in these areas. Using psychological sciences can explain sub-optimal health care communication, with an egocentric heuristic identified [22]. This describes how professionals greatly overestimate the effectiveness of their communication, perceiving they have been clearly understood the majority of the time. Information richness theory [23] describes how different modes of communication are likely to be effective based on the information being transferred, again highlighting potential weaknesses in health care where communication methods are often dictated by resources available and not the nature of the task at hand.

Bystander apathy has been reported as early as the 1950s as occurring in groups, described in social science theories concerning diffusion of responsibility [24]. This can lead to dysfunctional collaborative working. Finally, the use of a pyramid power structure in healthcare can lead to problems with hierarchal communication. Political and business researchers have considered biological models suggesting systems of lateral communication to combat this phenomenon and facilitate effective and efficient transfer. Crew resource management designed with the aviation industry combat such hierarchal communication problems by the use of several tools, techniques and systems to facilitate lateral communication.

For the learner, communication and teamworking are perceived as being often at the core of error, particularly barriers to hierarchal or multidisciplinary teamworking. Education to enhance teamworking can improve the recognition of the role of such skills within safe practice [11]. This author has reported new educational interventions to enhance communication that have been underpinned by several elements of the

SECTORS model [13], as well as their use as part of a generic non-technical skills training programme [12] in which they effectively enhanced safety attitudes.

Observation and simulation

In the aerospace industry there is an invariable focus on teaching methods that situate concepts in practice, drawing on real life models and learning through observation or simulation. This would suggest that non-technical skills training must be built on the principles of situated cognition, where learning is seen in terms of student's increasingly effective ability in different scenarios rather than in terms of an accumulation of knowledge [25]. Since situated cognition views knowing as an action within specific contexts and views Direct Instruction models of knowledge transmission as impoverished, there are significant implications for pedagogical practices. Firstly, instructional design should draw on apprenticeship models common in real life [26]. Secondly, design should rely on contextual narratives that situate concepts in practice. When the first elements of the SECTORS model are considered, learning in each area clearly aligns with this theory through applications such as the cognitive apprenticeship or anchored instruction [27].

Despite the clarity of this underpinning outside of healthcare, when educators began to transfer non-technical skills training into healthcare didactic teaching methods or non-interactive technology enhanced learning were often employed [7,9]. The duplicity in such pedagogical choices was compounded by the quite clear parallels that the majority of educators tended to draw to such aviation methods [28]. It is proposed that non-technical skills learning must align with such a situated cognition view of education.

Risk assessment and situational awareness

The final element of non-technical skills training outside of healthcare is the importance of harbouring and enhancing situational awareness [28]. Whilst learning in each of the elements already described will clearly support situational awareness within the clinical setting, integration of these skills to allow analysis in a specific situation is key. Previously, it has been demonstrated that learning within the workplace supports development of this skill, although this is often through experience of adverse events that may harm patients.

Within healthcare, the role of risk assessment as a related skill is also well reported. Situational awareness facilitates informed risk assessment, which in turn drives safe decision making. An example of this that has been well reported is Reason's three bucket model [29]. This theory views the risk in any situation from the professional's perspective and asks them to

consider how full each of their buckets. The buckets describe the risks associated with the 'task', the 'context' and the 'self'. Situational awareness allows the 'buckets' to be accurately filled and therefore the risk assessment to be complete and appropriate.

The SECTORS model

Non-technical skills learning is grounded in an understanding and awareness of error and supported through developing expertise in communication and teamworking, as well as an appreciation for and proficiency in the use of human factor based systems and technology to reduce the risk of adverse events. Learning in these areas is facilitated by observation of others and experience within the workplace, following a situated cognition model of learning. The core elements of non-technical skill learning described inform and facilitate a constant process of improving situational awareness that feeds into enhancements in risk assessment skills and ultimately decision making. Key to the understanding of learning in this context that the SECTORS model describes is the cyclical and self perpetuating nature of learning in this context. Similar to our understanding of how children develop skills using error correction strategies, the results of actions is shown to enhance learning in each of the key areas and thus enhance analytical skills.

Learning in non-technical skills within healthcare has always and continues to take place in this way, but unfortunately this model indicates that adverse events and potential harm to patients drives learning. The current trends in patient safety culture will help this issue by increasing awareness of errors and ensuring such learning is facilitated at each and every opportunity. The potential application of the SECTORS model is to inform instructional design that can enhance and drive learning in non-technical skills without any need for errors to occur within the clinical environment. Whilst the author has completed pilot work designing interventions that pay attention to the SECTORS model [12] that have shown improved safety attitudes, it is hoped that researchers will apply and report their findings using SECTORS and in particular consider investigating if the use of education designed using this model can enhance outcomes for patients.

CONCLUSION

A theoretically grounded model has been developed to understand how non-technical skills learning occurs within healthcare. This model has been used to support instructional design, but much more work is needed. Medical educators need to assess the appropriateness of this model for understanding learning in this context.

The utility and effectiveness of this model for designing non-technical skills training must also be investigated. Although difficult, the ultimate aim of such research should be confirmation of improved outcomes for patients through appropriately underpinned and reported educational developments.

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Appendix 2

Supporting papers



Pre-mixed intravenous infusions on a neonatal unit: A potential danger

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KEYWORDS

Neonatal;
Intravenous injections;
Drug error;
Medication errors;
Adverse Drug events

A term baby was admitted to our neonatal unit with a poor cord pH, metabolic acidosis and seizures. The baby was prescribed a saline bolus and over the next few hours, the acidosis slowly resolved. On the morning ward round we found a ready-mixed bag of intravenous Metronidazole next to the incubator. No other babies were prescribed this medication and the volume missing was identical to that of the saline bolus. It could not be confirmed that baby received saline rather than Metronidazole and so liver function was monitored, as per Toxbase guidance, and baby suffered no ill effects.

A risk assessment was immediately undertaken and during this process the similarities between ready-made Metronidazole bags and fluid infusion bags became evident (Fig. 1). It also became clear that all infusion bags, drugs or fluids, are stored in

the same area and that this has directly contributed to the wrong infusion being given to this baby.

In the past 10 years medication errors have come to be recognised as an important cause of iatrogenic disease in paediatric patients (Rossa, 2000). The importance of a system based approach to such errors has previously been stated (Leape, 1995), where the emphasis shifts from individuals making errors to the system within which they function. In line with this approach, and in response to widespread reporting in many disciplines of such problems, the use of premanufactured infusions has become widespread. This has been significantly effective in reducing the amount of drugs made up by staff on wards (Apkon, 2004) and thereby reducing the opportunity for error.

However, we feel this case highlights a potential risk still exists when these pre-mixed intravenous fluid and drug infusions are stored in close proximity.

Previous research (Simpson, 2004) has suggested that separation of drugs where potential exists for error and the use of smart infusions (Stokowski, 2006) that prevent over administration of drugs

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Figure 1

are effective measures and may be appropriate in this circumstance. Our recommendation would be for clinical areas to carry out their own risk assessment.

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Knowledge and attitudes of parents and professionals to neonatal BCG vaccination in light of recent UK policy changes: A questionnaire study

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Abstract

Background: Universal BCG vaccination in the UK ended in 2005. The new vaccination policy instead offers a number of different forms of selective vaccination to newborns based on risk of acquiring TB. We set out to assess the attitudes and knowledge of both parents and professionals to the new policy for neonatal BCG vaccination.

Methods: A short questionnaire was designed, made up of demographic and attitude questions, as well as very basic knowledge questions. The researchers handed out the questionnaire to all parents and professionals in the antenatal and postnatal areas, as well as the paediatric and neonatal units during a 6-week period. The site was the Royal Oldham hospital, a district general hospital with 3250 deliveries per year and multi-ethnic in its population mix.

Results: A total of 253 completed questionnaires were collected. The ethnic origin of responders was 50.6% White British, 18.2% Bangladeshi, 8.7% Indian, 4% White/Asian, the remaining 18.5% of other origins. 71.5% of responders said they had heard of BCG vaccine. When asked if they knew the new policy for its use, 33.2% answered yes. 24.5% gave the most accurate response when asked who now receives BCG.

Conclusion: We have found that amongst parents and professionals alike there is a lack of knowledge of the new policy. This has led to confusion and as knowledge amongst the professionals who identify neonates for vaccination is low, uptake may be sub-optimal. We suggest that units investigate the issue and ensure that the new policy is understood and implemented correctly.

Background

The UK BCG vaccination strategy for the last 50 years was based on universal vaccination of teenage school children if they had not previously been vaccinated, offering protection to the young adults in whom TB was most prevalent and most likely to be infectious [1,2]. In more recent years, a policy of selective vaccination was also introduced

[3], providing protection to new immigrants and newborns perceived to be at high risk. Indeed, the BCG vaccine for newborns and infants has been shown to offer significant protection against TB [4]

Based on the changing make up of the UK population and the declining rates of TB in the age group in whom univer-

sal vaccination was taking place, the joint committee on vaccination and immunisation introduced new guidelines in July 2005, which were then made policy by the department of health [5]. The new policy [6] abolishes universal vaccination and instead offers vaccination to all newborns in areas of high TB incidence and selective vaccination in other areas, based on the country of origin of parents and grandparents [7].

We set out to assess the attitudes and knowledge of both parents and professionals to the new policy for the use of the BCG vaccine at the Royal Oldham hospital, a district general hospital with 3250 deliveries per year and multi-ethnic in its population mix.

Methods

A short questionnaire was designed [see Additional file 1], made up of demographic and attitude questions, as well as very basic knowledge questions. This was piloted on a random sample of parents and professionals to check the clarity of the questions and appropriate language changes were made to allow the questions to gather the information required. The researchers handed out the questionnaire to all parents and professionals in the antenatal and postnatal areas, as well as the paediatric and neonatal units during a 6-week period. Health care workers who do not work in antenatal, postnatal or neonatal units were not asked to complete the questionnaire. A brief description of the study and explanation that participation was optional accompanied the questionnaire, no other guidance being offered by the interviewers. If a question was not understood, participants were asked to leave it blank. Patients who did not speak English were offered the use of the resident interpreters to complete the questionnaire. The completed questionnaires were collected immediately and data was coded and entered into SPSS for Windows version 11.5 for descriptive analysis (SPSS Inc, Chicago, USA).

Results

A total of 253 completed questionnaires were collected. No one declined to take part in the study. Responders were made up of parents and professionals, consisting of 133 parents (52.6%), 63 midwives (24.9%), 26 nurses (10.3%), 17 allied professionals (6.7%) and 14 doctors

(5.5%). The majority of responders had zero (32%), one (36%) or two (18.6%) children. The ethnic origin of responders was 50.6% White British, 18.2% Bangladeshi, 8.7% Indian, 4% White/Asian, the remaining 18.5% made up of 12 other origins, with no one declining to disclose their origin.

71.5% had heard of BCG and 48.6% said they were aware of rules governing who receives it. 63.3% of professionals and 6.0% of parents asked said they were aware of the new 2006 policy that now governs who receives the vaccine. Looking at parents alone, 0.0% of those who had no children and 8.1% of those with children said they were aware of the new policy. Table 1 shows a summary of who responders thought receive BCG in this current policy. When broken down, 50.0% of professionals and 0.0% of parents asked chose the most accurate answer.

It is worth noting that this question is limited in its scope as it does not allow a responder to give a detailed response if they are fully aware of the new policy. However, after piloting the questions, it was found this was the best way of ascertaining whether responders were aware that selective neonatal vaccination is the mainstay of the new policy and vaccination in other age groups is reserved for immigrants or as catch up for those missed.

40 responders had looked for further information on the topic. Only 14 of the 40 said this information was useful. Finally, participants were asked to make any comments they wished. A summary of the most common responses is shown in Table 2.

Discussion

The recent consultation by the national institute for clinical excellence [8] concluded that the school program was no longer cost effective in light of declining rates of TB in teenagers. The new policy for selective immunisation, shown in Table 3, offers targeted protection to newborns based on the rates of TB in their area of the UK [9] or their country of origin, as shown in Table 4.

Our hospital is in an area with less than 40/100,000 cases of TB and therefore as per the policy shown in Table 3, only new immigrant infants or infants whose parents or

Table 1: Responses when participants were asked who currently receives BCG vaccine

Response	Frequency	Percentage
Don't Know	166	65.6
All babies	13	5.1
Some babies	62	24.5
All teenagers	8	3.2
Some teenagers	2	0.8
Only new immigrants	2	0.8

Table 2: General comments recorded by participants

Comment	Frequency
Would like more information	26
Appears to be a racist policy at present	15
Have tried to find out information, but not been successful	7
Know about BCG, but not current policy	6
Doesn't care	6
People around me seem very confused	5
I don't know much about it	5
Thinks all babies should be getting it	4
Policy seems correct, but implementation is not	4
Has no knowledge and concerned as has other children who might need the BCG	2
Not enough leaflets for parents	2
Should be given by trained staff in a postnatal outpatient setting	2
There are too many vaccines	2
More emphasis needed on choice	2
Confused BCG with Vitamin K	2

grandparents are from high risk areas should be offered BCG.

We have found that awareness of this policy is generally quite limited, with one third of responders not knowing what BCG is and two thirds not knowing the current policy for vaccination. It should be noted that lack of awareness of the new policy was widespread amongst professionals as well as parents. In particular only 27% of midwives were aware of the new policy and they are currently responsible for identifying those who need the BCG and informing the paediatricians who administer it. This was reflected in the comments made, with many midwives stating that they need more information and knowledge to inform parents effectively.

This general lack of knowledge seems to be having an impact on parents, with a number perceiving and then commenting that they felt the policy was racist. This is an understandable viewpoint with a policy that apparently vaccinates ethnic minorities with no clear explanation as to why and limited knowledge amongst professionals responsible for providing the relevant information. Wherever in the UK knowledge amongst professionals is limited, similar problems in the perceptions of the vaccine by parents may be seen. Also, it is also clear that when parents are motivated to find information they are generally unsatisfied (65% did not find information useful) and this may again be due to the lack of knowledge amongst professionals advising them.

We have discussed this with the local primary care trust (PCT) and they are working with the new policy within the area. They have educated all Health Visitors so that they can identify new immigrant infants who are eligible. In addition, all head teachers have been contacted and school age children have been sent a questionnaire to identify if they are eligible under the new policy. The immunisation coordinator has informed us that this has been well received and led to identification of many eligible children, as well as allowing concerns to be addressed. Unfortunately, our study has shown that this education program has not been introduced into secondary care in the area and both parents and professionals in this sector lack the knowledge needed to implement the new policy effectively for neonates. In trying to improve this situation, a general program of education surrounding the new policy and its implementation will be required for parents antenatally and for all professionals involved in their antenatal and postnatal care.

It has been previously suggested that vaccinating with BCG within the community in specialist clinics has a role [10]. This offers the advantage of being cost effective by using entire vials of vaccine. It also allows the vaccine to be given by someone very experienced both technically and in terms of their knowledge and could have a positive effect on understanding and awareness amongst parents. It has previously been suggested that vaccinating at birth is less effective than at three months [11], another reason to consider community clinics as an attractive alternative which needs further study.

Table 3: Newborn groups to be offered BCG vaccination [13]

- All babies living in areas where the incidence of TB is 40/100,000 or greater
- Babies whose parents or grandparents have lived in a country with a TB prevalence of 40/100,000 or higher
- Unvaccinated infant immigrants from countries with a high TB prevalence

Table 4: Countries with TB incidence greater than 40 per 100,000 in 2004 [14]

Afghanistan	Chad	Georgia	Malaysia	Peru	Thailand
Algeria	China	Ghana	Maldives	Philippines	Timor-Leste
Angola	China, Hong Kong	Guam	Mali	Portugal	Togo
Argentina	China, Macao SAR	Guatemala	Marshall Islands	Qatar	Turkmenistan
Armenia	Colombia	Guinea	Mauritania	Rep. Korea	Uganda
Azerbaijan	Comoros	Guinea-Bissau	Mauritius	Republic of Moldova	Ukraine
Bahrain	Congo	Guyana	Micronesia	Romania	UR Tanzania
Bangladesh	Côte d'Ivoire	Haiti	Mongolia	Russian Federation	Uzbekistan
Belarus	Croatia	Honduras	Morocco	Rwanda	Vanuatu
Belize	Djibouti	India	Mozambique	Sao Tome & Principe	Venezuela
Benin	Dominican Republic	Indonesia	Myanmar	Saudi Arabia	Viet Nam
Bhutan	DPR Korea	Iraq	Namibia	Senegal	Yemen
Bolivia	DR Congo	Kazakhstan	Nepal	Sierra Leone	Zambia
Bosnia & Herzegovina		Kenya	New Caledonia	Singapore	Zimbabwe
Botswana	Ecuador	Kiribati	Nicaragua	Solomon Islands	
Brazil	El Salvador	Kyrgyzstan	Niger	Somalia	
Brunei Darussalam	Equatorial Guinea	Lao PDR	Nigeria	South Africa	
Burkina Faso	Eritrea	Latvia	Northern Mariana Is	Sri Lanka	
Burundi	Estonia	Lesotho	Pakistan	Sudan	
Cambodia	Ethiopia	Liberia	Palau	Suriname	
Cameroon	Gabon	Lithuania	Panama	Swaziland	
Cape Verde	Gambia	Madagascar	Papua New Guinea	Syrian Arab Republic	
Central African Republic	Georgia	Malawi	Paraguay	Tajikistan	

We have shown in this study that lack of clarity as to the reasons for selective use of BCG causes anxiety amongst parents and it has been previously identified that white British infants who are eligible may not be vaccinated in such an environment [12]. Therefore, instigating a program aimed at identifying antenatally those eligible for BCG should increase uptake and educate all parents about the current policy and the reasons behind it. This will help allay concerns caused by the incorrect notion of a 'racial' factor in the use of neonatal BCG, as commented on by several respondents in this study (Table 2).

Conclusion

We have found that amongst parents and professionals alike there is a significant lack of knowledge of the new BCG administration policy. In our district general hospital, this has led to much confusion and as knowledge amongst the professionals who identify neonates for vaccination is low, uptake may be sub-optimal. We suggest that units investigate the issue and ensure that the new policy is understood and implemented correctly. If problems are being encountered, a clear policy of antenatal education of parents and identification of eligible babies will ensure an appropriate uptake of BCG, as well as addressing concerns as to the distribution of the vaccine by the new policy by improving knowledge and understanding.

Abbreviations

BCG – Bacillus Calmette-Guerin

TB – Tuberculosis

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

MG participated in the design of the study, its coordination and drafted the manuscript. HR participated in the design and collected the data. EO conceived of the study, and participated in its design and coordination. All authors read and approved the final manuscript.

Additional material

Additional file 1

Questionnaire. The questionnaire as used for this study.

Click here for file

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Factor XIII Deficiency: A Differential Diagnosis to Be Considered in Suspected Nonaccidental Injury Presenting With Intracranial Hemorrhage

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Keywords: factor XIII; deficiency; bleeding; nonaccidental injury; subdural hemorrhage

Pediatricians must be constantly vigilant for children who may have been subjected to physical abuse, and in cases of reasonable suspicion, they must alert appropriate authorities.¹ Along with that awareness comes the understanding that there are indeed medical conditions that may mimic nonaccidental injury (NAI).² We must investigate appropriately to rule out such conditions for the sake of the child in question, their family, and our relationship with that family, a mistaken diagnosis having devastating and long-lasting consequences for all involved. In the case of an underlying bleeding disorder, a delay in diagnosis puts the child at risk of further morbidity.³ We present a case of a child with multiple subdural hemorrhages and describe her investigation and the eventual discovery of her underlying disorder.

Case Report

A baby was born in Pakistan, from where limited history is available. Birth was an elective section for breech presentation and high maternal blood pressure. There were no immediate concerns after birth,

though she was treated for jaundice with phototherapy. At 4.5 months of age while she was in Pakistan, she started to vomit and was treated for possible dehydration. She is said to have fitted in hospital and several tests were performed and a blood transfusion given. A computed tomography (CT) scan showed an extradural hematoma and she was operated on for the same. No clear history of injury was obtained, and there was no family history of bleeding disorders. She came to the UK, 2 weeks later.

When she was 8 months old, she was seen in our accident and emergency department for bruising over the operation site. There was no history of injury from parents, systemic examination was normal, and she was clean and well groomed. She was sent home without further action. However, this bruising became a large fluctuant swelling the next day and parents returned to accident and emergency department. She was transferred to the care of the pediatric neurosurgeons at a tertiary centre where she was treated for bilateral subdural hematomas and the suspicion of NAI was raised by the team due to the nature of the diagnosis. On CT scanning, the attenuation of the collection was dual being consistent with an acute on chronic subdural hematoma. It was also stated that the acute change could be related to sedimentation of blood components.

Bloods were taken and showed a full blood count, platelet count, prothrombin time, activated partial thromboplastin time, and fibrinogen level all were within normal limits. In addition, factor VIII

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levels, Von Willebrand antigen, risocetin cofactor, and PFA100 platelet function assay were all normal. A number of different agencies were also involved, including social services, primary health care services, local general pediatricians, and the tertiary pediatric team, and with these results a case conference was held. It was concluded that in a child under 1 year of age with an unexplained extradural hematoma and subsequent acute on chronic subdural hematomas, NAI must be a seriously considered differential diagnosis. It was also concluded that in light of the blood results, a hematological disorder was highly unlikely.

A number of further assessments and case conferences took place to discuss the best future course of action for the care of this child. Despite this, a number of episodes of unexplained bruising took place over the next few months. This was independent of the environment she was in, taking place with or without presence of parents. She was therefore referred to the pediatric hematologists for review and all the bloods rechecked, including factor XIII levels. These came back low at 13%, and a repeat test confirmed this result.

She has received monthly factor XIII injections for the last year and is doing well with parents with no episodes of further bleeds or bruising.

Discussion

Factor XIII deficiency was first described in 1960, following its discovery 16 years earlier. It is traditionally described as the final enzyme in the coagulation cascade although is now understood to play a role throughout the clotting process and is essential for normal hemostasis.⁴ It functions to cross-link α and γ fibrin chains, resulting in a stronger clot with an increased resistance to fibrinolysis.⁵ This very rare form of bleeding diathesis is reported to occur in 1 to 5 million individuals,^{5,6} with only 200 cases reported worldwide. In factor XIII deficiency, the clot solubility test will dissolve the fibrin clot in 5 M urea or weak organic acid.⁷

Monthly injections of factor XIII concentrate are an adequate therapy because of the very long half-life of factor XIII and the low plasma concentrations required for a normal coagulation.

The hallmark of factor XIII deficiency is umbilical stump bleeding and delayed separation of the

umbilical cord, which allows diagnosis in the neonatal period,^{4,8} but presentation varies widely.⁹ We currently have 2 other patients with factor XIII deficiency who were presented in the neonatal period, one with umbilical stump bleeding and the other with a large progressing cephalohematoma. It is well recognized that factor XIII deficiency is particularly associated with intracranial bleeds,^{10,11} more so than all other congenital bleeding disorders and occurring in up to 30% of patients.^{12,13} However, this occurs usually in the neonatal period and along with the other features of bleeding allows a swift diagnosis. There are no other case reports of factor XIII deficiency presenting with multiple subdural hemorrhages later in infancy mimicking NAI. However, there are reports in adults of spontaneous chronic subdural hematoma formation.¹⁴

Subdural bleed in infancy is relatively common with incidence in recent studies estimated at between 21 and 24 cases per 100 000 population.^{15,16} Nonaccidental injury is recognized as the major cause of the intracranial injuries in these studies. The role of magnetic resonance imaging in investigating these patients has also been outlined, its ability to distinguish acute and chronic bleeds using weighted scans.¹⁷

The case presented highlights the varied course this condition can take. It was commented that factor XIII levels of 13% would not usually be low enough to cause the level of bleeding seen in this child, but the manifestations are variable. In the end, it was the continuing presence of unexplained bruising in all environments that prompted the further investigations to take place and allowed eventual diagnosis. The child and family in question have endured a long process, which was no doubt very distressing, in reaching this little girl's diagnosis of factor XIII deficiency. Although very rare, early consideration of this condition in patients with intracranial bleeding without other hallmarks of NAI is vital. In addition, there are a number of other rare disorders with normal standard coagulation screening results, including platelet function defects, alpha antiplasmin deficiency, and PAI 1 deficiency. Therefore, referral for an expert opinion is often needed.

The most likely cause of subdural hemorrhage in an infant is NAI. However, this case highlights that the routine screen for bleeding disorders performed in these infants may not test for several conditions, including factor XIII deficiency. Although rare, if other aspects of the history are not consistent with

NAI in a child with intracranial hemorrhage, testing for rare bleeding disorders, including factor XIII deficiency, should be arranged to complete the screening process. We would advise all cases of suspected NAI and bleeding to be referred for an expert opinion from a pediatric hematologist.

Acknowledgment

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**TRANSCROTAL ORCHIDOPEXY FOR UNDESCENDED TESTES:
20 YEARS OF EXPERIENCE IN MANCHESTER
AND A REVIEW OF THE LITERATURE**

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Keywords

Undescended testis; Palpable testis; Orchidopexy; Transcrotal orchidopexy;
Paediatric; High scrotal orchidopexy; Single incision orchidopexy

Word Count: 2,005

Abstract

Objectives: To evaluate the results and complication rates of transscrotal orchidopexy for palpable undescended testis done in Manchester since 1985 and review the literature on this subject.

Methods: A retrospective case record review of transscrotal orchidopexies for palpable undescended testes performed at Royal Manchester Children's Hospital from 1993 - 2005 and a structured review of literature published since the proposal of this technique.

Results: 122 procedures were included. The transscrotal approach was successful in 119 (97.5%). Additional groin incision was needed in 3 (2.5%). No immediate complications were recorded and 8.4% required a redo procedure.

On review of the literature, a total of 10 articles spanning 900 transscrotal procedures, including the experience published from our centre previously, were found. On combining all this data, 5.1% required an additional groin incision, 3.0% experienced immediate complications and the overall recurrence rate was 3.1%.

Conclusions: The transscrotal orchidopexy for the treatment of the palpable undescended testes is a safe procedure with an excellent success rate and a low complication rate.

1. Introduction

The majority of undescended testicles are palpable distal to the inguinal canal [1]. In 1989, Bianchi and Squire [2] proposed that orchidopexy for the palpable undescended testis should commence with a scrotal incision and that an additional groin incision be reserved for the few high testes that will not otherwise reach the scrotum, after maximal possible mobilization through the scrotum. The ‘Transcrotal Orchidopexy’ has the advantage of much less dissection, greater comfort for the patient, rapid healing, excellent cosmesis and a well maintained testicular position. In 1995, Bianchi followed this up with a case series of 367 orchidopexies [3] that confirmed low complication rates and a high success rate. This paper presents the results of a further case record review of transcrotal orchidopexies for the palpable undescended testes performed at the Royal Manchester Children’s Hospital from 1993 to 2005, and a review of the published literature relating to this surgical technique.

2. Methods

We retrospectively reviewed the case records of all children who underwent transcrotal orchidopexies from 1st January 1993 to 1st January 2005. The children were under the care of one consultant surgeon and junior surgical staff who routinely practise the transcrotal approach [2]. It must be noted that only cases carried out at Royal Manchester Children’s Hospital were included in this review and although many cases are performed in other sites within the trust, they were not within the scope of this study. Cases in which conversion to a two incision took place were included in the study. Attention was given to testicular position before and immediately after the procedure, complication rates and overall outcome as documented at follow up. Patients excluded from the study were those in which case records were incomplete, those who were having a redo procedure and patients

suffering from an Intersex disorder. Data was coded and entered into SPSS for Windows version 11.5 (SPSS Inc, Chicago, USA) for descriptive analysis.

A literature search was carried out using the search terms ‘transcrotal orchidopexy’, ‘single scrotal incision’ and ‘scrotal orchidopexy’ using the Medline database. Further articles were examined by searching for related articles on Medline and by reference searching. Articles that presented data from case series or trials looking at the outcomes of the transcrotal orchidopexy were included.

3. Results

A total of 141 procedures were identified for case review within the study period. Exclusion criteria led to 19 procedures being removed from the study: 12 redo procedures, four with poor note keeping and three patients with Intersex disorders. The remaining group consisted of 118 patients, of which four had bilateral procedures giving a total of 122 orchidopexies. The mean (SD) age at first operation was 5.1 years (3.8).

Before operation, the position of the testes was the neck of the scrotum in 11 patients (9.0%), the external inguinal ring in 34 (27.9%), the inguinal canal in 25 (20.5%), the internal inguinal ring in three (2.5%), ectopic position in one patient (0.8%) and 48 (39.3%) were not clearly specified.

At operation, 62 testes (50.8%) were recorded as being of good volume, and 60 were hypotrophic (49.2%). The transcrotal approach was successfully completed in 119 procedures (97.5%). An additional groin incision was needed on three occasions (2.5%). No immediate complications were recorded in any procedures.

The Mean (SD) follow up was 3.65 years (SD 2.9), with a range of 0.3 – 11.5. At follow up the testicular position was deemed unsatisfactory in 12 of 122 patients (9.8%) and it was elected that a redo procedure be performed. Of these 12 redo, two

were from the group of three transcrotal orchidopexies which were converted to a two incision procedure. Therefore, the long term recurrence rate for the group completed with a single transcrotal incision was 8.4% (10 of 119). The redo procedure was performed transcrotally for 10 patients. One required a conventional two incision procedure (groin and scrotum) and one a microvascular orchidopexy [5]. There were no immediate complications on reoperation and all testes at follow up were recorded to be in the scrotum. No testes were recorded to have atrophied from any of the 122 orchidopexies.

At the time of this report, a total of 489 transcrotal orchidopexies have been reviewed at the Royal Manchester Children's Hospital from 1984 to 2005 [2, 3, and this series]. Of these cases, 472 operations (96.5%) were completed transcrotally. 17 patients (3.5%) required an additional groin incision. Immediate complications, such as scrotal haematoma or infection were experienced on seven occasions (1.4%). Testicular position was deemed unsatisfactory and a redo procedure performed in 23 of the 472 patients (4.9%) in which a transcrotal approach had been carried out. A total of three testes atrophied (0.6%).

The review of the wider literature produced other eight articles [6-13] reporting case series for the transcrotal orchidopexy. A summary of these studies and Manchester experience is shown in Table 1.

These papers report a further 533 transscrotal procedures reported between 1996 and 2006. The rates of conversion to a conventional two incision procedure at first operation are between 0% and 13%. Reported rates of immediate complications varied from 1.3% to 5.4%. Overall recurrence rate for the transcrotal cases varied from 0% to 5.4%.

On combining data for the Royal Manchester Children's Hospital with the data that is available from the other eight case series, 5.1% of patients (52 of 1022) required an additional groin incision at first operation. Rates of immediate complications are reported for all but two of these studies [7, 12] and when combined the total rate is 3.0% (27 of 883). The overall recurrence rate for all cases in which a transcrotal approach was initially attempted was 3.1% (32 of 1022). For several of the studies [6, 8, 9, 10, 11] it is not specified whether the recurrence rate reported is for the entire initial cohort or just the patients in whom a procedure was completed transcrotally. If the overall recurrence rate is calculated for the series in which this is specified, 3.6% (23 of 633) of cases in which the orchidopexy was successfully completed transcrotally, not requiring an additional groin incision, suffered from a recurrence on follow up.

4. Discussion

Conventional orchidopexy today is still performed according to the concepts of Schuller [14] in 1881 and Bevan [15-16] in 1899 and 1903. The experiences of Bianchi and Squire [2] confirmed that the testicular vessels and the vas in the majority of palpable undescended testicle, after dissection of the cremaster and the processus vaginalis (fig. 1), are long enough to allow the testes to reach the scrotum without tension. Based on these observations, the approach was reversed and it was found that in most instances it was unnecessary to disrupt the inguinal canal, sufficient dissection being possible through the scrotal approach.

The details of the surgical technique have been described previously [2], but some points have to be emphasized due to a few misinterpretations which can be found in the literature. Misra et al [7] in 1997 illustrated a variation of the original technique described by Bianchi with a lower transverse scrotal incision. We believe that this

does not help to find the testis and does not allow the creation of an adequate scrotal pouch. A curved, high, scrotal skin incision (fig. 2) is, in our experience, the most convenient approach to the inguinal canal through the scrotum. In the article, Misra et al [7] also state that the inguinal approach is needed in the case of a hernial sac discovered on scrotal exploration. In our experience on 489 procedures, the processus vaginalis can be successfully dissected and tied from a scrotal incision. Indeed the scrotal approach is our preferred approach for the management of inguinal hernias and hydrocele [3].

But are the results of transcrotal orchidopexy comparable to those reported in the literature for the traditional two incision procedure? In 1995, Docimo [4] reviewed the literature for conventional orchidopexy techniques. From 64 articles pertaining to 8,425 testicles, a preoperatively location was reported for 2,491 testicles. Of these, 842 were intra-abdominal, leaving a total of 1,649 palpable testes. The location for these 1649 testes was at the internal ring in 294 (17.8%), 681 were cannicular (41.3%) and 674 beyond the external ring (40.9%), most ectopically in the superficial inguinal pouch. The overall recurrence rate for procedures in which six month follow up took place was 12.5% (176 of 1405). When the series was divided by date of publication and only those published after 1985 were included, recurrence rates of 0% (0 of 7) was reported for those testes described as ‘peeping’, 4.3% (15 of 345) for cannicular testes and 0% (0 of 19) for those beyond the external ring. The overall recurrence rate was 4.1% (15 of 371). Our own data combined with that in the literature showed an overall recurrence rate of 3.1% (32 of 1022).

However if we look at the preoperative position of the testes, where it was recorded, the only transcrotal series which includes clearly testes at the internal inguinal ring is the Manchester 2006 (3 cases - 2%). The majority of the Authors seem to have

excluded these high undescended testes from their transcrotal series. In our view, transcrotal orchidopexy can be attempted for proximal undescended testes, bearing in mind that if the dissection of the cord is not enough to bring the testis in the scrotum, a second groin incision can be safely made. However, our data suggests that if a second groin incision becomes necessary, the recurrence rate is much higher (two of the three patients who needed a conversion to a two incision operation in our last series experienced recurrence). This means that in our experience, if the testis can not be brought into the scrotum through a scrotal incision, it is likely that a second groin incision will not gain further significant testicular mobilisation.

If we compare our recurrence rate of 3.1% with 4.1% (15 of 364) from the Docimo [4] review for testes at or beyond the inguinal canal in papers after 1985 we find that the transcrotal approach seems to offer better results. This can be explained because less scarring is inflicted on the inguinal canal with the transcrotal approach with therefore minor incidence of secondary retraction of the cord.

There are very few further contemporary papers with results for the two incision approach [17-18] and so a more appropriate similarly sized control group is not available at this time.

5. Conclusions

Published data from the last 20 years confirms that transcrotal orchidopexy is followed by uncomplicated healing, and a well-placed scrotal testis. In comparison with the conventional two incision operation, transcrotal orchidopexy offers the advantage of an aesthetic single scrotal crease incision, less dissection and greater comfort for the day case child. Moreover the literature seems to suggest that transcrotal orchidopexy offers a lower recurrence rate than the two incision approach for the treatment of the testes pre-operatively located in the distal portion of the

inguinal canal. Further studies are necessary to evaluate the role of transscrotal orchidopexy for the treatment of more proximal undescended testes.

Acknowledgements

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Figure legends

Figure 1. Dissection of the processus vaginalis from a single scrotal incision.

Figure 2. Curved, high, scrotal skin incision used for the treatment of the palpable undescended testis, shown in red.

Take Home Message

The transscrotal orchidopexy in the palpable undescended testes is a safe procedure with excellent results. On combining our experience with the literature, the recurrence rate is 3.1% in 1022 testes, comparing favourably to the two incision orchidopexy published data.

Figure 1
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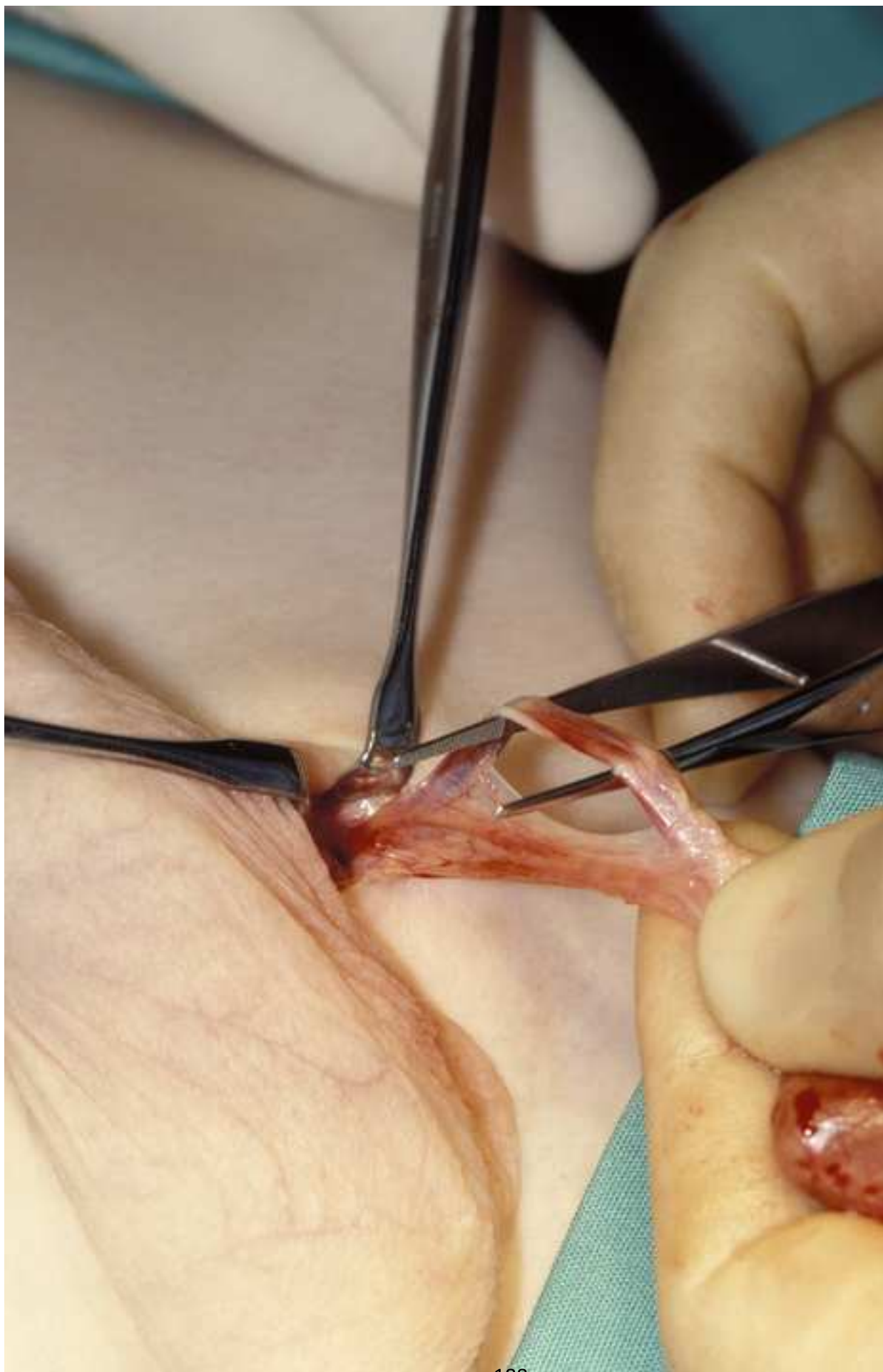


Figure 2
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Table 1. Review of the published literature regarding transscrotal orchidopexy.

Authors	Year	Num. of cases	Preoperative location	Inclusion criteria	Exclusion criteria	Conversion to a two incision procedure	Immediate complication rate	Number of recurrence (%) [follow-up time]	Ref.
Bianchi A, Squire B	1989	120	IC = 12(10.0%) EIR = 36(30.0%) SIP = 41(34.2%) NS = 27(22.5%) E = 4(2.5%)	Not Specified	Not specified	5(4.2%)	3.3% 4 scrotal haematomas	0 [6 months – 3 years]	2
Iyer KR, Kumar V, et al	1995	247 new cases	NK = 247(100.0%)	Not Specified	Not specified	9(3.6%)	1.2% 2 wound infections 1 unexplained pyrexia	13(5.3%) [1 – 8 years]	3
Lais A, Ferro F	1996	50	IC = 7(14.0%) EIR = 28(56.0%) E = 15(30.0%)	Not Specified	Not specified	3(6%)	6% 3 scrotal haematomas	1(2%) [3-5 years]	6
Misra D, Dias R, et al.	1997	67	EIR = 67(100.0%)	Testes that could be manipulated into the scrotum with difficulty and on release of pressure, returned into the inguinal region	Not specified	9(13%) All with hernia sac were converted to a two incision approach	Not specified	0 [1 – 5 years]	7
Jawad AJ	1997	106	IC = 18(17.0%) EIR = 29(27.3%) SIP = 35(33.0%) NS = 21(19.8%) E = 3(2.8%)	All palpable testes	Not Specified	14(13%)	1.9% 2 wound infections	5(5.4%) [8 – 36 months]	8
Caruso AP, Walsh RA, et al.	2000	45	EIR = 45(100%)	All cases distal to the external ring	Redo procedures (15)	1(2.2%)	2.2% 1 scrotal haematoma	1(2.2%) [1 year]	9
Russinko PJ, Siddiq FM, et al.	2003	83	IC = 13%, EIR = 20% NS = 18%, E = 5%, SIP = 44% Based on 85 cases (2 excluded)	Testes that could be drawn close to or into the scrotum	Retractile testes, redo procedures (2)	1(1.2%)	2.4% 1 wound cellulitis 1 wound haematoma	1(1.2%) [1 – 36 months]	10
Rajimwale A, Brant WO, et al.	2004	75	IC = 2(3%) SIP = 42(56%) E = 12(16%) G = 19(25%)	Testes that could be milked to the level of the midpubic tubercle or beyond under anaesthesia	Prior inguinal surgery, retractile testes	3(4.0%)	1.3% 1 scrotal haematoma	1(1.3%) [6 week – 1 year]	11
Dayanc M, Kibar Y, et al.	2004	72	IC = 29(40%) EIR = 43(60%)	Within or beyond inguinal canal	Retractile testes	4(5.5%)	Not specified	0 [1 -3 years]	12
Handa R, Kale R, et al.	2006	35	EIR = 35(100%)	Distal to the external ring	Retractile, ectopic and redo patients	0	2.8% 1 wound infection	0 [2 -6 months]	13

Gordon M, Cervellione RM, et al	2006	122	IIR = 3(2.5%) IC = 25(20.5%) EIR = 34(27.9%) NS = 11(9.0%) E = 1(0.8%) NK = 48(39.3%)	All palpable testes	Intersex disorder (3), redo procedure (12) or inadequate note keeping (4)	3(2.5%)	0	10(8.4%) [3 months – 11 years]	-
Total	1989 - 2006	1022	IIR = 3(0.3%) IC = 104(10.2%) EIR = 334(32.7%) SIP = 154(15.1%) NS = 74(7.2%) E = 39(3.8%) G = 19(1.9%) NK = 295(28.9%)	-	-	52(5.1%)	17/883(1.9%) Excluded 2 papers where complications not specified	32(3.1%) [2 months – 11 years]	-

Abbreviations: IIR = Internal inguinal ring, IC = Inguinal canal, EIR = External inguinal ring, NS = Scrotal

Neck, SIP = Superficial inguinal pouch, E = Ectopic, G = Gliding, NK = Not Known

Improved junior paediatric prescribing skills after a short e-learning intervention: a randomised controlled trial

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► Additional data are published online only at <http://adc.bmj.com/content/96/12.toc>

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ABSTRACT

Objective Medication errors are common, with junior doctors accounting for the majority in acute healthcare. Paediatrics is uniquely challenging, but the evidence base to guide prescribing education is limited. The authors set out to develop a short, educationally sound, low cost e-learning resource for paediatric prescribing to improve junior doctors' prescribing skills and to evaluate its effectiveness.

Design A non-blinded randomised controlled trial.

Setting North Western Deanery Foundation School, UK.

Participants 162 volunteer foundation (junior) doctors randomised into control (86) and intervention (76) groups.

Interventions On study entry, participants were assessed on prescribing skill, prescribing habits and confidence. The intervention group completed the e-learning course designed for the study, which took 1–2 h. At 1 and 3 months after the intervention, both groups were assessed on similar prescribing assessments, habits and confidence.

Main outcome measures Total score (expressed as a percentage) on prescribing assessments, confidence and satisfaction scores.

Results There were no preintervention differences in prescribing assessments (67% vs 67%, $p=0.56$). Postintervention, the e-learning group scored significantly higher than the control group (63% vs 79%, $p<0.0001$). At 3 months, the e-learning group still scored significantly higher (69% vs 79%, $p<0.0001$), with improved confidence scores ($p<0.0001$).

Conclusions This short e-learning resource significantly improved the paediatric prescribing skills of junior doctors. Outcomes were maintained at 3 months, suggesting the utility of low cost, low fidelity, educationally sound e-learning interventions. However, the direct impact on patient outcomes following this intervention has yet to be determined.

BACKGROUND

Errant prescribing is one of the most common errors in healthcare,¹ contributing to 7000 deaths annually in the USA.² A recent review³ identified systems such as electronic prescribing, computerised order entry systems and clinical pharmacy services as effective in reducing prescribing errors. Although a national undergraduate prescribing examination is being developed, current research suggests that graduates are at high risk of error,⁴ with trainees reporting low confidence⁵ and a desire for additional training. The General Medical and Medical School Councils^{1,2} convened a

What is already known on this topic

- Medication errors by junior doctors are a common source of adverse events in healthcare.
- Postgraduate education can improve paediatric prescribing, but poor reporting of the interventions and methodological weaknesses limit such research.

What this study adds

- A short, low cost and pedagogically sound e-learning intervention for junior doctors can significantly enhance paediatric prescribing skills.
- This improvement is maintained at 3 months after the intervention.

Safe Prescribing Working Group in 2009⁷ to tackle this issue. Although one of their key recommendations was enhanced prescribing continuing medical education, a recent study⁸ suggests that this is not being delivered by paediatricians in the UK, although there are some promising reports in the literature.

In one study, paediatric prescribing errors were halved after the introduction of a junior doctor prescribing tutorial.⁹ Other reported educational methods include problem based learning,^{10–12} interactive tutorials¹³ and computer games.¹⁴ All these studies share a key weakness: they do not report the educational interventions in sufficient detail to allow replication. There are also methodological limitations, with generally small sample sizes and no published randomised controlled studies within postgraduate training. A recent systematic review¹⁵ concluded there is only moderate evidence to inform the design of prescribing educational interventions for junior doctors.

Cook reviewed the evidence¹⁶ and found that e-learning is better than no teaching and similar to other forms of teaching. He argues¹⁷ that the various types of teaching are different but complementary, serving different purposes and functions suited to their own strengths. The question for medical educators is when and how to best employ e-learning. A paediatric prescribing intervention designed using e-learning could be standardised and yet individualised, convenient and

Original article

time efficient. When designing e-learning courses, the need for software support, technical infrastructure and training for educators all must be considered, as these factors can have significant logistical and cost implications.

We set out to investigate how effectively a short, low fidelity e-learning course on paediatric prescribing could improve skills among junior doctors.

METHODS

Ethics approval for this study was received from the University of Dundee.

Study design

We measured the effectiveness of the intervention on improvement in prescribing skills using a non-blinded randomised controlled trial.

Intervention

The intervention was designed in Microsoft PowerPoint 2007 and, using the Rapid E-learning Suite (v 5.6.5; Wondershare Software, Shenzhen, China), was converted to a self-contained flash program. This supported self-assessment exercises, video files and animations. The structure of the e-learning course is shown in online supplementary appendix 1. The programme was designed to be completed in 1–2 h. Paediatric pharmacists independently reviewed the intervention and the prescribing assessments and both were piloted among junior doctors. There were three different assessments of 10 questions, all structured similarly with questions in four categories: drug selection, prescribing calculations for children, discussing therapies and sources of error. The first assessment had 85 marks, while subsequent assessments had 100 marks each. The further assessments had additional elements added to prevent participant improvement due to a test–retest effect. An example question

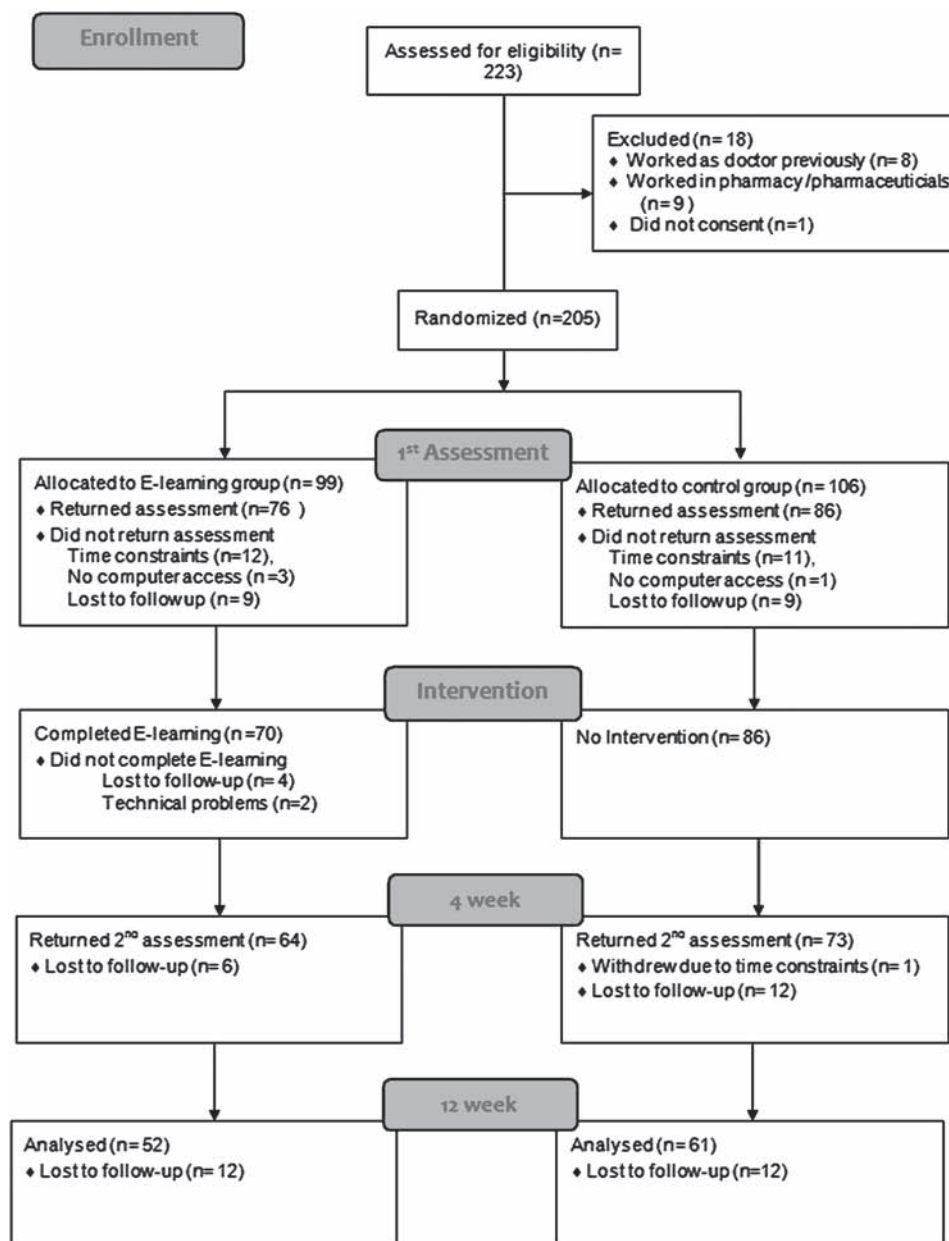


Figure 1 Flow diagram of trial.

Table 1 Scores comparing control and intervention groups

Outcome	Timing of assessment	E-learning group	Control group	p Value (unpaired two-tailed t test)
Prescribing skills	Baseline, mean (SD) (85 marks possible, % shown)	66 (12.6)	67 (11.9)	0.56
	4 weeks postintervention, mean score (SD) (100 marks possible)	79 (12.1)	63 (13.5)	<0.0001*
	12 weeks postintervention, mean score (SD) (100 marks possible)	79 (10.1)	69 (12.4)	<0.0001*
Confidence scores	Baseline, mean % (SD)	17 (2.4)	17 (2.9)	0.55
	4 weeks postintervention, mean % (SD)	16 (2.1)	15 (2.7)	0.01*
	12 weeks postintervention, mean % (SD)	19 (4.5)	17 (3.7)	0.02*
Teaching satisfaction scores	Baseline, mean % (SD)	8 (1.4)	8 (1.4)	0.66
	4 weeks postintervention, mean % (SD)	9 (1.3)	8 (1.4)	0.02*
	12 weeks postintervention, mean % (SD)	7 (2.1)	6 (1.8)	0.04*

*Denotes statistically significant results.

is shown in box 1 and the full assessments and marking guides are shown in online supplementary appendix 2.

Instructional objectives were derived from the Foundation and Royal College of Paediatrics and Child Health^{18 19} curricula (online supplementary appendix 3). Gagne's nine events of instruction were used to design the course structure.²⁰ Cognitive load theory,²¹ which aims to prevent overload of working memory,^{22 23} was used to increase the learning efficiency of the intervention. These theories are presented in online supplementary appendix 4.

Recruitment

Volunteer trainees within the North Western Deanery Foundation School enrolled during July and August 2010. The school has approximately 1150 trainees. Exclusion criteria included: having a pharmacy degree; a history of working within the drugs industry; previously working as a doctor; and limitations on prescribing. It was calculated that a sample of 124 participants was needed to provide 90% power ($p < 0.05$, two tailed test) to detect a 25% difference in scores. To allow for a 15%–20% drop-out at each assessment, a sample of over 200 was obtained.

A computerised random number generator allocated the 206 participants into control and experiment groups. Allocation in a 1:1 ratio was performed by providing assignments in sealed, light-proof envelopes, prepared by an independent researcher. These were opened sequentially once a participant had consented for inclusion. Participants were given identical baseline prescribing assessments. The intervention group were then sent the e-learning package and given 4 weeks to complete it. All participants were sent a second assessment and questionnaire. A final assessment was sent to all participants 8 weeks later.

Data analysis

The primary outcome measure was prescribing skill, measured by the total correct responses on each prescribing assessment. As the baseline assessment offered 85 instead of 100 marks, scores were converted to percentages to allow comparison to subsequent assessments. Secondary outcomes were prescribing confidence and satisfaction with prescribing education, measured by totalling Likert scores.

The researcher was blinded as to the allocation group of participants when marking assessments and performing 194 training.

analysis. The Student's t test was used for prescribing scores. A Wilcoxon signed rank test was used for secondary outcomes. Data were analysed in Statsdirect (v 2.7.8; StatsDirect, Altrincham, Cheshire, UK).

RESULTS

Figure 1 shows the study profile, reported in line with the Consolidated Standards of Reporting Trials guidelines.²⁴ There were 106 participants randomised to the control group and 99 to the intervention group, with demographics such as gender, age and previous degrees equally distributed between groups.

The baseline and postintervention scores for each of the outcomes are shown in table 1. There was no significant difference in baseline scores between the groups for any outcome measure. At 4 weeks after the intervention, there was a significant increase in the intervention group's prescribing scores and this was maintained at 12 weeks. Confidence and satisfaction scores in the intervention group also showed statistically significant increases at 4 and 12 weeks. There was no significant difference in the prescribing scores of the control group between the baseline and 12-week postintervention assessments (66% vs 68%, $p = 0.36$).

Further analyses assessed the potential impact of participant characteristics. These excluded participants who had received prescribing teaching since recruitment, those with previous degrees and year two trainees, with no change in the results. A 'per protocol' analysis, removing all participants who did not complete all three assessments, again had no impact on the results, with similar differences in scores seen. Feedback on the e-learning intervention was almost universally positive.

DISCUSSION

It is unsurprising that prescribing scores in the group who received the e-learning program had increased on re-assessment. The persistence of improvements at 12 weeks and the corresponding lack of improvement in the control group's scores are much more informative. In previous studies, longer term retention is rarely investigated. The fact that such a short module is able to produce a measurable improvement in prescribing skills at 12 weeks suggests the potential utility of such interventional design within early postgraduate

Box 1 Example question from prescribing assessments

You are asked to make up an intravenous morphine bolus for a patient. You firstly check the prescription. If he weighs 21 kg and the dosage is 200 micrograms/kg, what is the dose?

4 Marks

It comes in strengths of 1 mg in 1 ml and 10 mg in 1 ml. Please select an appropriate strength and solution for dilution for making up the morphine bolus: (Delete as applicable) 1 mg in 1 ml or 10 mg in 1 ml.

1 ml of water or 10 ml of water or 1 ml 0.9% saline or 10 ml 0.9% saline.

3 Marks

Given the high rates of error in paediatric prescribing by junior doctors, the use of this or similar interventions would seem advisable and could be easily implemented. If this became a mandatory element of induction, prescribing skills and ultimately outcomes for patients could be improved. The intervention was designed with a widely available and simple piece of software that allows educators to create most material in a familiar program. The finished e-learning course is easy to deliver as a self-contained intervention and does not require any new infrastructure or expenditure. As it is low fidelity, the need for continuing support is minimal and updating is easy. This manuscript and its supporting materials should allow educators to produce similar programs to be used in their own settings.

With the flurry of recent investment in e-learning at all levels of medical education, it is disappointing that so little of this work is guided by evidence. The authors maintain the view that the divide between theory and practice is limiting the effectiveness of much e-learning, with too much faith in the technology and too little focus on pedagogy. This study has attempted to challenge the role of 'technology' in technology-enhanced learning. Work is clearly needed to investigate other low fidelity e-learning interventions in medical education.

This study does have a number of limitations. Participants were volunteers, presenting an initial bias. There was also a large drop-out from recruitment to the first assessment, although a subsequent subgroup analysis of the participant demographics found no significant difference. Finally, this study has investigated improvements in skills and knowledge, but not the transfer of these into practice.

Previous work on patient safety issues has identified a gap between demonstrating improvement in skills and improvements in outcomes for patients.²⁵ As this is the ultimate aim of all quality improvement projects, research investigating transfer of these skills into practice and reduced adverse events for patients is needed.

In summary, a short e-learning module, taking less than 2 h, is able to improve paediatric prescribing skills significantly. The intervention uses simple and low cost production tools with a sound educational grounding and should be reproducible by others. Improvements are maintained at 3 months and this suggests the utility of such an intervention to improve the skills of junior doctors.

Competing interests None.

Ethics approval The University of Dundee Ethics Committee approved this study.

Provenance and peer review Not commissioned; externally peer reviewed.

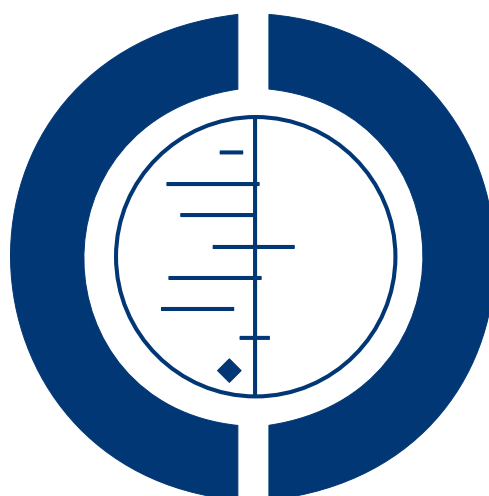
Contributors This study formed the dissertation project for Morris Gordon's Masters in Medical Education. MG conceived the study and led the design, creation of the educational intervention, analysis and study write up. MC was supervisor of the masters project. He provide input on design, sampling, analysis and rewrote a number of drafts of the manuscript. PB helped with design and recruitment and commented on drafts of the manuscript.

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Oral 5-aminosalicylic acid for maintenance of surgically-induced remission in Crohn's disease (Review)

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Oral 5-aminosalicylic acid for maintenance of surgically-induced remission in Crohn's disease

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ABSTRACT

Background

The use of 5-aminosalicylates (5-ASAs) in Crohn's disease (CD) is controversial. A recent Cochrane review found that 5-ASAs are not effective for the maintenance of medically-induced remission in CD, but their role in the maintenance of surgically-induced remission is unclear.

Objectives

The objectives were to evaluate the efficacy and safety of 5-ASA agents for the maintenance of surgically-induced remission in CD.

Search methods

The search was standardised and not limited by language and included electronic searching (MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Inflammatory Bowel Disease Group Specialized Trials Register), reference searching of all included studies, abstracts from major meetings, personal contacts and drug companies.

Selection criteria

Randomised controlled trials (RCTs) which compared 5-ASAs with either placebo or another intervention, with treatment durations of at least 6 months were considered for inclusion. Participants were patients of any age with CD in remission following surgery. Primary outcome measures were clinical relapse or endoscopic recurrence as defined by the primary studies. Secondary endpoints were the occurrence of adverse events.

Data collection and analysis

Relevant papers were identified and the authors independently assessed the eligibility of trials. Methodological quality was assessed using the Cochrane risk of bias tool. The Cochrane RevMan software was used for analyses. Patients with final missing outcomes were assumed to have relapsed. Odds ratio (OR) and 95% confidence intervals (95% CI) were calculated based on the fixed effects model. The chi square and I^2 statistics were used to assess statistical heterogeneity.

Oral 5-aminosalicylic acid for maintenance of surgically-induced remission in Crohn's disease (Review)

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Main results

Nine RCTs were included in the review. Seven studies compared oral 5-ASA with placebo and two compared oral 5-ASA with purine antimetabolites (azathioprine or 6-mercaptopurine). 5-ASA was significantly more effective than placebo for preventing relapse (OR 0.68, 95% CI, 0.52 to 0.90). There was no statistically significant heterogeneity among the 8 trials comparing 5-ASA with placebo ($P=0.47$). No statistically significant difference in adverse events was found for 5-ASA versus placebo (OR 1.02, 95%CI, 0.60 to 1.76). No statistically significant difference was found between 5-ASA and purine antimetabolites for preventing relapses (OR 1.08 95% CI, 0.63 to 1.85).

Authors' conclusions

The pooled analyses suggest that 5-ASA preparations may be superior to placebo for the maintenance of surgically-induced remission in patients with CD. The results of the pooled analyses should be interpreted with caution because adequately powered studies demonstrated no difference and publication bias (failure to publish negative studies) may be an issue. The potential benefit provided by 5-ASA drugs is modest with a number needed to treat of approximately 16 to 19 patients to avoid one relapse which raises issues about the cost-effectiveness of this therapy. However, 5-ASA drugs are safe and well tolerated. The incidence of adverse events was not different in patients receiving 5-ASA compared with those receiving placebo. There is insufficient evidence to allow any conclusions on how 5-ASA preparations compare with azathioprine or 6-mercaptopurine.

PLAIN LANGUAGE SUMMARY

Oral 5-aminosalicylic acid for maintenance of surgically-induced remission in Crohn's disease

Prevention of relapse is a key objective in the management of Crohn's disease. There is no current treatment available that completely maintains remission and is without significant side-effects. 5-ASA (aminosalicylic acid) preparations have previously been shown to be ineffective in maintaining medically-induced remission of Crohn's disease. This review included nine studies. Seven studies compared 5-ASA drugs with placebo (inactive pills or tablets) and two studies compared 5-ASA drugs with antimetabolites (azathioprine or 6-mercaptopurine). The results of this review suggest that 5-ASA preparations may provide a modest benefit for maintaining surgically-induced remission of Crohn's disease. The results of the review should be interpreted with caution due to methodological and statistical issues in the included studies. 5-ASA drugs are safe for patients with Crohn's disease. Side effects were generally mild in nature and typically included nausea, vomiting, diarrhea, abdominal pain and dyspepsia (upset stomach or indigestion). There is insufficient evidence to allow any conclusions on how 5-ASA preparations compare with azathioprine or 6-mercaptopurine. In conclusion, there is some evidence that suggests 5-ASA preparations may provide a modest benefit for the maintenance of surgically-induced remission in patients with Crohn's disease.

BACKGROUND

Crohn's disease is a chronic inflammatory disorder that can involve any part of the gastrointestinal tract. There is no cure for the disease and management strategies are mainly focused on the induction and maintenance of remission. Prevention of relapse is a major issue in the management of Crohn's disease. Corticosteroids, the mainstay of treatment of acute exacerbations, are not effective for maintenance of remission (Steinhart 2008) and their chronic use is limited by numerous adverse events.

5-aminosalicylates (5-ASA) are a group of compounds that have long established use in inflammatory bowel disease. The first 5-

ASA agent to be used in clinical practice was sulphasalazine, which was used in the 1940's as a treatment for arthritis (Svartz 1942). Improvement in gastrointestinal symptoms was noted in patients who had concurrent ulcerative colitis leading to further use of this agent in inflammatory bowel disease. Since then, their role as an agent for inducing and maintaining remission in ulcerative colitis and Crohn's disease has been extensively investigated.

A Cochrane review on the use of 5-ASA agents for the maintenance of medically-induced remission in Crohn's disease was completed in 2005 (Akobeng 2005a). This systematic review concluded that there was no evidence to suggest that 5-ASA preparations were

superior to placebo for the maintenance of medically-induced remission in Crohn's disease. However, the use of 5-ASA agents to prevent recurrence following surgery was not investigated as part of that review.

Surgical resection can induce remission in Crohn's disease, but endoscopic recurrence has been reported to be 71% at 1 year (Rutgeerts 1990) and clinical relapse rates have been reported to range from 22 to 55% at 5 years (Williams 1991). There is no standard therapy for the prevention of post-operative recurrence or relapse in Crohn's disease (Hanauer 2001). A number of agents have been studied, but considerable uncertainty remains as to the efficacy of such treatments.

5-ASA agents have been studied extensively in the post-operative setting, and a previous meta-analysis published in 1997 suggested that 5-ASA agents may be beneficial for the prevention of postoperative recurrence in Crohn's disease (Camma 1997). However, at least, one subsequent multicentre randomised controlled trial failed to show an overall benefit compared with placebo (Lochs 2000). An up to date systematic review using the Cochrane Collaboration format is indicated to summarise the current evidence on the use of 5-ASA agents for the maintenance of surgically-induced remission in Crohn's disease.

OBJECTIVES

The primary objective was to evaluate the efficacy of 5-ASA agents for the maintenance of surgically-induced remission in Crohn's disease. The secondary objective was to determine the frequency of adverse events associated with the use of 5-ASA agents for the maintenance of remission in Crohn's disease.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials which compared 5-ASA agents with either placebo or another intervention, with treatment durations of at least 6 months were considered for inclusion.

Types of participants

Patients of any age with Crohn's disease who were in remission following surgery, defined by a recognized Crohn's disease activity index or endoscopy, or who have undergone a curative surgical resection, as defined by the authors were considered for inclusion.

Types of interventions

Interventions where patients received oral 5-ASA agents versus placebo or another intervention for maintenance of surgically-induced remission were considered for inclusion.

Types of outcome measures

The primary outcome measures were clinical relapse or endoscopic recurrence as defined by the primary studies.

Secondary endpoints were the occurrence of adverse events such as:

- a. gastrointestinal: nausea, abdominal pain, diarrhoea, rectal bleeding;
- b. haematologic: aplastic anaemia, leucopenia, neutropenia, thrombocytopenia;
- c. renal: interstitial nephritis, nephrotic syndrome, renal failure;
- d. pulmonary: alveolitis, eosinophilic pneumonia;
- e. cardiac: pericarditis, myocarditis;
- f. pancreatitis; and
- g. headache.

Search methods for identification of studies

A. Electronic searching

The following electronic databases were searched for relevant studies:

1. MEDLINE (1966 to May 2010; National Library of Medicine, Bethesda, USA)
2. EMBASE (1984 to May 2010; Elsevier Science, New York, USA)
3. Cochrane Central Register of Controlled Trials
4. Cochrane Inflammatory Bowel Disease Group Specialized Trials Register

The search strategy was not limited by language.

MEDLINE on PUBMED was searched using the following search strategy:

- #1 crohn* disease
- #2 crohn disease [MeSH]
- #3 regional enteritis
- #4 ileitis
- #5 ileitis [MeSH]
- #6 inflammatory bowel disease
- #7 Inflammatory bowel diseases [MeSH]
- #8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7
- #9 aminosalicylic acid OR aminosalicylate
- #10 5-ASA
- #11 mesalazine OR mesalamine
- #12 Mesalamine [MeSH]
- #13 olsalazine
- #14 balsalazide
- #15 #9 OR #10 OR #11 OR #12 OR #13 OR #14
- #16 Surgery OR Surgical OR Surgically

#17 Surgic*
 #18 Post-surgical OR post-surgery
 #19 postoperative OR Post-operative
 #20 resection
 #21 operation
 #22 #16 OR #17 OR #18 OR #19 OR #20 OR #21
 #23 #8 AND #15 AND #22

Similar search strategies, but modified appropriately, and using the above keywords were used to search the other electronic databases listed above.

B. Reference searching

The references of all identified studies were inspected for more trials.

C. Abstracts of major gastroenterology meetings

A manual search of abstracts submitted to recent major gastroenterology meetings (2008-2009) was performed in the following journals to identify more trials:

1. Gastroenterology (American Gastroenterological Association);
2. Gut (British Society of Gastroenterology);
3. American Journal of Gastroenterology (American College of Gastroenterology);
4. Journal of Pediatric Gastroenterology and Nutrition (European / North American Society of Paediatric Gastroenterology, Hepatology and Nutrition);

When a relevant abstract was identified, details of the full study methodology and results were requested from the authors in order to allow a thorough assessment of the quality of identified studies. Abstracts for which this information could not be obtained were excluded.

D. Personal contacts

Leaders in the field were contacted to try to identify other studies.

E. Drug companies

The manufacturers of 5-ASA agents were contacted for any additional data.

Data collection and analysis

Step 1. Using the above search strategy, papers (or abstracts) that appeared to be potentially relevant were identified by two authors (MG and KN).

Step 2. The authors, after reading the full texts, independently assessed the eligibility of all trials identified based on the inclusion criteria above. Disagreement amongst authors was discussed and agreement reached by consensus.

Step 3. The methodological quality of selected trials was assessed independently by two authors using the Cochrane risk of bias tool (Higgins 2009). Factors assessed included:

1. sequence generation (i.e. was the allocation sequence adequately generated?);
2. allocation sequence concealment (i.e. was allocation adequately concealed?);

3. blinding (i.e. was knowledge of the allocated intervention adequately prevented during the study?);

4. incomplete outcome data (i.e. were incomplete outcome data adequately addressed?);

5. selective outcome reporting (i.e. are reports of the study free of suggestion of selective outcome reporting?); and

6. other potential sources of bias (i.e. was the study apparently free of other problems that could put it at a high risk of bias?).

A judgement of 'Yes' indicates low risk of bias, 'No' indicates high risk of bias, and 'Unclear' indicates unclear or unknown risk of bias. Disagreements were resolved by consensus. Study authors were contacted for further information when insufficient information was provided to determine the risk of bias.

DATA COLLECTION

A data extraction form was developed to extract information on relevant features and results of included studies. Two authors (MG and KN) independently extracted and recorded data on the pre-defined checklist. Extracted data included the following items:

- a. characteristics of patients: age, sex, disease distribution, disease duration, disease activity index;
- b. total number of patients originally assigned to each treatment group;
- c. intervention: type and dose of 5-aminosalicylate;
- d. control: placebo, other drugs;
- e. concurrent medications; and
- f. outcomes: time of assessment, length of follow up, type of Crohn's disease activity index used, definitions of remission and relapse, relapse rates, adverse events.

STATISTICAL ANALYSIS

The Cochrane Collaboration review manager (RevMan) software (version 5.0.23) was used for data analyses. Data were analysed according to the intention to treat principle. Patients with final missing outcomes were assumed to have relapsed. Analyses were grouped by length of follow up.

Dichotomous variables

The Odds ratio (OR) and 95% confidence interval (CI) were calculated based on the fixed effects model.

Heterogeneity

Heterogeneity among trial results was assessed by inspection of graphical presentations, and by calculating the chi square test of heterogeneity (a P value less than 0.10 regarded as statistically significant). We also used the I² statistic to quantify the effect of heterogeneity (Higgins 2003). A random effects model was used in situations of unexplained heterogeneity. Potential sources of heterogeneity were also investigated.

Publication Bias

The possibility of a publication bias was investigated through the construction of funnel plots (trial effects vs trial size).

Number needed to treat

For the comparison 5-ASA versus placebo, the number needed to treat (NNT) was calculated using the formula in the Cochrane

Handbook for Systematic Reviews of Interventions (Higgins 2009) section 12.5.4.3 and checked using an online calculator (Cates 2008). This formula uses the pooled odds ratio and assumed control risks to compute the NNT. This formula was used because it is not appropriate to compute a NNT from the aggregated total numbers of participants and events amongst the included trials (Cates 2002).

Subgroup analyses

Subgroup analyses were carried out to further study the effects of the following variables on the outcomes:

- risk of bias;
- type of 5-ASA;
- dose of 5-ASA; and
- follow-up time

Sensitivity analyses

Sensitivity analyses were also conducted based on the following:

- only including patients whose outcome is known i.e. number of patients who completed the study used as denominator; and
- random effects versus fixed effects models.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Twenty-eight potentially relevant studies on the use of 5-ASA agents for the maintenance of surgically-induced remission in Crohn's disease were identified. Nineteen studies were excluded for various reasons. Seven studies were excluded because they included patients in medically induced remission without enough detail to permit separation of the two groups (Anonymous 1990, Bresci 1991; Bresci 1995; Brignola 1992; Del Corso 1995; Gendre 1993; Wellmann 1988). Seven studies were excluded because they were not randomised controlled trials (Caprilli 1994, Caprilli 2003, Frieri 1999; Papi 2009, Nos 2000, Steinhart 1992, Sullivan 2001). Four studies were excluded because their data had been previously reported in earlier papers (Caprilli 1996; McLeod 1997, Schwartz 2005; Scribano 2006). One study was excluded because the follow up time of 12 weeks did not meet the inclusion criteria (Florent 1996). Four potentially relevant studies in abstract form were identified (Arber 1994, Fiasse 1990, Fiasse 1991, Rizello 2000). Attempts were made to contact the authors of these studies for full information on study methodology and results. No responses were received, and these studies were excluded.

Nine studies were identified which satisfied the inclusion criteria and were included in the review. Eight of the studies compared oral 5-ASA agents with placebo (Brignola 1995, Ewe 1977, Ewe 1989, Hanauer 2004, Lochs 2000, McLeod 1995, Sutherland 1997, Wenckert 1978), one study compared oral 5-ASA agents

with azathioprine (Ardizzone 2004) and one study compared 5-ASA with 6-mercaptopurine (Hanauer 2004). Sutherland 1997 included patients with medically and surgically-induced remission. For this review only data for surgically-induced remission were utilized (*see characteristics of included studies*).

The participants of the included studies ranged in age from 15 to 70 years. The total number of participants in the included trials was 1,203. The duration of follow up ranged from 11 months (Sutherland 1997) to 36 months (Ewe 1989, McLeod 1995). In one study (Sutherland 1997), remission was measured using the Crohn's Disease Activity Index (CDAI). In all the other included studies, remission criteria were not specifically stated, but patients had all undergone a resective surgical procedure to remove macroscopic disease.

Studies comparing 5-ASAs with Placebo:

Brignola 1995

Sample

Eighty-seven patients (mean age 36.5 years) were recruited from eight Italian centres. Patients had undergone surgical resection for Crohn's disease. Patients with active Crohn's in another region of the bowel or having >100 cm of bowel resected were excluded.

Treatment

Patients were randomised to receive either 5-ASA (Pentasa) 3 g/day or placebo. Concurrent medications were not described.

Endpoints

Patients were followed up for 12 months. The primary outcome measure was clinical relapse defined as worsening symptoms with a CDAI >150 and 100 points greater than baseline.

Ewe 1977

Sample

Thirty-three patients were recruited from a German centre. Patients had undergone surgery at least three months prior to inclusion. The interval between surgery and inclusion was 3 months to 7 years (mean 2 years). 14 patients were included within 1 year of operation.

Treatment

Patients were randomised to receive either sulfasalazine 3 g/day or placebo. No mention was made of concurrent medications.

Endpoints

Patients were followed up for 24 months. The primary outcome measure was clinical relapse, defined as a combination of symptoms and with CDAI > 150, histological, endoscopic, or radiological findings.

Ewe 1989

Sample

Two hundred and thirty-two patients (age range 15 to 66 years) were recruited from sixteen German centres. Patients had undergone surgical resection for their Crohn's disease, leaving no macroscopically inflamed intestine locally or in any other area of the GI tract.

Treatment

Patients were randomised to receive either sulfasalazine 3 g/day or placebo. No mention was made of concurrent medications.

Endpoints

Patients were followed up for 36 months. The primary outcome measure was clinical relapse indicated by symptoms, CDAI calculation and laboratory data and proven by radiology, endoscopy or operation.

[Hanauer 2004](#)

Sample

Eighty-four patients (mean age 34.1 years) were recruited from five US centres. No specific remission criteria were stated. Patients were eligible if they were undergoing an ileocolic resection. Patients with minimal evidence of Crohn's disease at other sites were not excluded. Patients were excluded if there was evidence of gross disease at the operative margins or in other intestinal segments.

Treatment

Patients were randomised to receive either 5-ASA (mesalamine) 3 g/day or placebo. Other medications were not allowed, except corticosteroids in tapering doses to be completed 3 months after hospital discharge and topical therapies for perianal disease. No report was made as to how many participants received these treatments in each of the study groups

Endpoints

Patients were followed up for 24 months. The primary outcome measures were clinical, radiographic or endoscopic relapse at 24 months. Clinical relapse was defined as symptoms of active disease.

[Lochs 2000](#)

Sample

One hundred and thirty-one patients (age range 18 to 70 years) were recruited from twenty-nine European centres. No specific remission criteria were stated. Patients were eligible if they were undergoing a resective surgical procedure. Diagnosis of Crohn's disease must have been established at least 6 months before surgery. Patients were excluded if they had completed more than 3 surgeries preceding the index surgery or had an ileocolonic stoma.

Treatment

Patients were randomised to receive either 5-ASA (mesalamine) 4 g/day or placebo. Other medications were not allowed before or during the study, except corticosteroids in tapering doses to be completed 6 weeks after hospital surgery and symptomatic treatments if well documented (antidiarrhoeal, antacid or spasmolytic medication). No report was made as to how many participants received these treatments in each of the study groups.

Endpoints

Patients were followed up for 18 months. The primary outcome measure was clinical relapse at 24 months. Clinical relapse was defined as either: an increase in CDAI to > 250, increase of CDAI to > 200 and 60 points greater than lowest 2 consecutive values, an indication for surgery, or a new fistula development with septic complications.

[McLeod 1995](#)

Sample

One hundred and seventy-seven patients (mean age 38.5 years) were recruited from four Canadian centres. No specific remission criteria were stated. Patients were eligible if they were undergoing a resective surgical procedure and had no gross residual disease. Patients were excluded if they had any residual Crohn's disease in the GI tract, with the exception of skin tags or anal stenosis.

Treatment

Patients were randomised to receive either 5-ASA (Mesalamine) 3 g/day or placebo. Other medications that had to be stopped included sulfasalazine, metronidazole and imuran. Corticosteroids in tapering doses, had to be completed 3 months after hospital surgery.

Endpoints

Patients were followed up for 18 months. The primary outcome measure was clinical relapse at 18 months. Clinical relapse was defined as symptomatic recurrence severe enough to warrant treatment, as well as radiological or endoscopic evidence or the need for surgery which confirmed disease.

[Sutherland 1997](#)

Sample

Two hundred and ninety-three patients (mean age 36.5 years) were recruited from 31 Canadian centres, of which 66 had a surgically induced remission. Patients had to be in remission (CDAI < 150 and no symptoms for the previous 30 days) and have reported at least two flare-ups of active disease within the last four years, one within the last 19 months or a recent resection. They should not have taken immunosuppressives within the last 90 days, corticosteroids within the last 30 days or mesalamine or metronidazole within the last seven days.

Treatment

Patients were randomised to receive either 5-ASA (mesalamine) 3 g/day or placebo. Other active medications for Crohn's disease were not allowed, but codeine and loperamide were permitted for the control of diarrhoea.

Endpoints

Patients were followed up for 11 months. The primary outcome measure was relapse defined as CDAI > 150 or an increase of at least 60 points from baseline. Withdrawals and adverse events were reported as summary data for both medical and surgical remission patients. The author was contacted to ask for the data pertinent to the surgical group, but he was unable to provide this data.

[Wenckert 1978](#)

Sample

Sixty-six patients were recruited from seven Nordic centres. Patients had Crohn's disease of the small and/or large bowel that had been macroscopically resected, at first surgical resection. Histological examination of the specimens had to show granulomas and/or transmural, focal-lymphocytic inflammation. Patients had to have normal ESR within 6 weeks after operation, but no other remission criteria were stated. Patients should not have been on corticosteroids or immunosuppressive drugs. Other exclusion criteria included doubtful diagnosis and allergy to salicylic acids.

Treatment

Patients were randomised to receive either sulfasalazine (Salazopyrin) 3 g/day or placebo. Other specific treatments were avoided during the study period.

Endpoints

Study design stated a 12 months patient follow up. Follow up was continued beyond 12 months for patients but as data were incomplete and this represented a change to the protocol, we have not reported results past 12 months. The primary outcome measure was clinical relapse, defined by symptoms and positive examination findings.

Study comparing 5-ASAs with 6-Mercaptopurine:

[Hanauer 2004](#)

Sample

Eighty-seven patients (mean age 34.6 years) were recruited from five US centres. No specific remission criteria were stated. Patients were eligible if they were undergoing an ileocolic resection. Patients with minimal evidence of Crohn's disease at other sites were not excluded. Patients were excluded if there was evidence of gross disease at the operative margins or in other intestinal segments.

Treatment

Patients were randomised to receive either 5-ASA (Mesalamine) 3 g/day or 6-Mercaptopurine 50 mg daily. Other medications were not allowed, except corticosteroids in tapering doses to be completed 3 months after hospital discharge, and topical therapies for perianal disease. No report was made as to how many participants received these treatments in each of the study groups.

Endpoints

Patients were followed up for 24 months. The primary outcome

measures were clinical, radiographic or endoscopic relapse at 24 months. Clinical relapse was defined as symptoms of active disease.

Study comparing 5-ASAs with Azathioprine:

[Ardizzone 2004](#)

Sample

One hundred and forty-two patients (aged 18 to 70 years old, mean age 38.4 years) were recruited from a single Italian centre. Patients had received surgery for symptomatic intestinal stenoses or occlusion. Patients should not have taken immunosuppressives within the last 3 months, anti-TNF agents within the last 6 months or have undergone previous surgery.

Treatment

Patients were randomised to receive either 5-ASA (mesalamine) 3 g/day or azathioprine 2 mg/kg/day. Other medications were not allowed, except corticosteroids in tapering doses and antibiotics for less than 10 days.

Endpoints

Patients were followed up for 24 months. The primary outcome measures were clinical and surgical relapse at 24 months. Clinical relapse was defined as symptoms, variably associated with radiological, endoscopic and laboratory findings, with a CDAI > 200, needing treatment.

Risk of bias in included studies

The methodological quality of the included studies, as assessed using the Cochrane risk of bias tool ([Higgins 2009](#)), is summarised in [Figure 1](#).

Figure 1. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ardizzone 2004	+	?	-	+	+	+
Brignola 1995	?	?	?	+	+	+
Ewe 1977	?	?	?	?	?	+
Ewe 1989	?	?	?	+	-	+
Hanauer 2004	+	+	+	+	+	+
Lochs 2000	+	+	+	+	+	?
McLeod 1995	+	+	+	+	+	+
Sutherland 1997	+	+	+	+	+	+
Wenckert 1978	+	?	?	+	?	+

Sequence Generation

In all the included studies allocation of participants to intervention or placebo was described as random, although the method of randomisation was not described in three studies (Ewe 1989; Ewe 1977; Wenckert 1978).

Allocation concealment

Allocation concealment was graded adequate and of low risk of bias in three studies (Hanauer 2004; Lochs 2000; Sutherland 1997) and unclear in the other studies. The authors of these studies were contacted to clarify allocation concealment, but only one response was received. This was from Dr. McLeod, who gave further information to confirm her study (McLeod 1995) had adequate allocation concealment.

Blinding

One of the studies included was not blinded (Ardizzone 2004). All the remaining studies were described as double-blind, but the method of blinding was not described clearly in four studies (Brignola 1995; Ewe 1977; Ewe 1989; Wenckert 1978). These studies either failed to state which parties were blinded or did not state that the placebo was identical to the intervention.

Incomplete outcome data

Ewe 1977 was judged 'unclear' with regards to risk of bias from incomplete outcome data. Ewe 1977 was translated from the German original, and was unclear as to outcome data, reporting a death and some patients requiring reoperation, but gave no other details for these patients. This author was contacted for clarification,

but no response was received. In the remaining studies, the outcome data were judged as having been addressed adequately. The main reasons for incomplete outcome data were: not complying with study protocol, becoming lost to study follow up and withdrawal from treatment due to adverse effects, pregnancy or perceived lack of efficacy.

Selective reporting

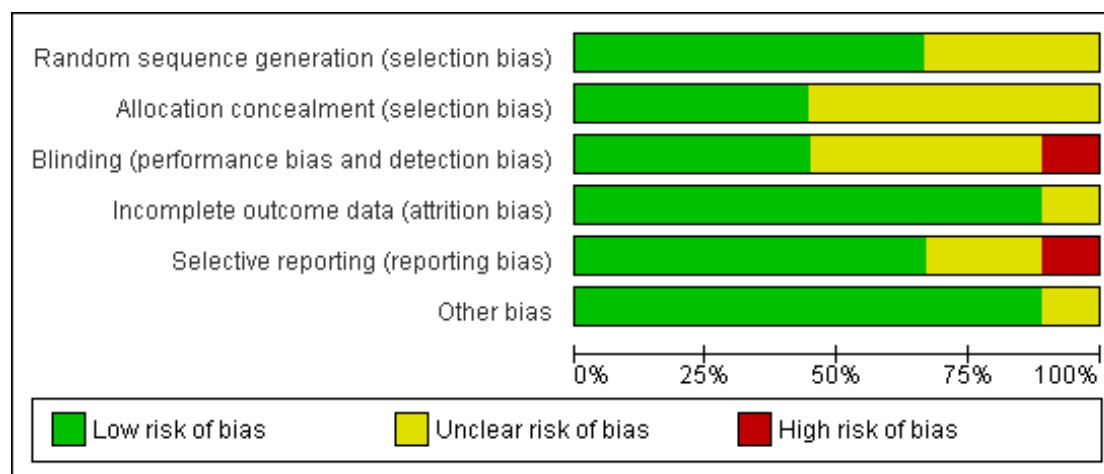
Two studies (Ewe 1977; Wenckert 1978) did not report secondary endpoints in sufficient detail to allow analysis. The authors were contacted, but sufficient information was not obtained and so a judgment of 'unclear' was made. One study (Ewe 1989) reported no adverse event data, a key outcome expected for a study of this type and so a judgement of 'no' (high risk of bias) was made.

Other potential sources of bias

Three studies stated that they were supported by pharmaceutical companies. The authors were contacted to clarify the role of these pharmaceutical companies. The authors of two studies (Hanauer 2004; Sutherland 1997) confirmed that the companies had no role in the study design, data analysis or writing of the paper and so a judgement of 'yes' (low risk of bias) was made. The remaining author did not respond (Lochs 2000) and so a judgement of 'unclear' was made for this study. The remaining studies had no other apparent sources of potential bias.

Figure 2 presents the methodological quality data as summary percentages across all included studies.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



Effects of interventions

Efficacy

Occurrence of relapse

5-ASA versus placebo

In the main analysis, the total number of patients randomised was used as the denominator. It was assumed that participants who dropped out of the study, and on whom there was no post withdrawal information, had relapsed during the study period. Using a fixed effects model, 5-ASA was significantly more effective than placebo for preventing relapses (Odds Ratio (OR) 0.68; 95% CI 0.52 to 0.90), see Analysis 1.1. Using a random effects model in a sensitivity analysis did not change the results (OR 0.69; 95% CI 0.52 to 0.92), see Analysis 1.2.

A further sensitivity analyses included patients who completed the study and ignored dropouts. 5-ASA was significantly more effective than placebo for preventing relapses (OR 0.65; 95% CI 0.50 to 0.85), see Analysis 1.3.

Number needed to treat

The NNT was calculated using the minimum and maximum control risk of relapse amongst the included studies. In a population whose baseline risk of developing a relapse following curative surgery was similar to the study reported by Wenckert (Wenckert 1978) the NNT was 19 (95% CI 12 to 62). In another population whose baseline risk was similar to the study by Ewe (Ewe 1989) the NNT was 16 (95% CI 9 to 63).

5-ASA versus purine antimetabolites

A pooled analysis of the studies comparing 5-ASA with azathioprine (Ardizzone 2004) and 6-mecaptopurine (Hanauer 2004) was performed. Using the fixed effects model, there was no statistically significant difference found between purine antimetabolites and placebo for preventing clinical relapses (OR 1.08; 95% CI 0.63 to 1.85), see Analysis 2.1.

Safety

5-ASA versus placebo

A meta-analysis of all adverse events was performed for the 4 studies for which data were available. This found no statistically significant difference in the proportion of patients who experienced any adverse event between 5-ASA or placebo (OR 1.06; 95% CI 0.61 to 1.85), see Analysis 1.4. Using a random effects model in a sensitivity analysis made no difference to the result (OR 1.06; 95% CI 0.61 to 1.85), Analysis 1.5.

5-ASA versus purine antimetabolites

An analysis of adverse events in the 2 studies was performed. Using a fixed effects model, patients in the 5-ASA group were significantly less likely to experience an adverse event than those in the purine antimetabolites group (OR 0.46; 95% CI 0.22 to 0.97), see Analysis 2.2.

Subgroup analysis

Methodological quality

The quality of four studies comparing 5-ASA to placebo was noted to be such that there was the possibility of an increased risk of bias (Brignola 1995; Ewe 1977; Ewe 1989; Wenckert 1978) and a subgroup analysis was performed excluding these four studies. 5-ASA was still significantly more effective than placebo for preventing relapses (OR 0.63; 95% CI 0.45 to 0.89), see Analysis 1.6.

Dosage of 5-ASA agent

The dosage of 5-ASA used was 3 grams per day in all but one of the studies (Lochs 2000), which employed a dosage of 4 grams per day. An analysis was completed that only included the remaining seven studies. 5-ASA was significantly more effective than placebo for preventing relapses (OR 0.61; 95% CI 0.43 to 0.85), see Analysis 1.7.

Choice of 5-ASA agent

The choice of 5-ASA agent was Sulphasalazine in 3 of the studies (Ewe 1977; Wenckert 1978; Ewe 1989) and mesalamine / mesalazine in the other 5 studies (Brignola 1995; Hanauer 2004; Lochs 2000; McLeod 1995; Sutherland 1997). There was no statistically significant difference seen between sulphasalazine and placebo (OR 0.78; 95% CI 0.45 to 1.35), see Analysis 1.8. Mesalamine / mesalazine agents were found to be significantly more effective than placebo for preventing relapses (OR 0.65; 95% CI 0.47 to 0.90), see Analysis 1.9.

Follow up time

The follow up time for the 8 studies comparing 5-ASA with placebo varied and so a further subgroup analysis was completed. For the 3 studies with a follow up of 12 months or less (Brignola 1995; Sutherland 1997; Wenckert 1978), there was no statistically significant difference seen between 5-ASA and placebo (OR 0.72; 95% CI 0.38 to 1.36), see Analysis 1.10. For the 5 studies (Ewe 1977; Ewe 1989; Hanauer 2004; Lochs 2000; McLeod 1995) with a follow up time greater than 12 months, 5-ASA was found to be significantly more effective than placebo for preventing relapses (OR 0.68; 95% CI 0.50 to 0.92), see Analysis 1.11.

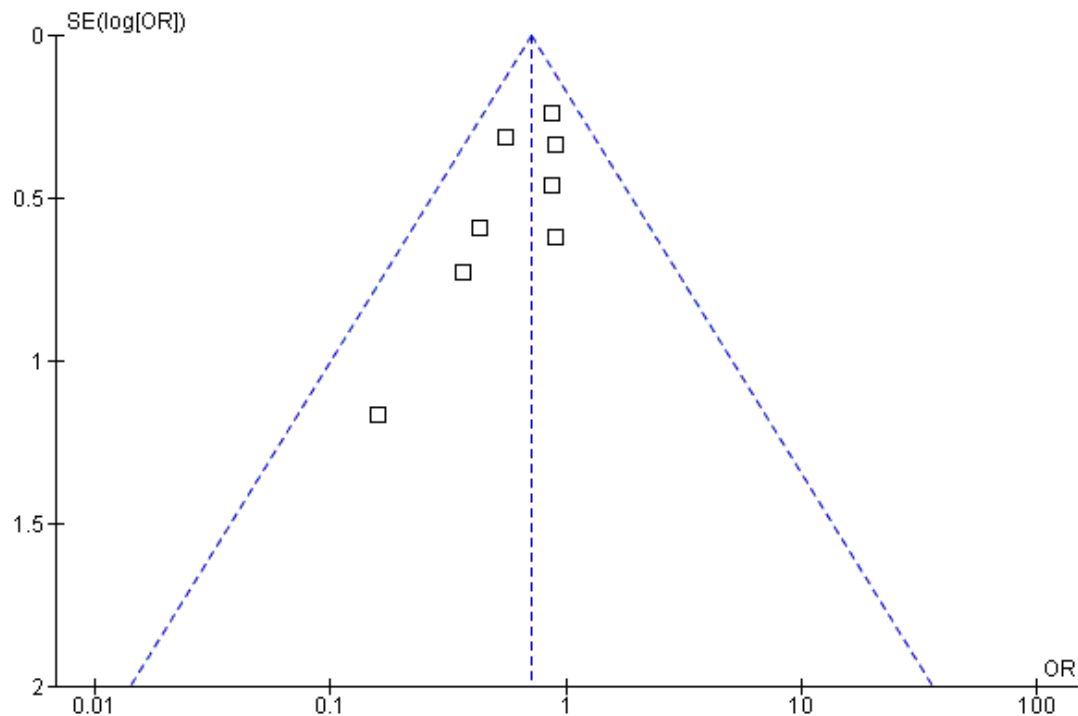
Statistical heterogeneity

The chi square test showed that no heterogeneity ($P = 0.47$) appeared to exist among the 8 trials comparing 5-ASA with placebo. This did not change in the sensitivity analyses where dropouts were ignored in the analyses ($P = 0.47$). The I^2 statistic was 0% for both of these analyses.

Funnel Plot

A funnel plot was produced to investigate the potential of publication bias (Figure 3). The funnel plot appears to be asymmetric indicating that small negative studies may be missing from the review.

Figure 3. Funnel plot of comparison: 1 5-ASA versus Placebo, outcome: 1.1 Relapse - fixed effects model.



DISCUSSION

Maintaining disease remission is a major challenge in the management of Crohn's disease and until recently there was little convincing evidence that any medication had a role to play in prolonging remission (Sutherland 1997). Corticosteroids, which are the mainstay of therapy for induction of remission, are not effective as maintenance therapy (Steinhart 2008). Probiotic agents have also been shown to be ineffective (Rolfe 2006) and there is no evidence to support or refute the use of thalidomide and its analogues (Akobeng 2005b). Recent reviews have suggested that 6-mercaptopurine, its prodrug, azathioprine (Prefontaine 2009), intramuscular methotrexate (Patel 2009) and tumour necrosis factor-alpha antibodies (Behm 2008) may be effective in maintaining remission. However, the possibility of significant adverse events may limit the use of these agents.

In spite of medical maintenance therapies, a significant proportion of patients with Crohn's disease require surgical intervention (Becker 1999). Assessment of short term quality of life measures following surgery in Crohn's disease has shown rapid improvement

for patients during the post operative period (Delaney 2003). Long term studies have shown that recurrence is the most important factor that may negatively impact quality of life (Thaler 2005). It has also been shown that patients in remission have quality of life approaching that of the general population (Andersson 2003), and maintenance of remission must be a key goal after surgery.

5-ASA preparations are ineffective for maintenance of medically-induced remission in Crohn's disease (Akobeng 2005a). For surgically induced remission of Crohn's disease, there have been conflicting reports as to the effectiveness of 5-ASA agents (Camma 1997, Lochs 2000). The results of this review suggest that 5-ASA agents may be superior to placebo for the maintenance of surgically-induced remission in Crohn's disease. However, the potential benefit of 5-ASA is modest with a number needed to treat ranging from 16 to 19 patients to prevent one relapse which raises issues about the cost-effectiveness of this therapy. The NNT was calculated for two different baseline risks, the minimum and maximum control risk amongst the included studies. Whilst the NNT may be considered a clinically useful way to present results, the limitations of a NNT calculated from pooled data must be considered (Smeeth 1999). It is suggested that readers use data from their own populations to allow a more representative NNT to be calculated

for their own patients.

Subgroup analysis taking into account variations in dosage of 5-ASA agent and the risk of bias associated with studies also had little effect on the result, still finding 5-ASA to be superior to placebo for the maintenance of remission. When a subgroup analysis was carried out to look at the choice of 5-ASA agent, a statistically significant result was found in favour of mesalazine/mesalamine over placebo, but the result was not statistically significant for sulfasalazine. This may be because of the limited number of studies and reduced sample size available for analysis of this drug. Subgroup analysis investigating length of follow up found a statistically significant result in favour of 5-ASA over placebo for studies with a follow up of greater than 12 months, but the result was not statistically significant for studies with a follow up of less than 12 months. This may be because of the limited number of studies and reduced sample size available for analysis of this group of studies. Further subgroup analyses related to endoscopic relapse as an outcome and patient characteristics, such as disease site or smoking habits of patients were planned but were not performed due to lack of data.

It is not clear why the evidence suggests a difference in efficacy for 5-ASA agents in patients with medically and surgically induced remission. One possibility could be that assessments of disease activity used in studies may not accurately portray the disease activity of participants. The limitations of a CDAI score within clinical trials has previously been noted (Caprilli 1994) and most of the clinical trials performed to evaluate the role of 5-ASA in the maintenance of medically induced remission defined remission using the CDAI score. As most of the trials involved in this review used surgical resection of macroscopically diseased bowel as their inclusion criterion, it follows that many of these patients may actually have less active disease compared to patients in trials of medically induced remission. This may explain the observed difference in efficacy of 5-ASA agents.

It is also possible that the length of time in remission may partly explain this difference in efficacy. Many of the studies in the review of medically induced remission (Akobeng 2005a) included patients who had been in remission for significant periods of time at study entry. By contrast, most of the studies in this review required entry and initiation of therapy within 12 weeks of surgery. Evidence obtained from studies with a follow up of greater than 12 months still favoured the use of 5-ASA agents, but as the longest study follow-up was 36 months, it is possible that if a longer follow-up was used this effect would not be sustained.

A pooled analysis of the two studies comparing 5-ASA with purine antimetabolites (Ardizzone 2004, Hanauer 2004) found no statistically significant difference in relapses. However, these studies had a combined population of 233 and the strength of any conclusions that may be drawn from this analysis is limited. The small number of studies also prevents subgroup analysis investigating

specific agents. It is worth noting that the study investigating azathioprine (Ardizzone 2004) found no difference in efficacy, while the study investigating 6-mercaptopurine (Hanauer 2004) found a statistically significant difference favouring 6-mercaptopurine. Clearly, further studies are needed before any conclusion as to the relative efficacy of these agents can be made.

Adverse events were not clearly reported in 4 of the 8 studies comparing 5-ASA with placebo. For the studies for which data were available to allow analysis, no difference was found between 5-ASA agents and placebo for the overall occurrence of reported adverse events. The 2 studies comparing 5-ASAs with purine antimetabolites found significantly fewer adverse events in the 5-ASA group. In particular, leucopenia was seen in a number of patients in the purine antimetabolite group in both studies, whilst no placebo or 5-ASA patients suffered from this adverse event. This suggests that 5-ASA agents have a superior safety profile when compared with these purine antimetabolites, but again the overall paucity of trials and small sample sizes must be considered when interpreting this result.

The primary studies in this review have a number of limitations that should be considered when interpreting the results of the pooled analyses. One study (Sutherland 1997) had a clear definition of remission at study entry, but this was not the case for the remaining studies. These studies stated that the surgery induced remission, but varying clinical, biochemical and radiological investigations were carried out to support this and so this variation must be taken into account when interpreting results. There were also variations in the specific criteria for clinical relapse, some studies employing a CDAI index with varying specific scores needed for relapse, as well as endoscopic and radiological criteria. Other studies used clinical and radiological criteria, without any recognised activity index. This clinical heterogeneity may account for some of the variations in individual study findings and must be taken into account when interpreting the results of the pooled analyses.

Although the pooled analyses suggest that oral 5-ASA may provide a modest benefit for maintenance of surgically-induced remission, it is notable that none of the included studies show a statistically significant difference between 5-ASA and placebo. The two largest and most adequately powered studies Lochs 2000 (n = 324) and Ewe 1989 (n = 232) appear to show no effect at all. Although the smaller studies suggest a possible benefit a funnel plot analysis indicates that publication bias may be an issue. The funnel plot analysis suggests that small negative studies may be missing from this review. The third largest study, McLeod 1995 (n = 169) has been criticized for a forced change in study medication from Rowasa® to Salofalk®, the use of a one-tailed significance test and the use of 90% confidence intervals (Breslin 1998). Thus, the results of the pooled analyses presented in this review need to be interpreted with caution.

AUTHORS' CONCLUSIONS

Implications for practice

The results of the pooled analyses suggest that 5-ASA preparations may be marginally superior to placebo for the maintenance of surgically induced remission in patients with Crohn's disease. The results of the pooled analyses should be interpreted with caution due to methodological and statistical issues as well as possible publication bias. The potential benefit provided by 5-ASA drugs is modest with a number needed to treat of approximately 16 to 19 patients to avoid one relapse which raises issues about the cost-effectiveness of this therapy. However, 5-ASA drugs are safe and well tolerated. The incidence of adverse events did not appear to be different in patients receiving 5-ASA compared with those receiving placebo. We found no evidence in this review to suggest that 5-ASA preparations differ in efficacy to purine antimetabolites, although there was only study involving each agent in this class.

Implications for research

Determining if there are unpublished studies and obtaining the

results of these studies would help to resolve any issues in the interpretation of the pooled analyses in this systematic review. Further studies would be needed to assess any possible difference in efficacy or safety between 5-ASA and either azathioprine or 6-mercaptopurine if this is an important clinical question. Further research should ensure adequate sample size, clear definitions of remission and relapse, collection of adverse event data and complete follow-up of patients.

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Williams 1991

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ardizzone 2004

Methods	Single centre study. Described as randomised:Yes. Randomisation method described:Yes. Described as double blind:No. Blind method described: No. Follow-ups described: Yes	
Participants	Inclusion criteria: Age 18-70 years. Remission defined as a Crohn's Disease Activity Index (CDAI) score of <150	
Interventions	Oral 5-ASA vs Azathioprine. Allocation: 71 patients allocated to 5-ASA, and 71 patients allocated to Azathioprine. Name 5-ASA: Pentasa. Manufacturer: Ferring S.p.A. Dose: 3 g per day	
Outcomes	24 months follow up. Clinical relapse defined as the presence of symptoms, variably associated with radiologic, endoscopic, and laboratory findings, with a CDAI score >200, needing steroids	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random number generator used
Allocation concealment (selection bias)	Unclear risk	Unclear. Author contacted for further details, but no response received
Blinding (performance bias and detection bias) All outcomes	High risk	Open label study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Published paper includes all expected outcomes, including all those pre-specified
Other bias	Low risk	No other sources of bias apparent

Brignola 1995

Methods	Multicentre study. Described as randomised:Yes. Randomisation method described:Yes. Described as double blind:Yes. Blind method described: No. Follow-ups described: Yes
Participants	Inclusion criteria: No age restriction mentioned. Patients had curative resection of disease in the ileal or ileocecal region. Patients with localization of CD in another region or having resection of >100 cm excluded.
Interventions	Oral 5-ASA vs placebo. Allocation: 44 patients allocated to 5-ASA, and 43 patients allocated to placebo. Name 5-ASA: Pentasa. Manufacturer: Yamanouchi Pharma S.p.A. Dose: 3 g per day
Outcomes	12 months follow up. Relapse defined as a worsening of the symptoms by at least 100 Crohn's Disease Activity Index points above the patient's level at the previous visit and attainment of a Crohn's Disease Activity Index score of more than 150
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation in balanced blocks, but method not described. The author was contacted, but no response received
Allocation concealment (selection bias)	Unclear risk	Unclear from study. No response from author.
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Insufficient blinding information provided to make a judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Published paper includes all expected outcomes, including all those pre-specified
Other bias	Low risk	No other sources of bias apparent

Ewe 1977

Methods	Single centre study.Described as randomised:Yes Randomisation method described:No Described as double blind:Yes Blind method described: No Follow-ups described: Yes
Participants	Inclusion criteria: No age restriction mentioned. Patients had undergone surgery at least three months prior to inclusion. The interval between surgery and inclusion was 3 months - 7 years (Mean 2 years 2 Months). 14 patients were included within 1 year of operation. No other specific inclusion or exclusion criteria
Interventions	Patients were randomised to receive either 5-ASA (Sulfasalazine) 3 g/day or placebo. No mention was made of other medications allowed
Outcomes	24 months. The primary outcome measure was clinical relapse indicated by symptoms, CDAl>150, or histology, endoscopic findings, and radiology, formulating a combination relapse criteria
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Reference to a statistical allocation scheme, but no further details. No response from author when contacted
Allocation concealment (selection bias)	Unclear risk	Unclear. Author contacted for further details, but no response received
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Insufficient blinding information provided to make a judgement. Author did not respond to request for information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Outcome data provided, but details given as to which groups affected participants were from. As stated previously, the author was contacted, but no response received
Selective reporting (reporting bias)	Unclear risk	Unclear. Primary endpoints reported. Secondary endpoints not clearly reported. Author was contacted, but no response received
Other bias	Low risk	No other sources of bias apparent

Ewe 1989

Methods	Multicentre study. Described as randomised:Yes. Randomisation method described:No. Described as double blind:Yes. Blind method described: No. Follow-ups described: Yes
Participants	Inclusion criteria: Age>18years. Patients had curative resection of disease as judged at operation. 3 months post operation, clinical evaluation and CDAI was calculated and if no evidence of relapse, participants entered the trial
Interventions	Oral 5-ASA vs placebo. Allocation: 111 patients allocated to 5-ASA, and 121 patients allocated to placebo. Name 5-ASA: Sulphasalazine. Manufacturer: not stated. Dose: 3 g per day
Outcomes	Follow up was 36 months. Relapse defined as clinical recurrence proven by radiological, endoscopy or operation
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No description of method of randomisation given. Author was contacted for further details of the study, but no response was received
Allocation concealment (selection bias)	Unclear risk	Unclear. Author contacted for further details, but no response received
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Insufficient blinding information provided to make a judgement. As stated, no response was received from the author
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups
Selective reporting (reporting bias)	High risk	The study fails to include results for adverse events, which would be expected for such a study. The author was contacted, but no response received
Other bias	Low risk	No other sources of bias apparent

Hanauer 2004

Methods	Multicentre study. Described as randomised: Yes. Randomisation method described: Yes. Described as double blind: Yes. Blind method described: Yes. Follow-ups described: Yes
Participants	Inclusion criteria: No age restriction mentioned. Ileocolic resection, disease confined to ileum and adjacent colon. No mention of remission criteria. Preoperative treatment with corticosteroids was completely tapered by 3 months after discharge
Interventions	Oral 5-ASA vs Mercaptopurine (data not captured) vs placebo. Allocation: 44 patients allocated to 5-ASA, 40 to placebo and 47 to 6-MP. Name 5-ASA: Pentasa. Manufacturer: Marion Merrill Dow. Dose: 3 g per day
Outcomes	Follow up was 24 months. Relapse defined as a score of greater than 2 on authors grading scale (moderate symptoms with linear ulcers / cobblestoning on radiography)
Notes	This study compared 5-ASA to placebo and 6-MP. For analysis, the data for these different interventions were analysed separately

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Central Computer randomisation.
Allocation concealment (selection bias)	Low risk	Pharmacy controlled allocation at each site.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding procedure described in sufficient detail.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Published paper includes all expected outcomes, including all those pre-specified
Other bias	Low risk	One of the authors had worked as a consultant for Marion Merrill Dow, who supplied the study drug. Author contacted and confirmed the company had no involvement in the study

Lochs 2000

Methods	Multicentre study. Described as randomised: Yes. Randomisation method described: Yes. Described as double blind: Yes. Blind method described: Yes. Follow-ups described: Yes
Participants	Inclusion criteria: Age 18-70 years, Diagnosis at least 6 months prior to surgery, resective surgery and investigation of the full GI tract within the last 12 months. CD location restrictions not mentioned No specific remission criteria
Interventions	Oral 5-ASA vs placebo. Allocation: 154 patients allocated to 5-ASA, and 170 patients allocated to placebo. Name 5-ASA: Pentasa. Dose: 4 g per day
Outcomes	Follow up was 18 months. Relapse defined as: increase in CDAI above 250; increase in CDAI above 200 but by a minimum of 60 points over the lowest postoperative value for 2 consecutive weeks, indication for surgery; development of a new fistula; or occurrence of a septic complication
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomisation scheme
Allocation concealment (selection bias)	Low risk	Central allocation.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding procedure described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Published paper includes all expected outcomes, including all those pre-specified
Other bias	Unclear risk	Supported by a grant by Ferring. Authors contacted for clarification, but no response was received

McLeod 1995

Methods	Multicentre study.Described as randomised:Yes. Randomisation method described:Yes. Described as double blind:Yes. Blind method described: Yes. Follow-ups described: Yes
Participants	Inclusion criteria: No age restrictions mentioned. CD location restrictions not mentioned. All patients who had surgical resection and who had no gross residual disease were eligible. No further remission criteria defined. Excluded if taking prednisone, sul-fasalazine, metronidazole, or imuran and these could not be discontinued. Steroids tapered over 3 months postoperatively
Interventions	Oral 5-ASA vs placebo. Allocation: 88 patients allocated to 5-ASA, and 81 patients allocated to placebo. Name 5-ASA: Rowasa 1 until March 19991, then Salofalk. Manufacturer: Not stated. Dose: 3 g per day
Outcomes	Follow up was 18 months. Relapse defined as symptomatic recurrent disease if there were symptoms compatible with Crohn's disease that were severe enough to warrant treatment in the opinion of the investigator plus radiological or endoscopic evidence of disease using defined criteria
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomisation scheme
Allocation concealment (selection bias)	Low risk	central allocation, described by author after being contacted for further information
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding procedure described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Low risk	Published paper includes all expected outcomes, including all those pre-specified
Other bias	Low risk	No other sources of bias apparent

Sutherland 1997

Methods	Multicentre study. Described as randomised:Yes. Randomisation method described:Yes. Described as double blind:Yes. Blind method described: Yes. Follow-ups described: Yes
Participants	Inclusion criteria: Age greater than 18. CD location restrictions not mentioned. CD in remission for 1 month, but at least 2 flare-ups within the last 4 years, one within the last 18 months or a recent resection. Remission defined as CDAI<150 at baseline and no symptoms within last 30 days. No steroid use within a month of study
Interventions	Oral 5-ASA vs placebo. Allocation: 141 patients allocated to 5-ASA, and 152 patients allocated to placebo. Name 5-ASA: microsphere coated with ethylcellulose, Mesalamine. Manufacturer: Not provided by authors. Dose: 3 g per day
Outcomes	Relapse measured at: 12 months. Definition of relapse: 1st occurrence of a CDAI that was >150 as well as the absolute value of at least 60 points higher than baseline or where physician diagnosed a flare-up of disease but a full diary card was not available for the calculation of the final CDAI
Notes	Reported for both medical and surgical remission. There was enough data available to describe the primary outcomes of the surgical group, but details of adverse events were unavailable. The author was contacted, but was unable to offer any further data at this time

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated randomisation scheme.
Allocation concealment (selection bias)	Low risk	sequentially numbered drug packages of identical appearance.
Blinding (performance bias and detection bias) All outcomes	Low risk	Blinding procedure described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcome data not available for the surgical group used in this review, but all outcome data for the published study are reported and withdrawals accounted for
Selective reporting (reporting bias)	Low risk	Adverse event data not available for the surgical group data used in this review, but all expected outcomes for the published study are present including those pre-specified
Other bias	Low risk	Supported by a grant by Marrion Merrill Dow. Author contacted and confirmed company had no part in the design, analy-

	sis or write up
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Wenckert 1978

Methods	Multicentre study.Described as randomised:Yes. Randomisation method described:No. Described as double blind:Yes. Blind method described: No. Follow-ups described: Yes
Participants	Inclusion criteria: No age restrictions mentioned. CD of small and / or large bowel, first resection and supporting histological evidence of active CD in resected specimens. ESR had to return to normal within 6 weeks of operation, no further remission criteria defined. No steroid use allowed
Interventions	Oral 5-ASA vs placebo. Allocation: 32 patients allocated to 5-ASA, and 34 patients allocated to placebo. Name 5-ASA: Salazopyrin. Manufacturer: Not provided by authors. Dose: 3 g per day
Outcomes	Relapse defined clinically based on history of symptoms.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Block randomisation described. Author contacted and confirmed that carried out in accordance with established acceptable randomisation methodology
Allocation concealment (selection bias)	Unclear risk	No details given. The author was contacted, but was not able to give further details on this issue
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Details of procedure not given. Author gave no further details when contacted
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for those missing, balanced between study groups, reasons for withdrawal unlikely to be related to true outcome
Selective reporting (reporting bias)	Unclear risk	The study includes results for adverse events, but these are not reported clearly enough to allow analysis and permit a judgement as to the risk of bias to be made
Other bias	Low risk	No other sources of bias apparent

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Anonymous 1990	Patients in medically induced remission
Arber 1994	Abstract - further details unavailable from author
Bresci 1991	Patients in medically induced remission
Bresci 1995	Patients in medically induced remission
Brignola 1992	Patients in medically induced remission
Caprilli 1994	No treatment for control group
Caprilli 1996	Re-analysis of Caprilli 1994 data (excluded)
Caprilli 2003	No control group
Del Corso 1995	Patients in medically induced remission
Fiasse 1990	Abstract - further details unavailable from author
Fiasse 1991	Abstract - further details unavailable from author
Florent 1996	Inadequate follow up (12 weeks)
Frieri 1999	Not a randomised controlled trial
Gendre 1993	Not patients in surgically induced remission
McLeod 1997	Reports old data (already included in this review in McLeod 1995)
Nos 2000	Paper in Spanish. A translator confirmed that the paper was not described as a randomised controlled trial. Attempts were made to obtain further information from the authors, but these were unsuccessful
Papi 2009	Not randomised controlled trial - retrospective review
Rizello 2000	Abstract - further details unavailable from author
Schwartz 2005	Commentary on old data (already included in this review in Hanauer 2004)
Scribano 2006	Commentary on Ardizzone 2004 (included)
Steinhart 1992	Not randomised controlled trial
Sullivan 2001	Review paper

(Continued)

Wellmann 1988	Patients not in remission and medical treated
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DATA AND ANALYSES

Comparison 1. 5-ASA versus Placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Relapse, drop-outs classed as relapse, fixed effects model	8	1061	Odds Ratio (M-H, Fixed, 95% CI)	0.71 [0.54, 0.94]
2 Sensitivity analysis - Relapse, drop-outs classed as relapse, random effects model	8	1061	Odds Ratio (M-H, Random, 95% CI)	0.72 [0.54, 0.95]
3 Sensitivity analysis - Relapse, dropouts ignored, fixed effects	8	1061	Odds Ratio (M-H, Fixed, 95% CI)	0.65 [0.50, 0.85]
4 Safety, drop-outs classed as relapse, fixed effects model	4	664	Odds Ratio (M-H, Fixed, 95% CI)	1.06 [0.61, 1.85]
5 Sensitivity analysis - Safety, drop-outs classed as relapse, random effects model	4	664	Odds Ratio (M-H, Fixed, 95% CI)	1.06 [0.61, 1.85]
6 Subgroup analysis - Relapse, removing studies at risk of bias, drop-outs classed as relapse, fixed effects model	4	643	Odds Ratio (M-H, Fixed, 95% CI)	0.67 [0.47, 0.94]
7 Subgroup analysis - relapse, dosage, dropouts classed as relapse, fixed effects model	7	737	Odds Ratio (M-H, Fixed, 95% CI)	0.64 [0.46, 0.90]
8 Subgroup analysis - relapse, sulphasalazine agents, dropouts classed as relapses, fixed effects model	3	331	Odds Ratio (M-H, Fixed, 95% CI)	0.78 [0.45, 1.35]
9 Subgroup analysis - relapse, mesalamine/mesalazine agents, dropouts classes as relapses, fixed effects model	5	730	Odds Ratio (M-H, Fixed, 95% CI)	0.69 [0.50, 0.95]
10 Subgroup analysis - relapse, 12 month follow up, dropouts classed as relapses, fixed effects model	3	219	Odds Ratio (M-H, Fixed, 95% CI)	0.72 [0.38, 1.36]
11 Subgroup analysis - relapse, follow up time greater than 12 months, dropouts classed as relapses, fixed effects model	5	842	Odds Ratio (M-H, Fixed, 95% CI)	0.71 [0.52, 0.96]

Comparison 2. 5ASA vs. purine antimetabolites

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Relapses, drop-outs classed as relapse, fixed effects model	2	233	Odds Ratio (M-H, Fixed, 95% CI)	1.08 [0.63, 1.85]
2 side effects, drop-outs classed as relapse, fixed effects model	2	233	Odds Ratio (M-H, Fixed, 95% CI)	0.46 [0.22, 0.97]

WHAT'S NEW

Last assessed as up-to-date: 9 May 2010.

Date	Event	Description
21 June 2011	Amended	Minor edit to Acknowledgements section

HISTORY

Protocol first published: Issue 3, 2010

Review first published: Issue 1, 2011

Date	Event	Description
3 December 2010	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Morris Gordon took the lead in writing the protocol and review, performed independent data extraction, quality assessment of the included trials and interpreted the data.

Khimara Nadoo performed independent data extraction and quality assessment of the included trials.

Adrian Thomas commented on drafts of the protocol and review and offered support in the interpretation of the data.

Anthony Akobeng initiated and conceptualised the review, contributed to the writing of the protocol and review and offered support in the interpretation of the data.

DECLARATIONS OF INTEREST

Morris Gordon received a travel grant from Warner Chilcott Pharmaceuticals Ltd to present the preliminary results of this review at Digestive Disease week 1st - 5th May 2010, New Orleans, USA. Warner Chilcott Pharmaceuticals Ltd had no role in the design, execution or write up of this review.

Anthony Akobeng and Adrian Thomas have previously sat on an advisory panel for Ferring Pharmaceuticals.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The odds ratio has been used for meta-analysis, instead of the risk ratio.

INDEX TERMS

Medical Subject Headings (MeSH)

Administration, Oral; Anti-Inflammatory Agents, Non-Steroidal [*administration & dosage]; Crohn Disease [*drug therapy; *surgery]; Mesalamine [*administration & dosage]; Randomized Controlled Trials as Topic; Remission Induction [methods]

MeSH check words

Humans

Gordon, M. (2012). Handover education in UK medical schools: Current practices and implications for educators. Med Teach, 34, 84-85 (Letter to the editor)

Fluctuation in student motivation may underlie these findings through its effect on beliefs about learning and perception of learning environment. Motivation has been found to decline over the course of one academic year of profession-oriented education (Braten & Olaussen 2005).

We found that DREEM scores for identical attachments can vary to a statistically significant level over time in the course of a single academic year. This has not been reported elsewhere. We suggest that colleagues consider this, as it may be of importance when interpreting and comparing DREEM studies.

Deirdre Bennett, Martina Kelly & Siun O'Flynn, Medical Education Unit, School of Medicine, University College Cork, Ireland. Email: d.bennett@ucc.ie

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- Braten I, Olaussen B. 2005. Profiling individual differences in student motivation: A longitudinal cluster-analytic study in different academic contexts. *Contemp Educ Psychol* 30:359–396.
- Roff S, McAleer S, Harden RM, Al-Qahtani M, Ahmed AU, Deza H, Groenen G, Primpayon P. 1997. Development and validation of the Dundee Ready Educational Environment Measure (DREEM). *Med Teach* 19(4):295–299.

Handover education in UK medical schools: Current practices and implications for educators

Dear Sir

Much evidence exists to demonstrate that poor handover can directly impact patient safety, leading to calls for formal education on this issue. Evidence to guide interventional design is limited, although examination of this evidence suggests a model for handover education consisting of awareness of handover systems, team working and harbouring of professional responsibility (Gordon 2011). It is unclear to what extent handover is currently being addressed in undergraduate medical education.

Recently, we carried out a qualitative study to determine current teaching and assessment methods, as well as attitudes towards handover within UK medical schools. Sixteen (50%) schools took part in the study. All schools reported ward-based exposure to handover, although no other education took place in 44% of schools. Thematic analysis of free text responses yielded a number of key themes. There was universal agreement that Handover is an important education issue. There was also agreement that limitations in handover research are delaying teaching innovations and there was recognition of a lack of validated assessment tools. There was disagreement on when such education should occur. Some respondents felt it should indeed be embedded in the undergraduate curricula, recognising the multi-faceted complexity of handover as a skill and its importance as a patient

safety issue. Conversely, the majority of respondents felt that handover should be taught when 'relevant to trainees' within postgraduate training.

Whilst the majority of schools felt that handover is a skill to be learnt 'on the job' in postgraduate training, this author feels that this is a flawed viewpoint. Handover cannot be viewed as a distinct free standing skill. Effective handover is built on a portfolio of generic professional skills and this skill set is acquired from the very start of undergraduate training. Considering the previously discussed theoretically grounded model, a systems approach to improving handover may indeed be appropriate to address in the postgraduate setting. However, the issues of professional responsibility and team-working are key areas that can and should be addressed in undergraduate training. The use of observation as a sole method of tuition is at odds with these theoretically sound elements of handover education.

A consensus must be reached on the extent of handover education in undergraduate medical training. Future research is also needed to describe and assess the efficacy of teaching and assessment innovations. This will offer guidance to medical educators hoping to incorporate training on this key patient safety issue.

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Reference

- Gordon M, Findley R. 2011. Educational interventions to improve handover in health care: a systematic review. *Med Educ* 45(11):1081–9.

General Practice Teachers

Dear Sir

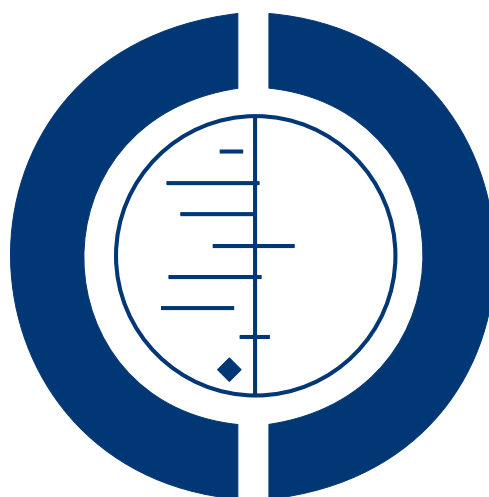
Increasing medical student numbers and a teacher workforce shortage, makes it important to understand general practitioners' current thoughts about teaching medical students in their practices.

Ninety-five teaching general practitioners (urban and rural) from the Notre Dame School of Medicine, Western Australia received a questionnaire concerning medical student attachments. Replies were anonymous. The Human Ethics Committee of the University of Notre Dame gave approval. Responses to open questions were categorised after consensus.

The response rate was 61% which limits extrapolation. Thirty-six (62%) of the respondents reported that a positive

Osmotic and stimulant laxatives for the management of childhood constipation (Review)

Gordon M, Naidoo K, Akobeng AK, Thomas AG



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Osmotic and stimulant laxatives for the management of childhood constipation (Review)
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Osmotic and stimulant laxatives for the management of childhood constipation

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ABSTRACT

Background

Constipation within childhood is an extremely common problem. Despite the widespread use of osmotic and stimulant laxatives by health professionals to manage constipation in children, there has been a long standing paucity of high quality evidence to support this practice.

Objectives

We set out to evaluate the efficacy and safety of osmotic and stimulant laxatives used to treat functional childhood constipation.

Search methods

The search (inception to May 7, 2012) was standardised and not limited by language and included electronic searching (MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, Cochrane Inflammatory Bowel Disease and Functional Bowel Disorders Group Specialized Trials Register), reference searching of all included studies, personal contacts and drug companies.

Selection criteria

Randomised controlled trials (RCTs) which compared osmotic or stimulant laxatives with either placebo or another intervention, with patients aged 0 to 18 years old were considered for inclusion. The primary outcome was frequency of defecation. Secondary endpoints included faecal incontinence, disimpaction, need for additional therapies and adverse events.

Data collection and analysis

Relevant papers were identified and the authors independently assessed the eligibility of trials. Methodological quality was assessed using the Cochrane risk of bias tool. The Cochrane RevMan software was used for analyses. Patients with final missing outcomes were assumed to have relapsed. For continuous outcomes we calculated a mean difference (MD) and 95% confidence interval (CI) using a fixed-effect model. For dichotomous outcomes we calculated an odds ratio (OR) and 95% confidence intervals (95% CI) using a fixed-effect model. The chi square and I^2 statistics were used to assess statistical heterogeneity. A random-effects model was used in situations of unexplained heterogeneity.

Main results

Eighteen RCTs (1643 patients) were included in the review. Nine studies were judged to be at high risk of bias due to lack of blinding, incomplete outcome data and selective reporting. Meta-analysis of two studies (101 patients) comparing polyethylene glycol (PEG) with placebo showed a significantly increased number of stools per week with PEG (MD 2.61 stools per week, 95% CI 1.15 to 4.08). Common adverse events in the placebo-controlled studies included flatulence, abdominal pain, nausea, diarrhoea and headache. Meta-analysis of 4 studies with 338 participants comparing PEG with lactulose showed significantly greater stools per week with PEG (MD 0.95 stools per week, 95% CI 0.46 to 1.44), although follow up was short. Patients who received PEG were significantly less likely to require additional laxative therapies. Eighteen per cent of PEG patients required additional therapies compared to 30% of lactulose patients (OR 0.49, 95% CI 0.27 to 0.89). No serious adverse events were reported with either agent. Common adverse events in these studies included diarrhoea, abdominal pain, nausea, vomiting and pruritis ani. Meta-analysis of 3 studies with 211 participants comparing PEG with milk of magnesia showed that the stools/wk was significantly greater with PEG (MD 0.69 stools per week, 95% CI 0.48 to 0.89). However, the magnitude of this difference is quite small and may not be clinically significant. One child was noted to be allergic to PEG, but there were no other serious adverse events reported. Meta-analysis of 2 studies with 287 patients comparing liquid paraffin (mineral oil) with lactulose revealed a relatively large statistically significant difference in the number of stools per week favouring paraffin (MD 4.94 stools per week, 95% CI 4.28 to 5.61). No serious adverse events were reported. Adverse events included abdominal pain, distention and watery stools. No statistically significant differences in the number of stools per week were found between PEG and enemas (1 study, 90 patients, MD 1.00, 95% CI -1.58 to 3.58), dietary fibre mix and lactulose (1 study, 125 patients, $P = 0.481$), senna and lactulose (1 study, 21 patients, $P > 0.05$), lactitol and lactulose (1 study, 51 patients, MD -0.80, 95% CI -2.63 to 1.03), and PEG and liquid paraffin (1 study, 158 patients, MD 0.70, 95% CI -0.38 to 1.78).

Authors' conclusions

The pooled analyses suggest that PEG preparations may be superior to placebo, lactulose and milk of magnesia for childhood constipation. GRADE analyses indicated that the overall quality of the evidence for the primary outcome (number of stools per week) was low or very low due to sparse data, inconsistency (heterogeneity), and high risk of bias in the studies in the pooled analyses. Thus, the results of the pooled analyses should be interpreted with caution because of quality and methodological concerns, as well as clinical heterogeneity, and short follow up. However, PEG appears safe and well tolerated. There is also evidence suggesting the efficacy of liquid paraffin (mineral oil), which was also well tolerated. There is no evidence to demonstrate the superiority of lactulose when compared to the other agents studied, although there is a lack of placebo controlled studies. Further research is needed to investigate the long term use of PEG for childhood constipation, as well as the role of liquid paraffin.

PLAIN LANGUAGE SUMMARY

Laxatives for the management of childhood constipation

Constipation within childhood is an extremely common problem. Despite the widespread use of laxatives by health professionals to manage constipation in children, there has been a long standing lack of evidence to support this practice. This review included eighteen studies with a total of 1643 patients that compared nine different agents to either placebo (inactive medications) or each other. The results of this review suggest that polyethylene glycol preparations may increase the frequency of bowel motions in constipated children. Polyethylene glycol was generally safe, with lower rates of minor side effects compared to other agents. Common side effects included flatulence, abdominal pain, nausea, diarrhoea and headache. There was also some evidence that liquid paraffin (mineral oil) increased the frequency of bowel motions in constipated children and was also safe. Common side effects with liquid paraffin included abdominal pain, distention and watery stools. There was no evidence to suggest that lactulose is superior to the other agents studied, although there were no trials comparing it to placebo. The results of the review should be interpreted with caution due to methodological quality and statistical issues in the included studies. In addition, these studies were relatively short in duration and so it is difficult to assess the long term effectiveness of these agents for the treatment of childhood constipation. Long term effectiveness is important, given the often chronic nature of this problem in children.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [\[Explanation\]](#)

PEG versus placebo for the management of childhood constipation					
Patient or population: patients aged 0 to 18 years with a diagnosis of functional constipation Settings: outpatient Intervention: PEG versus placebo					
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Control	PEG versus placebo			
	The mean number of The mean number of bowel movements ranged bowel movements in the across the placebo PEG group was on aver- groups from 1.6 to 2.4 age 2.61 higher per week per week (95% CI 1.15 to 4.08)				
Frequency of defecation (mean number of bowel movements per week)				101 (2 studies)	⊕⊕○○ low ^{1,2}
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval;					
GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.					

¹ Sparse data (101 patients)

² Inconsistency (moderate statistical heterogeneity $I^2 = 58\%$)

BACKGROUND

Description of the condition

Constipation within childhood is an extremely common problem (Van den Berg 2006), representing the chief complaint in 3% of visits to general paediatric clinics and as many as 30% of visits to paediatric gastroenterologists (Partin 1992). The term functional constipation is used when no underlying organic cause can be identified for the symptoms. Creating a workable diagnostic classification for functional constipation has proven difficult. Criteria vary, but are mostly based on a variety of symptoms, including decreased frequency of bowel movements, faecal incontinence and a change in consistency of stools (Pijpers 2008).

A team of paediatricians met in 1997 in Rome to standardize the diagnostic criteria for various functional gastroenterological disorders in children. The first paediatric Rome II criteria were published in 1999 (Rasquin-Weber 1999) and were updated during the Rome III process in 2006, producing guidance for functional constipation for neonates, toddlers and children (Hyman 2006; Rasquin 2006).

To diagnose constipation using the Rome III criteria, at least two of the symptoms below must be present for at least one month in infants and children up to age four and at least two months in children over four, with insufficient criteria for the diagnosis of irritable bowel syndrome:

- Two or fewer defecations per week;
- At least one episode per week of incontinence after the acquisition of toileting skills;
- History of retentive posturing or excessive voluntary stool retention (over 4 years) or excessive stool retention (under 4 years);
- History of painful or hard bowel movements;
- Presence of a large faecal mass in the rectum; and
- History of large diameter stools which may obstruct the toilet.

Effective management of childhood functional constipation depends on securing a therapeutic alliance with the parents, particularly through the first years when children cannot accurately report symptoms. Clinicians depend on the reports and interpretations of the parents, who know their child best, and their own training and experience to differentiate between health and illness (Hyman 2006).

Description of the intervention

Laxative therapies are often the mainstay of medical therapy used in children suffering with functional constipation, alongside adjunct therapies such as dietary and behavioural modification. Osmotic laxatives, such as lactulose, milk of magnesia and polyethylene glycol (PEG), are usually supplied as solutions or powders to

be dissolved in water and are therefore relatively easy to administer to young children. Stimulant laxatives, such as Senna and Bisacodyl, come in a variety of forms, including tablets, liquids, and suppositories.

How the intervention might work

Osmotic laxatives are poorly absorbed in the gut. They act as hyperosmolar agents, increasing water content of stool and therefore making stool softer and easier to pass, as well as increasing colonic peristalsis. Stimulant laxatives act on the intestinal mucosa, increasing water and electrolyte secretion. They also stimulate peristaltic action.

Why it is important to do this review

Despite the widespread use of these medications by health professionals to manage constipation in children, there has been a long standing paucity of high quality evidence to support this practice. Previous efforts have been made to produce guidance on this topic (Baker 1999; Anonymous 2006), most recently by the National Institute for Health and Clinical Excellence in the UK (Anonymous 2010).

In recent years, the widespread introduction of PEG to paediatric practice has led to a resurgence in research on paediatric constipation. Some studies have suggested that polyethylene glycol has greater efficacy when compared with placebo (Thomson 2007), as well as when compared to lactulose (Voskuyl 2004; Candy 2006). A recently published Cochrane review investigated the specific comparison of PEG versus lactulose (Lee-Robichaud 2010) in children and adults. There currently exists no other systematic review using the Cochrane collaboration format for the use of osmotic laxatives in children. A previous Cochrane review evaluating the effect of stimulant laxatives on constipation in children found no studies of sufficient quality to allow evaluation (Price 2001). An up to date systematic review using the Cochrane Collaboration format is indicated to summarise the current evidence on the use of osmotic and stimulant laxatives for the management of constipation in children.

OBJECTIVES

The primary objectives are to evaluate the efficacy and safety of osmotic and stimulant laxatives used to treat functional childhood constipation.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials were considered for inclusion.

Types of participants

Patients aged 0 to 18 years with a diagnosis of functional constipation, with or without incontinence were considered for inclusion. The diagnosis of constipation was patient self-reported, physician diagnosed, or by consensus criteria (e.g. Rome III). Studies with patients suffering from any underlying pathology, such as thyroid abnormalities, Hirschsprung's disease or having undergone previous bowel surgery at study entry, were excluded.

Types of interventions

Studies comparing osmotic or stimulant laxatives with another intervention or placebo were considered for inclusion. All preparations and dosing regimes were considered. Studies using multiple osmotic or stimulant laxative combinations or combinations of both as their intervention were also considered for inclusion.

Types of outcome measures

Primary outcomes

The primary outcome measure was the frequency of defecation (number of stools per week).

Secondary outcomes

Secondary outcomes included:

- 1) Faecal incontinence;
- 2) Disimpaction;
- 4) Need for additional therapies; and
- 5) Adverse events.

Search methods for identification of studies

Electronic searches

A. Electronic searching

The following electronic databases were searched for relevant studies:

1. MEDLINE (1966 to May 7, 2012; National Library of Medicine, Bethesda, USA)
2. EMBASE (1984 to May 7, 2012; Elsevier Science, New York, USA)
3. Cochrane Central Register of Controlled Trials

4. Cochrane Inflammatory Bowel Disease and Functional Bowel Disorder Group Specialized Trials Register

The search strategy was not limited by language.

MEDLINE on PUBMED will be searched using the following search strategy:

- #1 Constipation
- #2 Constipation [MeSH]
- #3 faecal impaction OR impaction
- #4 delayed bowel movement
- #5 obstipation
- #6 costiveness
- #7 retention
- #8 defecation
- #9 bowel function*
- #10 bowel habit*
- #11 bowel movement*
- #12 bowel symptom*
- #13 bowel motility
- #14 colon transit
- #15 evacuation
- #16 intestinal motility
- #17 stool*
- #18 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17
- #19 Polyethylene glycol*
- #20 macrogol*
- #21 PEG
- #22 polyethylene glycol 3350
- #23 polyethylene glycol 4000
- #24 Miralax OR Transipeg OR Movicol OR Forlax OR Idrolax OR GoLyte OR PMF-100 OR Golitely OR Nulitely OR Fortans OR TriLyte OR Colyte OR lactulose OR disaccharide OR Apo-Lactulose OR Chronulac OR lactitol OR sorbitol OR Generlac OR Cephalac OR Cholac OR Constilac OR Enulose OR cilac OR Heptalac OR Actilax OR Duphalac OR Kristalose OR milk of magnesia OR magnesium hydroxide OR Magnesium citrate OR citroma OR Osmoprep OR Visicol
- #25 senna OR docusate sodium OR Sodium picosulphate OR Bisacodyl OR Cascara OR casanthranol OR Buckthorn OR senokot OR Aloe Vera OR aloin Phenolphthalein OR Dulcolax
- #26 laxative*
- #27 stimulant
- #28 osmotic
- #29 #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28
- #30 For
- #31 Treat OR Treatment
- #32 Therapy
- #33 Efficacy
- #34 management OR manage

#35 #30 OR #31 OR #32 OR #33 OR #34
 #36 Children OR child
 #37 Child [MeSH]
 #38 Paediatric
 #39 Adolescent
 #40 Infant
 #41 Neonat*
 #42 Toddler
 #43 Pediatric
 #44 Young
 #45 Childhood
 #46 #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR
 #43 OR #44 OR #45
 #47 #18 AND #29 AND #35 AND #46

Similar search strategies, but modified appropriately, and using the above keywords were used to search the other electronic databases listed above.

There is some evidence that data from abstracts can be inconsistent with data in published articles (Pitkin 1999), therefore abstract publications were not included in this review.

Searching other resources

B. Reference searching

The references of all identified studies were inspected for more trials.

C. Personal contacts

Leaders in the field were contacted to try to identify other studies.

D. Drug companies

The manufacturers of osmotic and stimulant laxative agents were contacted for additional data.

Data collection and analysis

All identified abstracts and results from searches were reviewed by two authors (MG and KN). If the reference appeared relevant, a full copy of the study was obtained.

Selection of studies

Two authors (MG and KN), after reading the full texts, independently assessed the eligibility of all trials identified based on the inclusion criteria above. Disagreement among authors was discussed and agreement reached by consensus.

Data extraction and management

A data extraction form was developed and piloted to extract information on relevant features and results of included studies. The two reviewers separately extracted and recorded data on the pre-defined checklist.

Extracted data included the following items:

a. characteristics of patients: age, sex, duration of symptoms;

b. study methods, total number of patients originally assigned to each treatment group;
 c. intervention: preparations, dose, administration regime;
 d. control: placebo, other drugs;
 e. concurrent medications;
 f. outcomes (time of assessment, length of follow up, frequency of defecation, pain on defecation and/or straining, faecal incontinence, stool consistency, need for additional therapies, number and type of adverse events associated with treatment, adverse events); and
 g. withdrawals and reasons for withdrawals.

Assessment of risk of bias in included studies

The methodological quality of selected trials was assessed independently by two authors using the Cochrane risk of bias tool (Higgins 2011a). Factors assessed included:

1. sequence generation (i.e. was the allocation sequence adequately generated?);
 2. allocation sequence concealment (i.e. was allocation adequately concealed?);
 3. blinding (i.e. was knowledge of the allocated intervention adequately prevented during the study?);
 4. incomplete outcome data (i.e. were incomplete outcome data adequately addressed?);
 5. selective outcome reporting (i.e. are reports of the study free of suggestion of selective outcome reporting?); and
 6. other potential sources of bias (i.e. was the study apparently free of other problems that could put it at a high risk of bias?).
- A judgement of 'Yes' indicates low risk of bias, 'No' indicates high risk of bias, and 'Unclear' indicates unclear or unknown risk of bias. Disagreements were resolved by consensus. Study authors were contacted for further information when insufficient information was provided to determine the risk of bias.

We used the GRADE approach for rating the overall quality of evidence for the primary outcome. Randomised trials start as high quality evidence, but may be downgraded due to: (1) risk of bias, (2) indirectness of evidence, (3) inconsistency (unexplained heterogeneity), (4) imprecision (sparse data), and (5) reporting bias (publication bias). The overall quality of evidence for each outcome was determined after considering each of these elements, and categorized as high quality (i.e. further research is very unlikely to change our confidence in the estimate of effect); moderate quality (i.e. further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate); low quality (i.e. further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate); or very low quality (i.e. we are very uncertain about the estimate) (Guyatt 2008; Schünemann 2011).

Measures of treatment effect

The primary outcome, frequency of defecation, was assessed using the mean difference (MD) with 95% confidence intervals (CI). The secondary outcomes were assessed by calculating the odds ratio (OR) and 95% CI.

Dealing with missing data

The authors of included studies were contacted to supply any missing data.

Assessment of heterogeneity

Heterogeneity among trial results was assessed by inspection of graphical presentations and by calculating the chi square test of heterogeneity (a P value of 0.10 was regarded as statistically significant). We also used the I^2 statistic to quantify the effect of heterogeneity (Higgins 2003). A random-effects model was used in situations of unexplained heterogeneity. We aimed to further investigate potential sources of heterogeneity.

Assessment of reporting biases

If an appropriate number of studies was found, we aimed to investigate the possibility of a publication bias through the construction of funnel plots (trial effects versus trial size).

Data synthesis

For outcomes that were sufficiently homogenous, meta-analysis was carried out using a fixed-effect model. A random-effects model was used in situations of unexplained heterogeneity.

Subgroup analysis and investigation of heterogeneity

Subgroup analyses were to be carried out to further study the effects of a number of variables on the outcomes including:

- a. whether patients were being inducted in to 'remission' from constipation or whether this was a study of 'maintenance' therapy;
- b. the effect of length of therapy / follow up; and
- c. specifically what, if any agents, were initially allowed in the protocol to clear any impaction (such as enemas).

Sensitivity analysis

Sensitivity analyses was conducted based on the following:

- a. only including patients' whose outcome is known i.e. number of patients who completed the study used as denominator; and
- b. random-effects versus fixed-effect models.

We also planned to consider the effect of:

- c. allocation concealment;
- d. type of agent;
- e. dose of agent; and
- f. concurrent medications.

RESULTS

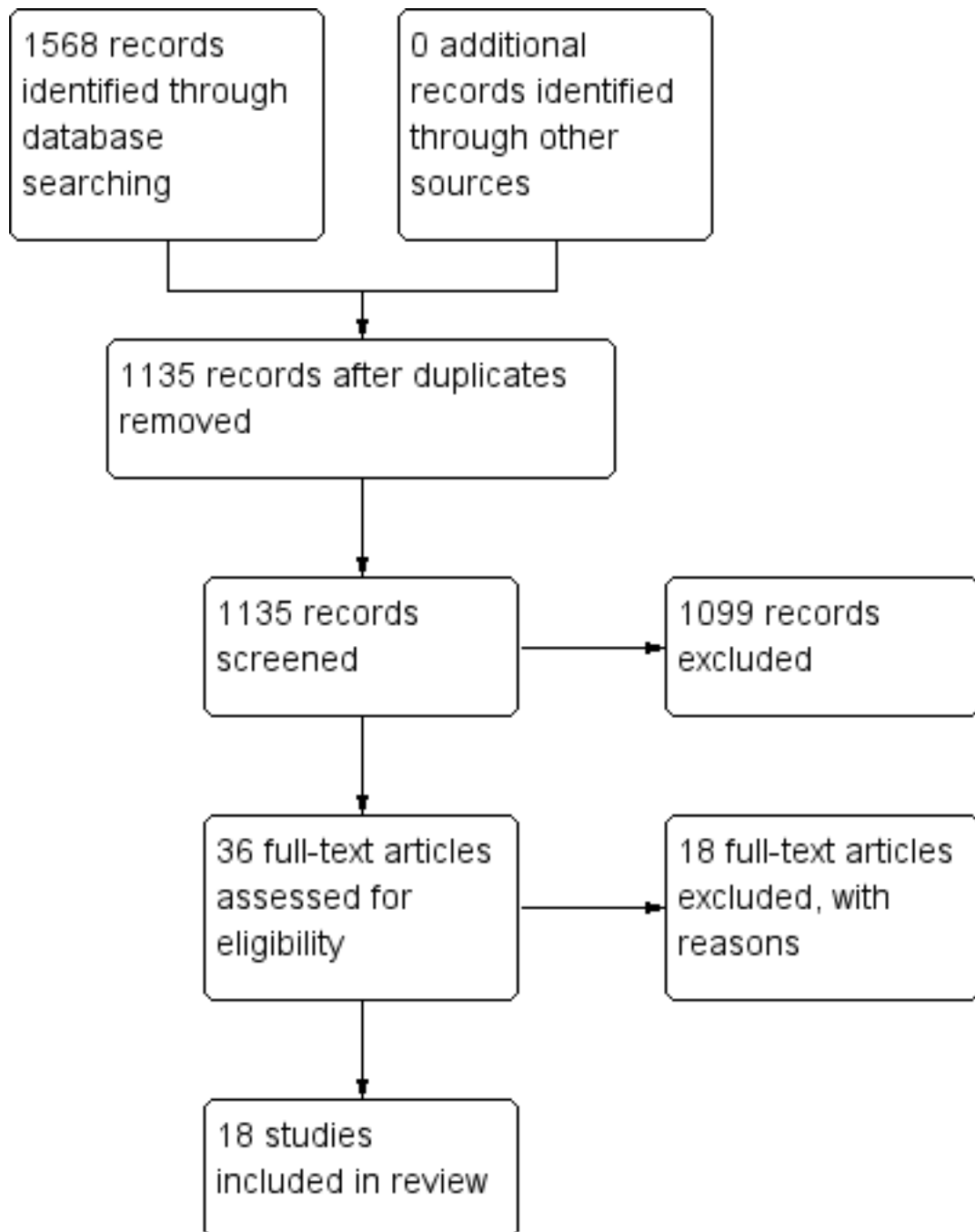
Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

The database searches on May 7, 2012, identified 1568 records. No further studies were identified through other sources. After duplicates were removed, 1135 records were screened for inclusion (see Study flow diagram [Figure 1](#)). Of these, we identified 36 potentially relevant studies for full text review. Eighteen studies were excluded for various reasons. Six studies were not randomised controlled trials (Moulies 1961; Sonheimer 1982; Tolia 1988; Loening-Baucke 2002; Loening-Baucke 2004; Shevtsov 2005) four studies had no comparison group (Hejl 1990; Youssef 2002; Dupont 2006; Hardikar 2007), two studies concerned adult patients (Ferguson 1999; Corazziari 1996) two were not research articles (Clayden 1978; Kinservik 2004), one study was of children with soiling (Berg 1983), one study was of children with faecal impaction without a diagnosis of functional constipation (Miller 2012); one study was of children with underlying bowel pathology (Kazak 1999) and one study was an abstract publication (Quitadamo 2010).

Figure 1. Study flow diagram.



Eighteen studies were identified which satisfied the inclusion criteria and were included in the review. Two compared PEG with placebo (Thomson 2007; Nurko 2008), five compared PEG with lactulose (Gremse 2002; Voskuyl 2004; Dupont 2005; Candy 2006; Wang 2007), three compared PEG with milk of magnesia (magnesium oxide) (Loening-Baucke 2006, Gomes 2011, Ratanamongkol 2009), two compared liquid paraffin with lactulose (Urganci 2005; Farahmand 2007) two compared liquid paraffin with PEG (Tolia 1993; Rafati 2011), one compared PEG with enemas (Bekkali 2009), one compared a dietary fibre mix with lactulose (Kokke 2008), one lactulose with senna (Perkin 1977) and one lactitol with lactulose (Pitzalis 1995).

The total number of participants in the included trials was 1,643. The age range varied from 6 months up to 16 years. The duration of the studies varied from 2 weeks to 12 months. The specific criteria for a diagnosis of constipation also varied between studies, as did the minimum length of symptoms. All studies excluded children with organic causes for their pathology (*see characteristics of included studies*).

Risk of bias in included studies

The risk of bias analysis for the included studies is summarised in Figure 2 and Figure 3.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

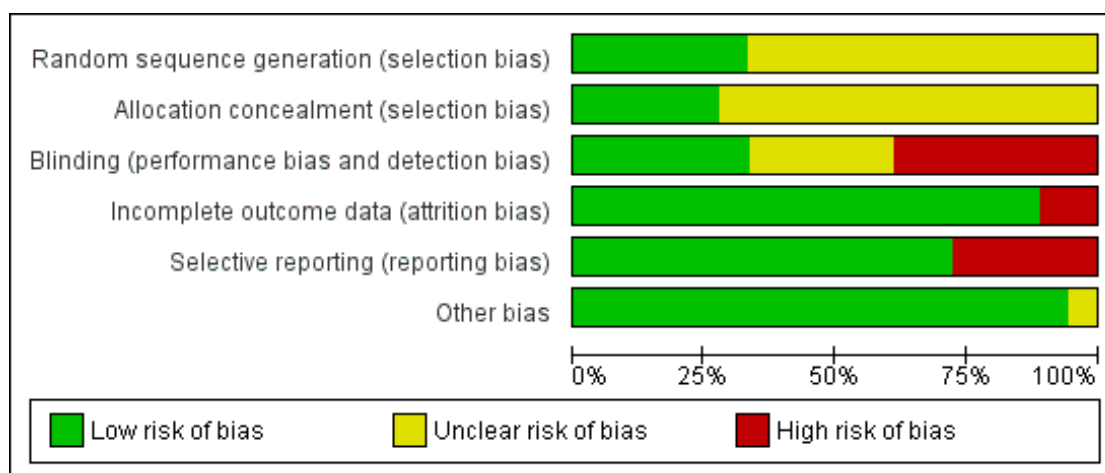


Figure 3. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding (performance bias and detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Bekkali 2009	?	?	-	+	-	+
Candy 2006	+	?	+	+	+	?
Dupont 2005	?	?	+	+	+	+
Farahmand 2007	?	?	-	+	+	+
Gomes 2011	?	?	-	-	-	+
Gremse 2002	?	?	-	+	-	+
Kokke 2008	+	+	+	+	+	+
Loening-Baucke 2006	+	+	-	+	+	+
Nurko 2008	?	?	+	+	+	+
Perkin 1977	?	+	?	+	+	+
Pitzalis 1995	?	?	?	+	-	+
Rafati 2011	?	?	?	-	-	+
Ratanamongkol 2009	+	+	?	+	+	+
Thomson 2007	+	+	+	+	+	+
Tolia 1993	+	?	-	+	+	+
Urganci 2005	?	?	-	+	+	+
Voskuyl 2004	?	?	+	+	+	+
Wang 2007	?	?	?	+	+	+

Allocation

In five of the included studies, the method of random allocation of participants to intervention groups was described and was judged as adequate (Tolia 1993; Loening-Baucke 2006; Thomson 2007; Kokke 2008; Ratanamongkol 2009). These studies were rated as low risk for sequence generation. For one study (Candy 2006), the sponsor gave a response to a request for more details and confirmed adequate sequence generation. This study was rated as low risk for sequence generation. Allocation was described as random in the 12 remaining studies, although the method of randomisation was not described. These studies were rated as unclear risk for sequence generation. Allocation concealment was rated as low risk in five studies (Perkin 1977; Loening-Baucke 2006; Thomson 2007; Kokke 2008; Ratanamongkol 2009) and as unclear risk in the other studies.

Blinding

Methods for blinding were described and judged to be adequate in six studies. These studies were rated as low risk for blinding (Voskuyl 2004; Dupont 2005; Candy 2006; Thomson 2007; Kokke 2008; Nurko 2008). In five studies, the use of blinding was reported but not described clearly. These studies were rated as unclear risk for blinding (Perkin 1977; Pitzalis 1995; Wang 2007; Ratanamongkol 2009; Rafati 2011). The remaining seven studies were described as open label and were rated as high risk for blinding (Tolia 1993; Gremse 2002; Urganci 2005; Loening-Baucke 2006; Farahmand 2007; Bekkali 2009; Gomes 2011).

Incomplete outcome data

Two studies were judged to be of high risk of bias (Gomes 2011, Rafati 2011). The outcome data was judged as to have been addressed adequately in all the remaining studies.

Selective reporting

In five studies, no details were given of adverse events given and therefore they were judged to be at risk of bias (Pitzalis 1995; Gremse 2002; Bekkali 2009; Gomes 2011; Rafati 2011). The remaining thirteen studies were not clearly free of selective reporting. In these studies there was not enough information available to make a judgement and so they were rated as unclear.

Other potential sources of bias

One study stated that they were supported by a pharmaceutical company, but details of the extent of involvement were unclear. Two studies were sponsored by pharmaceutical companies, but confirmation was received by the authors that industry had no involvement (Thomson 2007; Nurko 2008). Most of the remaining studies did not mention sources of funding and had no other potential sources of bias.

Figure 3 shows the review authors' judgements about each methodological quality item for each included study.

Effects of interventions

See: [Summary of findings for the main comparison](#) PEG versus placebo for the management of childhood constipation; [Summary of findings 2](#) PEG versus lactulose for the management of childhood constipation; [Summary of findings 3](#) PEG versus milk of magnesia (MOM) for the management of childhood constipation; [Summary of findings 4](#) Liquid paraffin (mineral oil) versus lactulose for the management of childhood constipation. In the analyses, we used as the denominator the total number of patients randomised. In all analyses, the frequency of defecation was measured as stools per week.

PEG versus Placebo

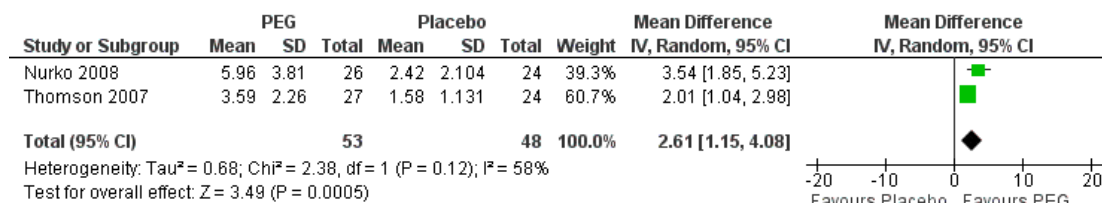
The published results for the two studies concerning 101 patients were inadequate to allow pooling for meta-analysis. The authors were contacted and directed us to the study sponsors who supplied unpublished data to allow analysis for outcomes at 2 weeks. One of the studies (Nurko 2008) used multiple dosing regimens, but data were obtained for the dose of 0.8 g/kg.

Efficacy

Frequency of defecation

Heterogeneity was noted to be moderate ($P = 0.12$, $I^2 = 58\%$) and using a random-effects model, the mean difference (MD) was 2.61 stools per week (95% CI, 1.15 to 4.08), favouring PEG, see [Analysis 1.1](#) and [Figure 4](#). The GRADE analysis indicated that the overall quality of the evidence for the primary outcome (frequency of defecation) was low due to sparse data (101 patients) and inconsistency (statistical heterogeneity $I^2 = 58\%$) in the pooled analysis (See [Summary of findings for the main comparison](#)).

Figure 4. Forest plot of comparison: 1 PEG versus Placebo, outcome: 1.1 Frequency of defecation.



Episodes of faecal incontinence

At 2 weeks, both studies reported higher rates of faecal incontinence in the PEG group. As there was some discrepancy in baseline data between groups in one study (Nurko 2008) and the difference before and after treatment was not reported, meta-analysis for this outcome was not completed.

Safety

Serious adverse events were not reported in the PEG groups in either study, but were seen in the placebo groups (8% of placebo patients experienced a serious adverse event). However, there was no statistically significant difference in the incidence of serious adverse events (OR 0.17, 95% CI 0.02 to 1.48). Minor adverse events were common and included flatulence, abdominal pain, nausea, diarrhoea and headache. However, data were not reported to allow meta-analysis. The studies both stated that no difference in the incidence of adverse events appeared to exist between the groups.

PEG versus Lactulose

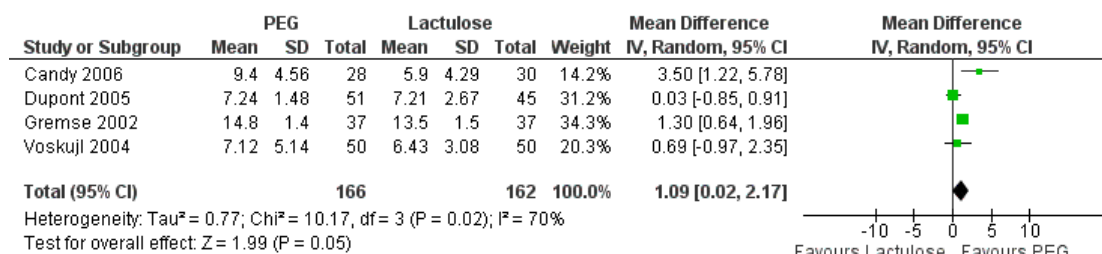
One of the five studies (Wang 2007) did not report data that could be used for meta-analysis. The authors were contacted, but no response was received and so the remaining 4 studies including 328 patients were analysed. One study separated results for babies and toddlers (Dupont 2005). Using the method described in the Cochrane handbook (Higgins 2011b) the mean and standard deviation for the entire sample were calculated.

Efficacy

Frequency of defecation

Heterogeneity was noted to be high ($P = 0.02$, $I^2 = 70\%$) and using a random-effects model a statistically significant difference in favour of PEG was seen, with a MD of 1.09 stools per week (95% CI, 0.02 to 2.17), see Analysis 2.1 and Figure 5. The GRADE analysis indicated that the overall quality of the evidence for the primary outcome (frequency of defecation) was very low due to sparse data (328 patients), inconsistency (statistical heterogeneity $I^2 = 70\%$), and a high risk of bias (i.e. lack of blinding and selective reporting) in one study in the pooled analysis (See Summary of findings 2).

Figure 5. Forest plot of comparison: 2 PEG versus Lactulose, outcome: 2.1 Frequency of defecation.



Need for additional therapies

Using a fixed-effect model, there was a statistically significant result favouring PEG. For the 3 studies (254 patients) that reported this outcome (Voskujl 2004; Dupont 2005; Candy 2006), 18% of PEG patients required additional therapy compared to 30% of lactulose patients, (OR 0.49, 95% CI 0.27 to 0.89), see Analysis

2.2. When a sensitivity analysis using a random-effects model was calculated the results were no longer statistically significant (OR 0.51, 95% CI 0.19 to 1.38), see Analysis 2.3.

Safety

Serious adverse events were only reported in one study (Candy

2006) and this was a chest infection in a patient in the PEG group, thought to be unrelated to therapy. Minor adverse events were seen in most studies, but were not reported in one study (Gremse 2002). Common adverse events included diarrhoea, abdominal pain, nausea, vomiting and pruritis ani. For the 2 studies (154 patients) that reported data allowing meta-analysis (Dupont 2005; Candy 2006), there was no statistically significant difference in the proportion of patients who experienced at least one adverse event. Twenty-four per cent of PEG patients experienced at least one adverse event compared to 37% of lactulose patients (OR 0.37, 95% CI 0.14 to 1.03), see Analysis 2.4.

PEG versus Milk of Magnesia

Three studies (211 participants) compared PEG to milk of magnesia. One study (Loening-Baucke 2006) reported outcomes at 1 month and 12 months. However, data for outcomes at 4 weeks were used for meta-analysis. Another study (Ratanamongkol 2009) reported median and interquartile ranges for results and these were used to estimate the mean and standard deviation.

Efficacy

Frequency of defecation

Using a fixed-effect model, there was a statistically significant result favouring PEG. The MD was 0.69 stools per week (95% CI, 0.48 to 0.89), see Analysis 3.1. There was no evidence of heterogeneity in the pooled analysis ($P = 0.87$, $I^2 = 0\%$). The GRADE analysis indicated that the overall quality of the evidence for the primary outcome (frequency of defecation) was low due to sparse data (211 patients) and a high risk of bias (i.e. lack of blinding in one

study and lack of blinding, incomplete outcome data and selective reporting in the other study) in two studies in the pooled analysis (See Summary of findings 3).

Safety

A serious adverse event of allergy to PEG was reported in one patient (Loening-Baucke 2006). Minor adverse events data were not reported to allow meta-analysis. One study (Ratanamongkol 2009) noted a statistically significant difference in proportion of patients experiencing diarrhoea. Twenty-eight per cent of patients in the milk of magnesia group experienced diarrhoea compared to 4% of PEG patients ($P = 0.002$). The final study (Gomes 2011) did not explicitly report adverse event data.

Liquid Paraffin versus Lactulose

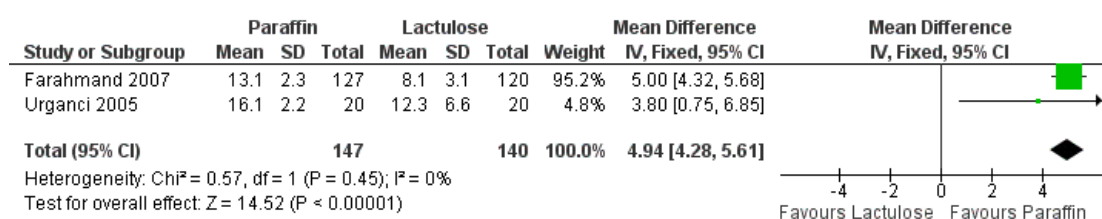
Two studies (Urganci 2005; Farahmand 2007) (287 participants) compared liquid paraffin to lactulose. These studies reported outcomes at 8 weeks.

Efficacy

Frequency of defecation

Using a fixed-effect model, there was a statistically significant result favouring paraffin. The MD was 4.94 stools per week (95% CI 4.28 to 5.61) see Analysis 4.1 and Figure 6. There was no evidence of heterogeneity in the pooled analysis ($P = 0.45$, $I^2 = 0\%$). The GRADE analysis indicated that the overall quality of the evidence for the primary outcome (frequency of defecation) was low due to sparse data (287 patients) and a high risk of bias (i.e. lack of blinding in both studies) in two studies in the pooled analysis (See Summary of findings 4).

Figure 6. Forest plot of comparison: 4 Paraffin versus Lactulose, outcome: 4.1 Frequency of defecation.



Safety

No serious adverse events were reported in either study. Minor adverse events such as abdominal pain, distention and watery stools were reported with both agents, but data were not presented in a manner to allow meta-analysis.

PEG versus Enemas

One study (Bekkali 2009) compared PEG to enemas (90 participants). This study reported outcomes at 4 weeks.

Efficacy

Frequency of defecation

There was no statistically significant difference in the frequency of defecation between PEG and enema groups. The MD was 1.00 stools per week (95% CI -1.58 to 3.58).

Successful disimpaction

Successful disimpaction was reported in 80% of enema patients compared to 68% of PEG patients. However, the difference was not statistically significant (OR 0.52, 95% CI 0.20 to 1.37).

Safety

Adverse event data were not explicitly reported within this study, although the authors reported significantly higher rates of faecal incontinence and watery stools with PEG.

Dietary fibre mix versus Lactulose

One study ([Kokke 2008](#)) compared dietary fibre with lactulose (125 participants). This study reported outcomes at 8 weeks.

Efficacy

Frequency of defecation

[Kokke 2008](#) reported that there was no statistically significant difference in the frequency of defecation between the two agents at eight weeks (mean 7 stools per week in the fibre group versus 6 stools per week in the lactulose group; $P = 0.481$).

Safety

The authors reported no serious or significant adverse effects. There were three cases of diarrhoea (one in the fibre mixture group and two in the lactulose group).

Senna versus Lactulose

One crossover study ([Perkin 1977](#)) compared senna with lactulose (21 participants),

Efficacy

Passage of stool

There was no statistically significant difference between the two agents in the number of patients passing stools of any kind each day.

Safety

No serious or significant adverse effects were reported in the 2 study groups. Minor adverse events such as colic or diarrhoea, were more commonly seen in the senna group.

Lactitol versus Lactulose

One study ([Pitzalis 1995](#)) compared lactitol to lactulose (51 participants). This study reported outcomes at 30 days.

Efficacy

Frequency of defecation

There was no statistically significant difference in the frequency of defecation between the two agents. The MD was -0.80 stools per week (95% CI -2.63 to 1.03).

Safety

Adverse events were not reported.

PEG versus Liquid paraffin

Two studies (196 participants) compared PEG to liquid paraffin ([Tolia 1993](#); [Rafati 2011](#)). The studies had varying lengths of follow up (2 days versus assessments at 7 to 120 days). The two studies were not pooled for meta-analysis because the primary outcomes were not similar enough to allow pooling.

Efficacy

Frequency of defecation

[Rafati 2011](#) found no statistically significant difference in the frequency of defecation between PEG and liquid paraffin. The MD was 0.70 stools per week (95% CI -0.38 to 1.78). [Tolia 1993](#) reported on the frequency of bowel movements after treatment (scored as > 5, 1 to 5 or none). The authors reported that PEG patients had more frequent bowel movements after treatment than liquid paraffin patients ($P < 0.005$).

Safety

No serious adverse events were reported. [Tolia 1993](#) reported significantly more vomiting in the PEG group compared to liquid paraffin ($P < 0.005$).

Subgroup and sensitivity analyses

Given the heterogenous nature of the included studies, further subgroup or sensitivity analyses were not completed.

Publication Bias

Publication bias was not investigated as there were not enough studies to construct a reliable funnel plot.

ADDITIONAL SUMMARY OF FINDINGS [\[Explanation\]](#)

PEG versus lactulose for the management of childhood constipation					
Patient or population: patients aged 0 to 18 years with a diagnosis of functional constipation Settings: outpatient Intervention: PEG versus lactulose					
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Control	PEG versus lactulose			
Frequency of defecation (mean number of bowel movements per week)	The mean number of bowel movements ranged across the lactulose groups from 5.9 to 13.5 per week	The mean number of bowel movements in the PEG group was on average 1.09 higher per week (95% CI 0.02 to 2.17)		328 (4 studies)	⊕○○○ very low ^{1,2,3}
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval;					
GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.					

¹ Sparse data (328 patients)


² Inconsistency (high statistical heterogeneity $I^2 = 70\%$; $P = 0.02$)

³ High risk of bias in one study in pooled analysis due to lack of blinding and selective reporting

PEG versus milk of magnesia (MOM) for the management of childhood constipation					
Patient or population: patients aged 0 to 18 years with a diagnosis of functional constipation Settings: outpatient Intervention: PEG versus MOM					
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	Control	PEG versus lactulose			
Frequency of defecation (mean number of bowel movements per week)	The mean number of The mean number of bowel movements ranged bowel movements in the across the MOM groups PEG group was on average from 4.3 to 9.7 per week age 0.69 higher per week (95% CI 0.48 to 0.89)			211 (3 studies)	⊕⊕○○ low ^{1,2}
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval;					
GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.					

¹ Sparse data (211 patients)

² High risk of bias in two studies in pooled analysis due to lack of blinding in one study and lack of blinding, incomplete outcome data and selective reporting in the other study

Liquid paraffin (mineral oil) versus lactulose for the management of childhood constipation						
Patient or population: patients aged 0 to 18 years with a diagnosis of functional constipation Settings: outpatient Intervention: Liquid paraffin (mineral oil) versus lactulose						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	PEG versus lactulose				
Frequency of defecation (mean number of bowel movements per week)	The mean number of bowel movements ranged across the lactulose groups from 8.1 to 12.3 per week	The mean number of bowel movements in the PEG group was on average 4.94 higher per week (95% CI 4.28 to 5.61)		287 (2 studies)	 low ^{1,2}	
*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval;						
GRADE Working Group grades of evidence High quality: Further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: We are very uncertain about the estimate.						

¹ Sparse data (287 patients)

² High risk of bias in two studies in pooled analysis due to lack of blinding in both studies

DISCUSSION

Summary of main results

Lactulose was the most studied agent. Despite the many agents that it was compared to, no trial found superiority of lactulose in terms of efficacy. All but one trial found lactulose was inferior to other agents. Although, it is worth noting that there were no studies comparing lactulose with placebo. In addition, the occurrence of minor adverse events, such as abdominal cramps and flatus, were more common in the lactulose groups.

PEG was also frequently studied, with trials comparing its efficacy for constipation with lactulose, milk of magnesia and placebo. All the results showed a statistically significant benefit favouring PEG. However, the effect size was modest in these analyses, particularly for the pooled analysis of PEG versus milk of magnesia. Although PEG was superior to milk of magnesia the magnitude of this difference is quite small and may not be clinically significant. With the exception of 1 case of allergy to PEG, no significant adverse events were associated with the use of PEG and the limited evidence reported suggests that minor adverse events occur with a similar or reduced frequency. There was one study that found that PEG was of similar efficacy to rectal enemas for treating faecal impaction.

The largest treatment effect seen within this review, in terms of the frequency of defecation (i.e. number of stools per week), was seen with liquid paraffin (mineral oil) when compared to lactulose. While a number of case reports have been made that raise safety concerns about liquid paraffin in terms of the risk of aspiration pneumonia (Zanetti 2007), no cases of this or any serious adverse events were noted in the trials in this review.

Overall completeness and applicability of evidence

While there are a large number of studies included in this review, it is clear that these studies are extremely heterogeneous, with nine different study agents and a variety of specific treatment regimens reported. As such, despite the common nature of the problem, it is difficult to draw particularly strong conclusions for any of the investigated agents. The scope of this study was osmotic and stimulant laxatives, but the vast majority of studies investigated osmotic laxatives.

If we consider PEG, while this was the most studied agent in 10 different trials, with a total of 1161 participants, these studies compared PEG to 5 different agents, as well as its use for constipation or faecal impaction. In addition, there was wide variation in study length and the time at which outcomes were assessed. Clearly, given the modest effect sizes and small sample sizes, coupled with these variations in treatment protocols (time of outcome assessment, use of additional therapies, specific form of interventional laxative used), the ability to use these findings to inform clinical practice is modest at best. These factors have certainly contributed

to the statistical evidence of heterogeneity in intervention effects observed in meta-analyses comparing PEG to placebo or lactulose. As constipation is a chronic problem, outcomes really need to be assessed in the medium to long term. However, only one study assessed outcomes beyond three months and half of the studies measured outcomes at 1 month or less. If management of chronic constipation is considered in terms of induction (disimpaction) and maintenance of remission, the limitation in the application of these results becomes apparent. It is difficult to comment on the ability of PEG or lactulose to maintain a child's normal bowel habits over the long term, when the studies have such short follow up periods. In addition, outcomes such as frequency of defecation are inherently limited in relation to the realities of clinical practice. While there may be a statistically significant increase in rates of defecation between study groups, this does not give any information as to whether the patient or their parents feel that there has been a functional improvement.

Quality of the evidence

There were no studies that were judged to be fully free of risk of bias. While the majority of studies described themselves as randomised, only six studies provided enough detail to be judged as at low risk of bias. The other studies were rated as unclear for random sequencer. This was also the case for allocation concealment, again with the majority of studies giving insufficient detail to be judged as low risk of bias. Seven studies were open label (high risk of bias) or reported insufficient information to be judged at low risk of bias. Four studies were judged to be at high risk of bias for selective reporting and two studies were judged to be at high risk of bias due to selective reporting. This has to be considered when judging the conclusions of this review. Furthermore, GRADE analyses indicated that the overall quality of the evidence for the primary outcome (number of stools per week) was low or very low due to sparse data, inconsistency (heterogeneity), and high risk of bias in the studies in the pooled analyses. Thus, given these concerns the results of the pooled analyses should be interpreted with caution.

AUTHORS' CONCLUSIONS

Implications for practice

The evidence base suggests that PEG is moderately effective at improving the frequency of defecation in children with chronic constipation when compared to placebo and more effective than other agents, such as lactulose, milk of magnesia or liquid paraffin (mineral oil). It also appears to have a good safety profile, with minor adverse events common, but less so than with these other agents. The strength of this evidence is limited by sparse data, inconsistency (clinical and statistical heterogeneity) and a high risk

of bias in some studies included in the pooled analyses. It is also difficult to comment on the use of PEG for the long term management of childhood constipation as most studies only measured short term outcomes. While only two studies investigated liquid paraffin in comparison with lactulose, they found a reasonable effect size supporting the use of liquid paraffin. There was no evidence found to suggest lactulose is more effective than the other agents studied, but there was a lack of placebo controlled trials.

Implications for research

The evidence base for this extremely prevalent problem is small and published papers are generally of sub optimal quality, as well as having problems with methodological, statistical and clinical heterogeneity. As such, the strength of our conclusions is extremely limited and more research is needed. Key questions that need addressing include the safety of liquid paraffin, given its apparent effectiveness, but limited investigation. In particular, future research should compare liquid paraffin with PEG. The role of PEG for the long term management of chronic constipation also needs further investigation to allow research to better inform actual clinical practice. There is a lack of studies comparing lactulose with

placebo.

Future research should be clear at the outset as to whether it seeks to investigate the use of agents for the induction of remission from severe constipation, or whether it will investigate maintenance of normal bowel habits. Studies should be reported in sufficient detail to allow the methodology to be assessed and replicated by other researchers.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Bekkali 2009

Methods	Randomised controlled open label trial of polyethylene glycol (PEG) + electrolytes versus enemas for faecal impaction
Participants	90 children between 4 and 16 years of age and demonstrated evidence of faecal impaction on rectal examination. to fulfill > 1 of the other Rome III criteria for functional constipation present for 8 weeks, that is, (1) defecation frequency of 3 times per week, (2) > 1 faecal incontinence episode per week, (3) history of retentive posturing or excessive volitional stool retention, (4) history of painful or hard defecation, and (5) history of large-diameter stools that may obstruct the toilet. Patients with a history of colorectal surgery or an organic cause for constipation were excluded
Interventions	Peg 3350 + electrolytes (Movicolon, Norgine, Amsterdam), 1.5 g/kg per day) for 6 consecutive days. Then maintenance (0.5 g/kg per day) for 2 weeks. Dioctylsulfosuccinate sodium enemas (Klyx, Pharmachemie, Haarlem, The Netherlands). Once daily for 6 consecutive days (60 mL for children < 6 years of age and 120 mL for children > 6 years of age)
Outcomes	The primary outcome was successful disimpaction. Secondary outcome measures of defecation and faecal incontinence frequency, abdominal pain, watery stools, CTT values, and child's behavior scores were calculated for children who completed the study protocol. Follow up for 2 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	High risk	No adverse event data reported
Other bias	Low risk	None apparent

Candy 2006

Methods	Open label treatment of faecal impaction with PEG + electrolytes followed by a randomised double blind controlled trial of PEG + electrolytes versus lactulose. Only data from second phase of the trial were analysed
Participants	Children aged 2 to 11 years could be enrolled in the study if they had intractable constipation that had failed to respond to conventional treatment and would require hospital admission for disimpaction. 58 children were enrolled. All patients included had successfully been disimpacted in phase 1 of the trial. Children were excluded if they had any condition contraindicating the use of PEG + E or lactulose or pre-existing organic pathology
Interventions	PEG 3350 + electrolytes (Movicol, Norgine, UK) 1 sachet per day (mean) versus lactulose (10 g lactulose powder dissolved in at least 125 mL water), 2.5 sachets per day (mean). Concomitant use of senna allowed
Outcomes	The primary outcome was the mean number of defecations per week. Secondary outcomes included amount of stool, problems on defaecation (pain, straining, abdominal pain, rectal bleeding or soiling). Follow up for 12 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Study sponsor contacted and confirmed they generated a computerised randomisation list
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Similar appearance of products, identical packaging
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Unclear risk	Supported by Norgine. Extent of involvement unclear

Dupont 2005

Methods	Randomised double blind controlled trial of PEG 4000 versus lactulose
Participants	96 children aged 6 months to 3 years with constipation despite the usual dietary treatment for at least 1 month. Children were ineligible if they had a history of intractable fecaloma or organic gastrointestinal disease such as Hirschsprung disease
Interventions	PEG 4000 1 sachet (4 g/sachet) versus Lactulose 1 sachet /(3.33g/sachet). The dose could be doubled if ineffective. If the maximum authorized dose was unsuccessful, one micro-enema (glycerol) per day could be prescribed for a maximum of 3 consecutive days. If the child produced no stools after treatment two enemas could be administered at a 48-hour interval
Outcomes	The primary endpoint was biological tolerance,. Secondary endpoints included clinical efficacy measured by stool frequency and consistency, disappearance of abdominal pain and bloating, Follow up was up to 12 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Described and appropriate
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Farahmand 2007

Methods	Randomised controlled open label trial comparing liquid paraffin versus lactulose
Participants	247 children aged 1 month to 12 years with diagnosis of functional constipation. Children with organic causes for defecation disorders were excluded from the study
Interventions	Liquid paraffin or lactulose, 1-2 ml/kg twice daily for each drug, for 8 weeks, increase or decrease of volume of each drug allowed by 25% every 3 days as required, to yield, 1 or 2, firm to loose stools. Patients received one or two enemas daily for two days to clear any rectal impaction at study entry

Outcomes	Primary outcome was the number of successful bowel movements per week, with treatment success defined as three or more episodes per week. Secondary outcomes were the incidence and severity of adverse events.Follow up was for 8 weeks	
Notes		
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Gomes 2011

Gomes 2011

Methods	Randomised controlled open label trial comparing PEG versus magnesium hydroxide
Participants	38 children aged 1 to 15 years old with functional constipation according to the Rome III criteria. Children with excluded organic causes, neurological problems or previous surgery to the digestive system were excluded
Interventions	1 mL/kg/day for magnesium hydroxide (maximum dose 3 mL/kg/day, up to 60 mL/day) and 0.5 g/kg/day for PEG (maximum dose 1.5 g/kg/day, up to 48 g/day)
Outcomes	Outcomes included: Stool characteristics (Bristol), ⁵ frequency of bowel movements (number of movements per week), abdominal pain, straining, faecal incontinence, and acceptance of medication. Therapeutic interventions were considered failures when there was lack of acceptance, vomiting upon administration or absence of improvement in frequency of bowel movements and/or ongoing Bristol types 1, 2 or with use of maximum doses of the medication from the moment of the first return appointment
Notes	
<i>Risk of bias</i>	

Gomes 2011 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	High risk	No details regarding dropouts reported
Selective reporting (reporting bias)	High risk	No details regarding adverse events reported
Other bias	Low risk	None apparent

Gremse 2002

Methods	Randomised controlled open label crossover trial of PEG versus lactulose
Participants	37 children aged 2 to 16 years of age who were referred for subspecialty evaluation of constipation completed the study. Those with organic disease were excluded
Interventions	PEG 3350 (Miralax, Braintree Laboratories, Inc, Braintree, MA) 10 g/m ² /day or lactulose 1.3 g/kg/day both for two weeks and then patients switched agents for a further two weeks
Outcomes	Primary outcome was number of defecations per week. Secondary outcomes included stool form, ease of passage and global assessments by parents. 4 week follow up
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label

Gremse 2002 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	High risk	Details not reported - no response from author
Other bias	Low risk	None apparent

Kokke 2008

Methods	Randomised double blind controlled trial of a dietary fibre mix versus lactulose
Participants	135 children ages 1 to 13 years were included. Children with organic causes of defecation disorders were excluded
Interventions	Patients received either a yogurt drink containing lactulose (10 g/125 mL, Duphalac Lactulose, Solvay, the Netherlands).or a mixed dietary fibres (10 g/125 mL). The fibre mixture yogurt contained 3.0 g transgalacto-oligosaccharides (Vivinal GOS Elixor Sirup, Friesland Foods Domo, Zwolle, the Netherlands), 3.0 g inulin (Frutafit TEX, Cosun, Roosendaal, the Netherlands), 1.6 g soy fibre (Fibrim 2000, J. Rettenmaier & Sohne, Ellwangen, Germany), and 0.33 g resistant starch 3 (Novelose 330, National Starch& Chemical GmbH, Neustadt, Germany) per 100 mL
Outcomes	The primary outcome parameter was defecation frequency per week. Secondary outcome parameters included faecal incontinence each day stool consistency and flatulence. Follow up was for 12 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated list
Allocation concealment (selection bias)	Low risk	Sequence allocation coordinated by external research organisation
Blinding (performance bias and detection bias) All outcomes	Low risk	Bottles with yogurt were prepared and packed by Numico Research (Wageningen, the Netherlands). Storage and delivery were supervised by the local hospital pharmacist. The treatment products could not be distinguished from each other with respect to colour, taste, or consistency

Kokke 2008 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Loening-Baucke 2006

Methods	Randomised controlled open label trial comparing PEG 3350 without electrolytes with milk of magnesia
Participants	79 children aged > 4 years and presence of functional constipation with faecal incontinence. Exclusion criteria included organic causes for symptoms, toileting refusal or medication refusal
Interventions	PEG 0.7 g/kg body weight daily or Milk of magnesia 2 mL/kg body weight daily. Instructions were given to parents on how to vary doses to achieve acceptable stools. Children were disimpacted with 1 or 2 phosphate enemas in the clinic on the day of the visit, if necessary, and started laxative therapy that evening. Senna was allowed
Outcomes	Primary outcome was Improvement defined as 3 bowel movements per week, 2 episodes of faecal incontinence per month, and no abdominal pain, with or without laxative therapy. Secondary outcomes included (1) improvement in stool frequency per week, improvement in episodes of faecal incontinence per week, and resolution of abdominal pain; (2) safety profile; and (3) patient's acceptance and compliance. Follow up was for 12 months
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Drawing lots
Allocation concealment (selection bias)	Low risk	Assignments in sealed envelopes
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately

Other bias	Low risk	None apparent
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Nurko 2008

Methods	Randomised, multicenter, double-blind trial comparing PEG 3350 with placebo
Participants	103 children 4 to 16 years of age. Patients who were taking other laxatives were included only if they had > 3 bowel movements per week while taking the laxative, and all laxatives were stopped at least 2 days before the run-in period started. Exclusion criteria included children with organic causes of constipation
Interventions	PEG3350, (MiraLax, Braintree Laboratories, Inc; Braintree, MA) at doses of 0.2, 0.4, 0.6 or 0.8 grams per kilogram per day or placebo. (CrystalLight, Proctor and Gamble; Cincinnati, OH). All received behavioural modification
Outcomes	The primary outcome was the proportion of patients who responded to treatment. Response to treatment was defined as >3 BM during the second week of treatment. Secondary efficacy variables included the weekly number of BM and faecal incontinence episodes and changes in the scores of stool consistency, straining, and abdominal cramping. 2 weeks follow up
Notes	Additional Mean and Standard deviation data regarding the frequency of defecations were obtained from Braintree Labs Inc

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Identically labelled bottles that were reconstituted with water to 4,000 mL by study personnel in the pharmacy. There was no difference in the colour, appearance, or taste among the different doses
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	Supported by Braintree Labs Inc. They confirmed they had no involvement in the running of the study or the writing of the published manuscript

Perkin 1977

Methods	Randomises controlled crossover trial of lactulose versus senna
Participants	21 children under 15 years of age with a history of greater than 3 weeks constipation. Children with other organic causes of constipation were excluded
Interventions	Lactulose 10-15 mL per day or Senna 10-20 mL per day for 1 week, then 1 week with no treatment and then patients switched to received the other treatment
Outcomes	Stool consistency, number of stools per day and adverse events. Follow up for 3 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random number list, but method of creation not described
Allocation concealment (selection bias)	Low risk	Assignments in sealed envelopes
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Although author describes that identical bottles with no identification were used, further detail to confirm blinding are not given
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Pitzalis 1995

Methods	Randomised controlled trial comparing lactitol with lactulose
Participants	42 children aged 8 months - 16 years old with less than 3.5 stools per week. Patients with other organic pathology were excluded
Interventions	Lacitol (Portolac zyma) 250 mg/kg/day single dose, Can be increased to 400mg/kg/day. Lactulose (Epalfen zambon) 500 mg/kg/day single dose, Can be increased to 750 mg/kg/day
Outcomes	Primary outcome measure was the frequency of defecation and secondary measures included palatability and colonic transit time. Follow up was for 1 month

Pitzalis 1995 (Continued)

Notes	Italian publication	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	High risk	No adverse events mentioned
Other bias	Low risk	None apparent

Rafati 2011

Methods	Randomised controlled trial comparing PEG with liquid paraffin	
Participants	158 children aged 2 to 12 years with a history of functional constipation	
Interventions	1.0-1.5 g/kg/day PEG 3350 or 1.0-1.5 ml/kg/day liquid paraffin orally for 4 months. PEG 3350 powder was prepared as a 40% solution to trust reliable to apply the paediatric dosing and to increase compliance and liquid paraffin was provided from a pharmaceutical factory. For rectal disimpaction, bisacodyl suppositories were applied at the beginning of the study	
Outcomes	Primary outcomes were stool and encopresis frequency per week	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described

Rafati 2011 (Continued)

Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropouts are not explained
Selective reporting (reporting bias)	High risk	No adverse event data reported
Other bias	Low risk	None apparent

Ratanamongkol 2009

Methods	Randomised controlled trial comparing PEG 4000 without electrolytes to milk of magnesia
Participants	94 infants and children aged one-four years. Patients were organic causes for their constipation or renal insufficiency were excluded
Interventions	PEG400 without electrolytes, 0.5 g/kg/day, maximal does 1 g/kg/day or milk of magnesia suspension, 400 mg/5mL, 0.5 mL/kg/day, maximal does 3 mL/kg/day
Outcomes	The primary outcome measure was the improvement rate, defined as the proportion of patients who had > three bowel movements per week, < two episodes of faecal incontinence per month, and no painful defecation, with or without laxative therapy. Other outcome studies were: 1) improvement in stool frequency per week; 2) the proportion of the patients who had any adverse effects; and 3) the compliance rate, defined as the proportion of patients who received more than 80% of the medication. Follow up was for 4 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random number list
Allocation concealment (selection bias)	Low risk	Sealed opaque assignment envelopes sequentially opened
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not clear whether this was a blinded study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported

Ratanamongkol 2009 (Continued)

Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Thomson 2007

Methods	Randomised controlled double blind crossover trial comparing PEG 3350 with electrolytes versus placebo
Participants	51 children aged 24 months to 11 years were eligible for enrolment. Constipation was defined according to the Rome criteria. Children were excluded from the study if they had current or previous faecal impaction or organic pathology causing their constipation. Also, if they were currently receiving doses of stimulant laxatives considered by local observers to be at the higher end of their own dose spectrum (senna or sodium picosulphate) with no effect, having assessed to their clinical satisfaction adequate compliance
Interventions	Placebo or PEG 3350 with electrolytes (Movicol, Norgine Pharmaceuticals, UK). The dosing regimen was based on age and clinical response. Participants received 2 weeks of therapy, followed by a 2 week washout period and then a further 2 weeks with the alternate therapy
Outcomes	The primary efficacy variable was the mean number of complete defaecations per week. Secondary efficacy variables included the total number of complete and incomplete defaecations per week, pain on defaecation, straining on defaecation, faecal incontinence, stool consistency, and a global assessment of treatment by the investigator and by the child or his or her parent or guardian, as well as recording of adverse events. Follow up for 6 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random number list
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes used
Blinding (performance bias and detection bias) All outcomes	Low risk	Described and appropriate
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately

Thomson 2007 (Continued)

Other bias	Low risk	Sponsored by Norgine Pharmaceuticals. The author confirmed that they had no involvement in the writing of the final manuscript
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Tolia 1993

Methods	Randomised controlled open trial comparing PEG 3350 with mineral oil (liquid paraffin) for the treatment of faecal impaction
Participants	36 children older than 2 years in age with constipation were potentially acceptable for the study. Patients were excluded if they had any other organic cause for their impaction. physical examination by the presence of firm to hard faecal impaction in the anal canal and rectal ampulla on an otherwise normal complete initial physical examination
Interventions	PEG 3350 (Colyte, 20 mL/kg/hour for 4 hours) on two days or 30 mL/10kg of mineral oil twice a day for two days. Those receiving PEG had a single dose of metoclopramide
Outcomes	Outcomes included time to first stool, frequency of stool movements, consistency, distention, cramps, nausea and vomiting, as well as side effects. Follow up were after two days

Notes	
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Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random number list
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Urganci 2005

Methods	Randomised open label trial of Liquid paraffin versus lactulose
Participants	40 children 2 to 12 years old with constipation with evidence of faecal impaction were enrolled in the study. Those with organic pathology were excluded
Interventions	Liquid paraffin or lactulose 1 ml/kg, twice daily for each drug. For determination of the best dose for each child, parents were asked to increase or decrease the volume of each drug by 25% every 3 days as required, to yield two firm-loose stools per day. The maximum dose used throughout the study was 3 mL/kg per day for each drug. All participants received behavioural advice and saw a nutritionist
Outcomes	Primary outcome was effective treatment, defined as clearance of the impaction (more than three bowel movements per week and improvement in stool consistency). Secondary outcomes included stool frequency and stool consistency in first 4 weeks and last 4 weeks, as well as adverse events. Follow up was for 8 weeks
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	High risk	Open label
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Voskuyl 2004

Methods	Randomised double blind trial comparing PEG 3350 with Lactulose
Participants	100 children aged six month to 15 years were included in this study. Children with an organic cause for their constipation were excluded
Interventions	Patients had a 1 week run in and then received daily rectal enemas for 3 days (<6 years of age received 60 ml Klyx (sodium dioctylsulfosuccinate and sorbitol) while those >6 years of age received 120 ml Klyx). Lactulose (6 g (sachet)) versus PEG 3350 (2.95 g (sachet))

Voskujl 2004 (Continued)

) 1 sachet per day under 6 starting, 2 over 6. Reassessed at 1 week and either increase by 1 sachet or decreased by 50%	
Outcomes	The primary outcomes were frequency of stools, frequency of encopresis, and overall treatment success at eight weeks. An increase in defecation frequency was considered to have improved if it rose to three or more times a week while encopresis had to decrease to an incidence of one episode or less every two weeks. The incidence of adverse events was also documented. Follow up was for 8 weeks	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Low risk	Identical sachets, released by central pharmacy
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Wang 2007

Methods	Randomised controlled multi-centre trial comparing PEG 4000 with lactulose	
Participants	216 children from 8-18 years old. Those with other organic disease were excluded	
Interventions	Patients received either PEG 4000 (Forlax, 2 sachets x 20g/day) versus lactulose (15 mL/day, then drop to 10 mL after 3 days)	
Outcomes	Primary outcome was frequency of bowel movements. Secondary outcomes included stool consistency, abdominal symptoms and safety. Follow up was for 2 weeks	
Notes	Chinese publication	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding (performance bias and detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Full details reported
Selective reporting (reporting bias)	Low risk	Data reported appropriately
Other bias	Low risk	None apparent

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Berg 1983	Study does not include patients with functional constipation, but those diagnosed with functional soiling
Clayden 1978	Not a RCT, Letter
Corazziari 1996	Not a Paediatric study
Dupont 2006	Not a RCT, no comparison group
Ferguson 1999	Not a Paediatric study
Hardikar 2007	Not a RCT, no comparison group
Hejl 1990	Not a RCT, no comparison group
Kazak 1999	Meets exclusion criteria, children have underlying pathology
Kinservik 2004	Review article
Loening-Baucke 2002	Not a RCT
Loening-Baucke 2004	Not a RCT, retrospective chart review
Miller 2012	The trial focused on the treatment of faecal impaction rather than treatment of constipation
Moulies 1961	Not a RCT

(Continued)

Quitadamo 2010	Abstract publication
Shevtsov 2005	Not a RCT
Sonheimer 1982	Not a RCT
Tolia 1988	Not a RCT
Youssef 2002	Not a RCT, no comparison group

DATA AND ANALYSES

Comparison 1. PEG versus Placebo

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	2	101	Mean Difference (IV, Random, 95% CI)	2.61 [1.15, 4.08]
2 Serious adverse events	2	101	Odds Ratio (M-H, Fixed, 95% CI)	0.17 [0.02, 1.48]

Comparison 2. PEG versus Lactulose

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	4	328	Mean Difference (IV, Random, 95% CI)	1.09 [0.02, 2.17]
2 Need for additional therapies	3	254	Odds Ratio (M-H, Fixed, 95% CI)	0.49 [0.27, 0.89]
3 Need for additional therapies (sensitivity analysis)	3	254	Odds Ratio (M-H, Random, 95% CI)	0.51 [0.19, 1.38]
4 Adverse events	2	154	Odds Ratio (M-H, Fixed, 95% CI)	0.37 [0.14, 1.03]

Comparison 3. PEG versus Milk of Magnesia

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	3	211	Mean Difference (IV, Fixed, 95% CI)	0.69 [0.48, 0.89]
2 Frequency of defecation (sensitivity analysis)	3	211	Mean Difference (IV, Random, 95% CI)	0.69 [0.48, 0.89]

Comparison 4. Paraffin versus Lactulose

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	2	287	Mean Difference (IV, Fixed, 95% CI)	4.94 [4.28, 5.61]

Comparison 5. PEG versus Enema

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	1	80	Mean Difference (IV, Fixed, 95% CI)	1.00 [-1.58, 3.58]
2 Successful disimpaction	1	90	Odds Ratio (M-H, Fixed, 95% CI)	0.52 [0.20, 1.37]

Comparison 6. Lactulose versus Lactitol

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	1	42	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-2.63, 1.03]

Comparison 7. PEG versus Paraffin

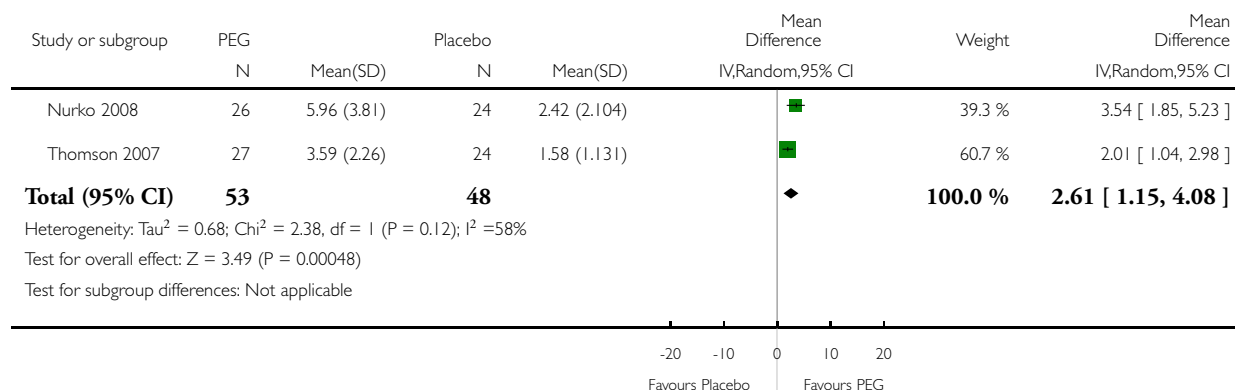
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Frequency of defecation	1	158	Mean Difference (IV, Fixed, 95% CI)	0.70 [-0.38, 1.78]

Analysis 1.1. Comparison 1 PEG versus Placebo, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 1 PEG versus Placebo

Outcome: 1 Frequency of defecation

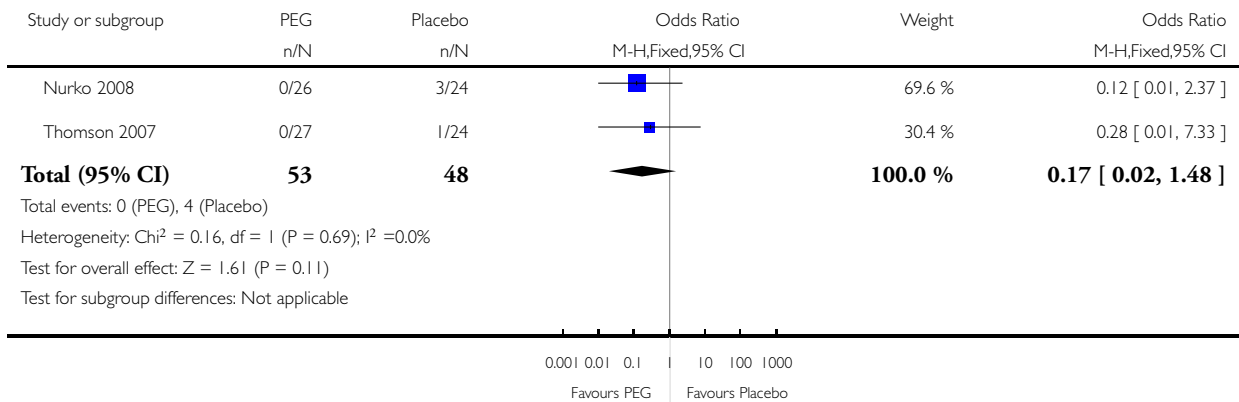


Analysis 1.2. Comparison 1 PEG versus Placebo, Outcome 2 Serious adverse events.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 1 PEG versus Placebo

Outcome: 2 Serious adverse events

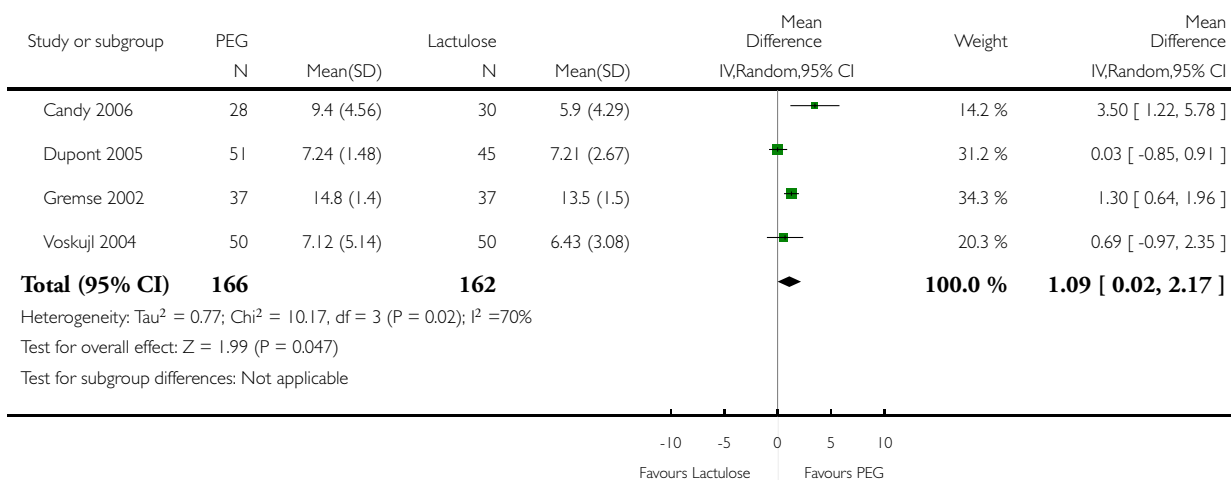


Analysis 2.1. Comparison 2 PEG versus Lactulose, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 2 PEG versus Lactulose

Outcome: 1 Frequency of defecation

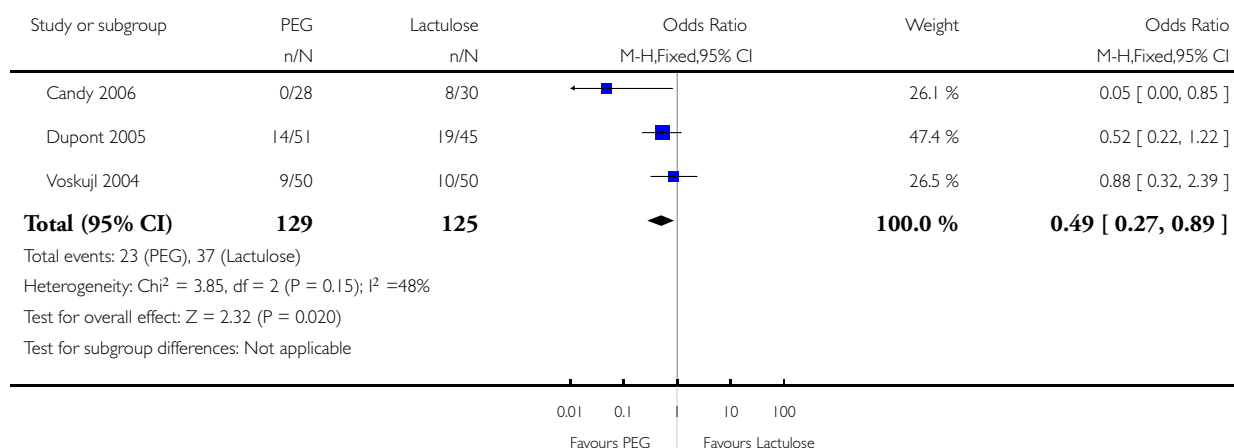


Analysis 2.2. Comparison 2 PEG versus Lactulose, Outcome 2 Need for additional therapies.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 2 PEG versus Lactulose

Outcome: 2 Need for additional therapies

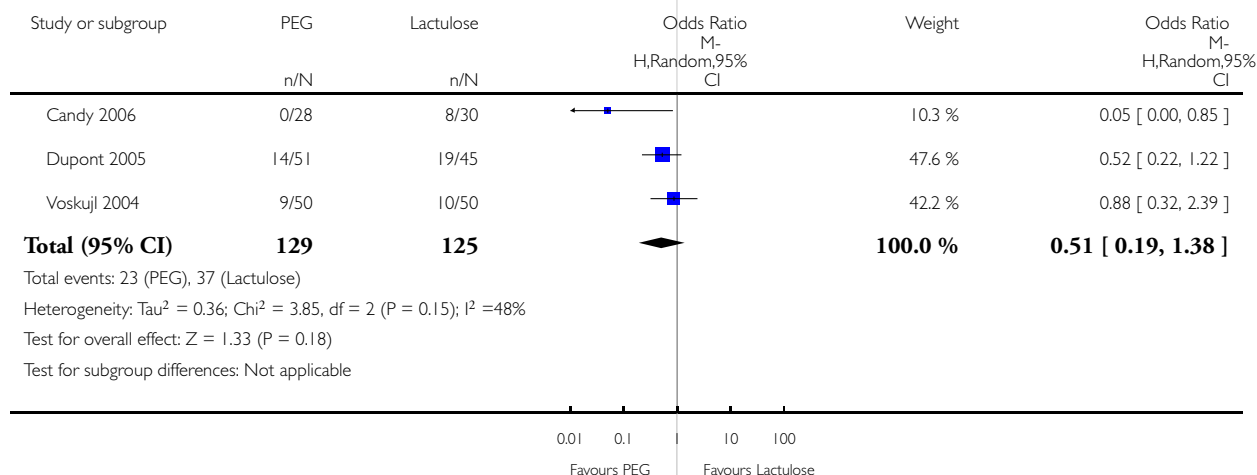


Analysis 2.3. Comparison 2 PEG versus Lactulose, Outcome 3 Need for additional therapies (sensitivity analysis).

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 2 PEG versus Lactulose

Outcome: 3 Need for additional therapies (sensitivity analysis)

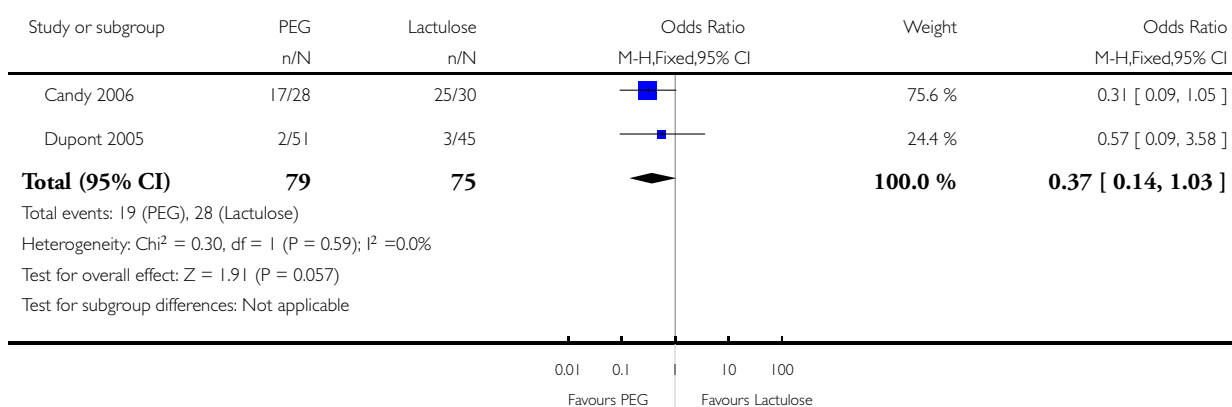


Analysis 2.4. Comparison 2 PEG versus Lactulose, Outcome 4 Adverse events.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 2 PEG versus Lactulose

Outcome: 4 Adverse events

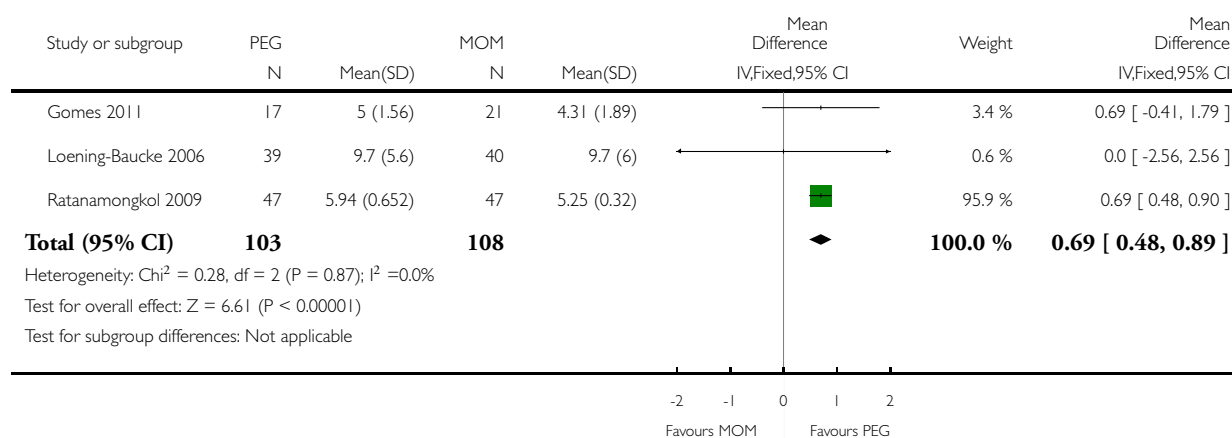


Analysis 3.1. Comparison 3 PEG versus Milk of Magnesia, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 3 PEG versus Milk of Magnesia

Outcome: 1 Frequency of defecation

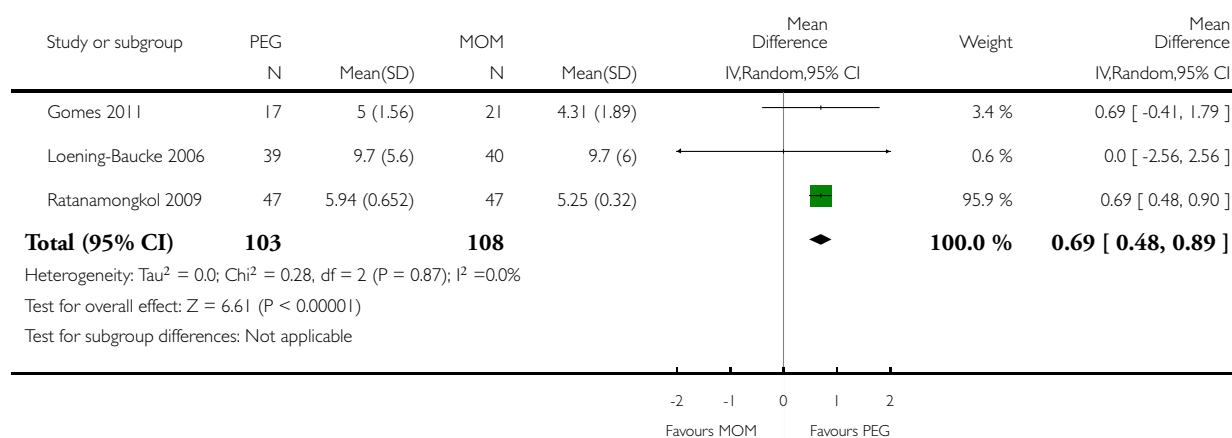


Analysis 3.2. Comparison 3 PEG versus Milk of Magnesia, Outcome 2 Frequency of defecation (sensitivity analysis).

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 3 PEG versus Milk of Magnesia

Outcome: 2 Frequency of defecation (sensitivity analysis)

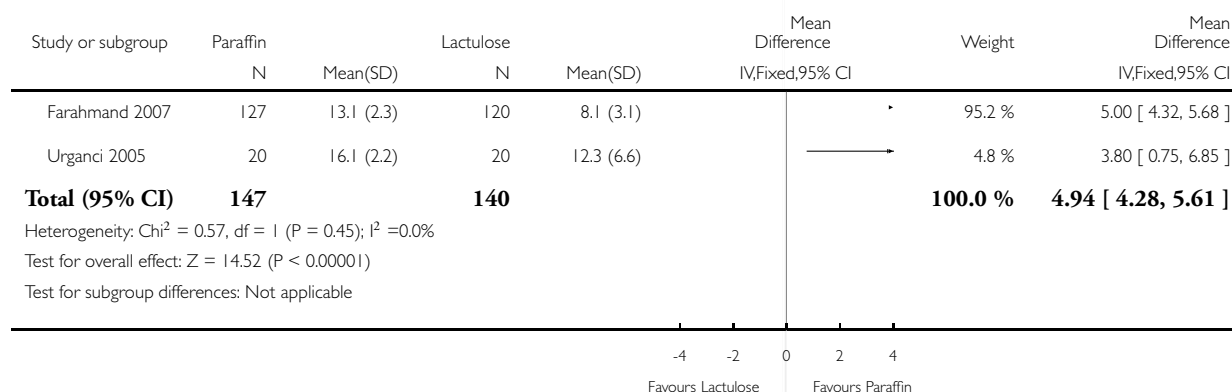


Analysis 4.1. Comparison 4 Paraffin versus Lactulose, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 4 Paraffin versus Lactulose

Outcome: 1 Frequency of defecation

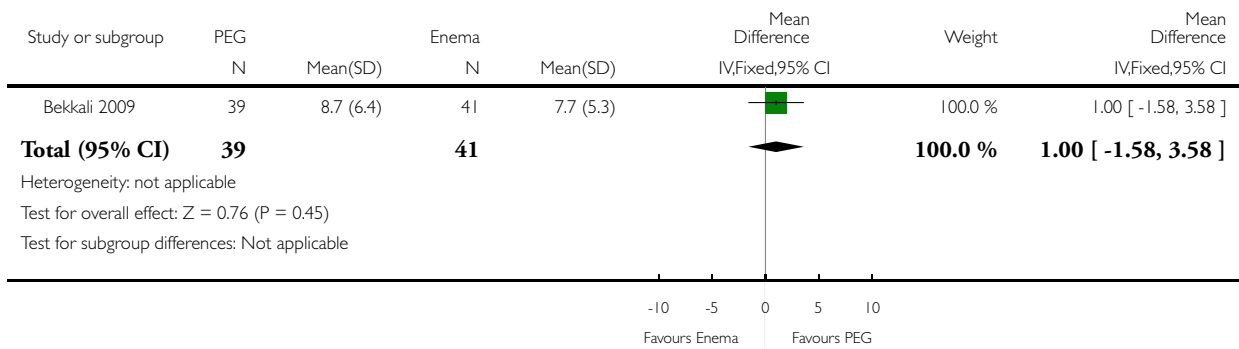


Analysis 5.1. Comparison 5 PEG versus Enema, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 5 PEG versus Enema

Outcome: 1 Frequency of defecation

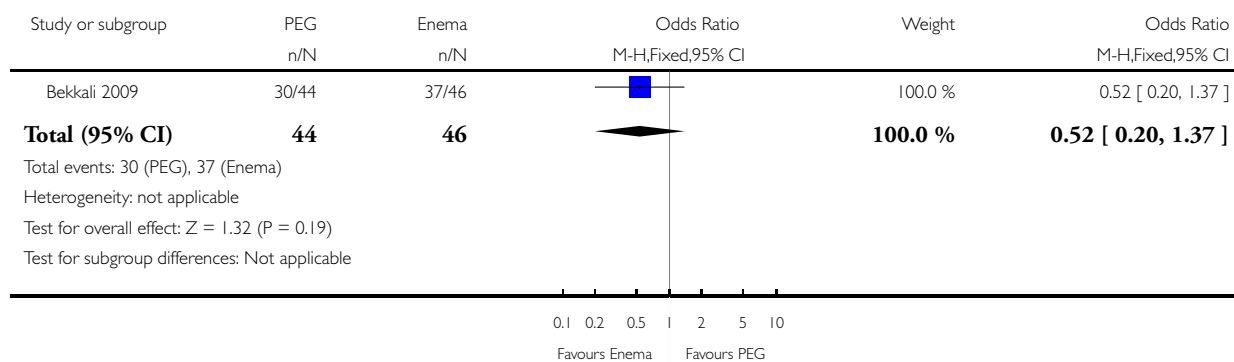


Analysis 5.2. Comparison 5 PEG versus Enema, Outcome 2 Successful disimpaction.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 5 PEG versus Enema

Outcome: 2 Successful disimpaction

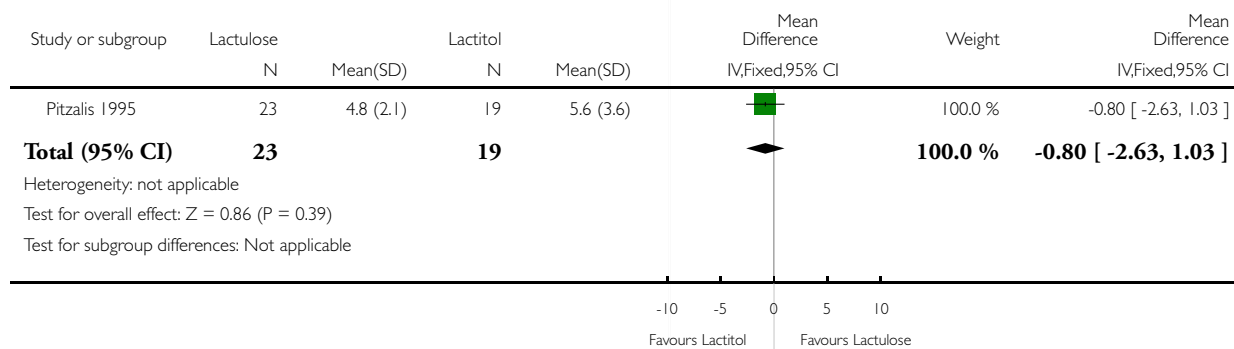


Analysis 6.1. Comparison 6 Lactulose versus Lactitol, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 6 Lactulose versus Lactitol

Outcome: 1 Frequency of defecation

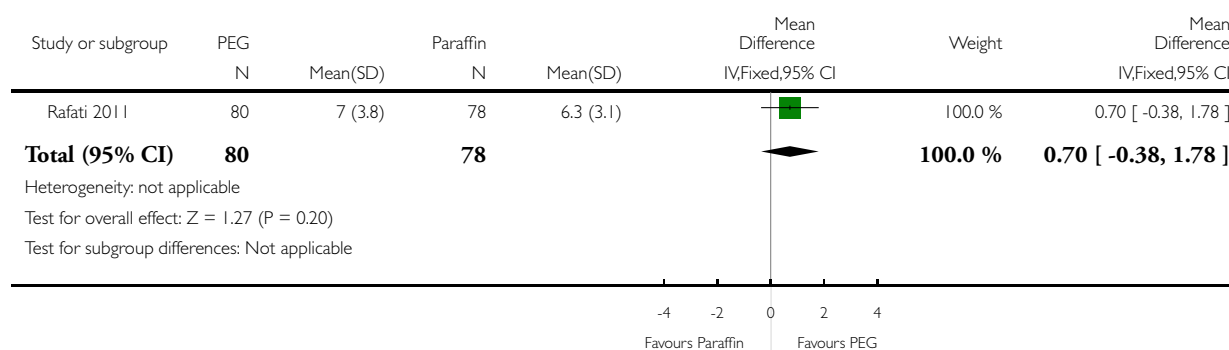


Analysis 7.1. Comparison 7 PEG versus Paraffin, Outcome 1 Frequency of defecation.

Review: Osmotic and stimulant laxatives for the management of childhood constipation

Comparison: 7 PEG versus Paraffin

Outcome: 1 Frequency of defecation



HISTORY

Protocol first published: Issue 5, 2011

Review first published: Issue 7, 2012

CONTRIBUTIONS OF AUTHORS

Morris Gordon conceived the review, carried out the search, data extraction and analysis and led the writing of the manuscript. Khimara Naidoo also conducted the search, data extraction and assisted with the analysis, as well as commenting on drafts of the manuscript. Anthony Akobeng and Adrian Thomas assisted with the analysis and contributed towards the writing and commented on drafts of the review.

DECLARATIONS OF INTEREST

Morris Gordon received a travel grant from Norgine Pharmaceuticals to present the results of this review at Digestive Disease Week in Chicago, May 2011. Norgine had no input in the design, execution or write up of the study. Additionally, Morris Gordon has received travel grants since completing this review from Cassen Fleet Pharmaceuticals and Ferring Pharmaceuticals to attend Digestive Disease Week 2012, but again they have had no involvement in this or any other research works completed.

INDEX TERMS

Medical Subject Headings (MeSH)

Constipation [*drug therapy]; Defecation [drug effects; physiology]; Dietary Fiber [adverse effects; therapeutic use]; Lactulose [adverse effects; therapeutic use]; Laxatives [adverse effects; *therapeutic use]; Magnesium Hydroxide [adverse effects; therapeutic use]; Mineral Oil [adverse effects; therapeutic use]; Osmosis; Polyethylene Glycols [adverse effects; therapeutic use]; Randomized Controlled Trials as Topic; Sugar Alcohols [adverse effects; therapeutic use]

MeSH check words

Adolescent; Child; Child, Preschool; Humans; Infant

Separating the wheat from the chaff: the role of systematic review in medical education

Morris Gordon,¹ Daniel Darbyshire² & Paul Baker³

Editor – We read with great interest Kilminster's commentary¹ on our systematic review of non-technical skills training in health care.² We agree that hierarchies of evidence and quality in general cannot and should not be characterised by any single measure³ and that this must be reflected within the design of educational systematic reviews. This issue has been previously discussed by Yardley and Dornan,⁴ who rejected the notion that Kirkpatrick's hierarchy⁵ could act as an arbiter of quality, but you will note that we used such a system merely to categorise evidence.²

Kilminster¹ asks whether a significant body of evidence, represented in our case² by 432 citations, can be summarised by reading 31 manuscripts. We believe this is the strength of systematic review. The vast majority of manuscript citations sourced by electronic searches have no relevance to the question posed. They are the fool's gold of the digital age and have the ability to lead astray those who casually investigate an issue of

interest. The repeatable, transparent and reliable methodology employed in such reviews cannot be faulted for its ability to separate the wheat from the chaff. The issue to consider is how each has been defined and how clearly these assumptions have been explained. The weakness of systematic review in medical education is its tendency to resort to statistical methods that are widely used to answer clinical questions, such as meta-analysis. Given the massive problems associated with the methodological, educational and statistical heterogeneity often encountered, the results of such analyses are often uninterpretable.

Kilminster's¹ plea for recognition of the content rather than the process of research in medical education is one we would second. Systematic review in medicine is largely focused on assessing effectiveness, in which process is key. Effectiveness is often conspicuous by its absence in the conclusions of educational systematic review. This does not devalue the process⁶ or the usefulness of the evidence gathered. Other interesting questions that may be addressed with reference to content are those that start with the words 'where', 'when', 'how' and 'why'.

The very questions Kilminster¹ poses after reading our review would suggest that it has indeed illuminated the issue for her.

The challenge lies in achieving a balance between fulfilling the desire for reviews that allow educators to make decisions related to their practice, and acknowledging the difficulties inherent in delivering such findings using educational systematic review. We would urge educators to continue to use systematic review, but to aim to answer questions other than 'whether' education is effective.

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Low fidelity, high quality: a model for e-learning

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Paul Baker, North Western Deanery, Manchester, UK

Most reports focus on whether the e-learning is effective, rather than 'how' and 'why' it is effective

SUMMARY

Background: E-learning continues to proliferate as a method to deliver continuing medical education. The effectiveness of e-learning has been widely studied, showing that it is as effective as traditional forms of education. However, most reports focus on whether the e-learning is effective, rather than discussing innovations to allow clinical educators to ask 'how' and 'why' it is effective, and to facilitate local reproduction.

Context: Previous work has set out a number of barriers to the introduction of e-learning interventions. Cost, the time to

produce interventions, and the training requirements for educators and trainees have all been identified as barriers. We set out to design an e-learning intervention on paediatric prescribing that could address these issues using a low-fidelity approach, and report our methods so as to allow interested readers to use a similar approach.

Innovation: Using low-cost, readily accessible tools and applying appropriate educational theory, the intervention was produced in a short period of time. As part of a randomised controlled trial, long-term retention of prescribing skills was demonstrated,

with significantly higher prescribing skill scores in the e-learning group at 4 and 12 weeks ($p < 0.0001$). Feedback was universally positive, with Likert responses suggesting that it was useful, convenient and easy to use.

Implications: A low-fidelity approach to designing can successfully overcome many of the barriers to the introduction of e-learning. The design model described is simple and can be used by clinical teachers to support local development. Further research could investigate the experiences of these clinicians using this method of instructional design.

INTRODUCTION

The proliferation of e-learning as a teaching method for continuing medical education appears unstoppable, and is attributable to various drivers (Box 1).¹ In his key review, Cook reassures the reader that e-learning is better than no intervention, and is similar (on average) to traditional instruction.² Dexter argues that evaluating e-learning in this way is as absurd as comparing printing press-based with quill-based learning.³ Much more useful questions include 'which', 'when' and 'how' to use technology-enhanced learning.

This is where the literature falls down. Further analysis of the many studies in Cook's review shows that the vast majority suffer from the same flaws.² The actual 'learning' is most often conspicuous by its absence. With little or no description of the instructional objectives, pedagogical basis, resources required or methods of design, clinical teachers are left with a surplus of research that answers a question we already knew the answer to. Ellaway suggested a heuristic for reporting e-learning interventions to address these issues.⁴ She notes that educators and clinicians have seemingly lacked the ability and discipline to describe technology in health care education.

CONTEXT

In their review of barriers to e-learning implementation, Child *et al.* identified issues such as organisational inertia, resistance of staff, costs (hardware, software, upkeep, infrastructure, and learners' and trainer's time) and concerns with the pedagogy of 'off-the-shelf' software.⁵ Wong *et al.* have reviewed how to choose between the methods on offer based on two theories: according to Davis's technology acceptance model, learners are more likely to

accept a course if an e-learning intervention offers a perceived advantage over available non-internet alternatives, is easy to use technically and is compatible with their values and norms; according to Laurillard's model of interactive dialogue, interactivity leads to effective learning only if learners are able to enter into a dialogue with a tutor, fellow students or virtual tutorials, and gain formative feedback.⁶ By considering this work, it is clear that from the educator's perspective, packages should be cheap, quick and easy to produce and update. From the learner's perspective, they should be convenient to use, offer a perceived advantage over traditional methods and give feedback on learning.

By incorporating the various requirements identified, we set out to produce and evaluate an effective e-learning package to support paediatric prescribing amongst recent graduates in the North Western Foundation School. We aimed to respond to Ellaway's call to discuss interventions more fully, and what development or preparation was involved,⁷ using her heuristic as a guide.⁴

INNOVATION

Selecting a template for design

We used POWERPOINT (PPT) as the basic template to build our intervention. Although PPT offers many easy to use options, most people use the traditional slide and bullet point format, leading to reduced interest in such presentations.⁸ We used the 'ani-

mate features' function to move images and text within slides, and the button tool to create navigation buttons that linked to other slides, producing high levels of interactivity. There are a variety of freely available templates with such features, such as quizzes and interactive games, some of which have been employed in medical education.⁹

Once completed, RAPID E-LEARNING SUITE 5.6.5 (Wondershare Software Co. Ltd, Shenzhen, Guangdong Province, China) was used to create a self-contained flash program. The suite had several elements allowing video conversion for inclusion within the final flash program, as well as allowing self-assessment exercises to be easily created. Finally, the suite had a demo creator that allowed screen-captured videos to be added. This suite was cheap and is one of many similar programs available.

INCORPORATING EDUCATIONAL THEORY

Gagne's nine instructional events were used for guiding the course design.¹⁰ Gagne's events of instruction are related to conditions of learning. For example, a well-designed introduction, posing a question about prescribing errors should gain attention, inform the learners of the objectives and stimulate recall of prior learning, essentially meeting the first three events of instruction. Other examples within our learning included a video of how to access a prescribing resource

Much more useful questions include 'which', 'when' and 'how' to use technology-enhanced learning

Box 1. Factors supporting the rise of e-learning

- Easy availability of computers
- The growth of the internet
- Tutor experience with e-learning
- Learner comfort with IT
- Learner expectations
- Advantages over traditional teaching methods

The long-term retention of prescribing skills was demonstrated

(providing learner guidance), a self-assessment exercise (to elicit performance), with immediate answers and explanations given (to provide feedback), and then offering questions based on video simulations of workplace prescribing (to enhance retention).

The principles for designing effective multimedia presentations are based on cognitive theory, which is derived from cognitive load theory. Cognitive load theory (CLT) assumes that the human cognitive system has a limited working memory that can hold no more than nine elements, and can actively process no more than four elements simultaneously.¹¹ This theory emphasises that these limitations only apply to novel information, not old knowledge. Therefore, a senior medic recognises a child with septicaemia caused by meningococcus at a single glance. By contrast, for a medical student, a patient with meningococcal septicaemia may appear to have a rash, fever and poor appetite.

This theory has been used to guide and enhance multimedia learning materials.¹² The design principles and strategies based on CLT are summarised in Table 1. When an initial draft of the e-learning intervention was complete, the slides were individually reviewed and based on each of the principles below, enhanced accordingly. Figure 1 shows several examples of how these principles were applied.

PILOTING AND IMPLEMENTATION

Once the content had been completed within the PPT format, the addition of different animation and interactive elements and compiling to FLASH took one author under 6 hours to complete. The FLASH conversion software allowed a password to be integrated into the program, and this was needed to start the intervention. The program was piloted by the other authors, as well as two paediatric pharmacists and two foundation doctors.

EVALUATION

We measured the effectiveness of the intervention on prescribing skills improvement using a non-blinded randomised controlled trial that has been previously reported in detail.¹³ Volunteers were taken from the 1150 trainees within the North Western Foundation School who enrolled during July–August 2010. A computer-generated random number table produced the allocation sequence, and this was concealed in opaque, sealed, sequentially numbered envelopes. There was no significant difference in the group demographics.¹³ The long-term retention of prescribing skills was demonstrated, with significantly higher prescribing skill scores in the e-learning group. Additionally, scores for teaching satisfaction and confidence surveys were also significantly greater in the e-learning group. These results are presented in Table 2.¹³

Table 1. Principles and strategies for e-learning instructional design based on cognitive load theory

Principle	Design strategy
Split-attention principle	Integration of materials from different sources of multimedia or at different times in a course
Modality principle	It is more effective to use spoken words to describe an image (unimodal) than to display an image with text (multimodal)
Goal-free principle	Use goal-free tasks that provide learners with a non-specific goal
Worked-example principle	Use worked examples that provide a full solution, rather than asking learners to independently find a solution
Completion principle	Use completion tasks that provide a partial answer that student's must finish
Redundancy principle	If one source of information can fully explain an issue to learners, then do not use other sources
Variability principle	Use information, cases or activities that illustrate variability to help learning, such as different patient characteristics
Contextual-interference principle	Randomly order activities, rather than artificially placing them in blocks
Self-explanation principle	Give detailed worked examples that prompt learners to explain new learning; show a video with information and then ask them to explain what they see
Expertise-reversal effect	This is seen when learning methods that worked at the start of instruction become ineffective as expertise increases, so expertise must be taken into account

Feedback was received from 60 of the 70 participants who completed the e-learning. Responses from Likert items were all positive, with mean scores of 4 out of 5 for 'usefulness', 'easy to navigate' and 'convenient'. Free-text feedback is presented as a word cloud in Figure 2. Half of the comments focused on how useful they found the program and its superiority to existing interventions. The time efficiency of this method and the enjoyment of using the program were also key themes. Finally, the grounding of the program in reality, with the use of appropriate scenarios, was mentioned by participants and was felt to give them useful practise, improve confidence and ultimately enhance safety.

IMPLICATIONS

The approach used was a rather novel 'low-fidelity' design, when the existing literature within the field is considered.² With minimal financial outlay, a short development time, no need for new infrastructure, easy future updating and ability to include a variety of media, this approach has indeed overcome many of the previously identified barriers to e-learning.⁵ Given that one of the key challenges for continuing medical education is keeping material contemporaneous, this approach is highly attractive. From the participant feedback, it seems that it has successfully met the theoretical elements identified by Wong as being key to successful e-learning: it has a perceived advantage to learners and offers interactivity with feedback.⁶

This combination of a low-fidelity design approach with clear theoretical underpinning has potential applications throughout medical education. Its strengths not only lie in low cost, but in the ability for this methodology to be used by working


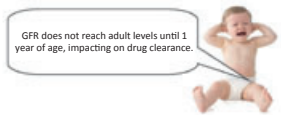
BEFORE	AFTER
<p>Goal free principle – Multiple choice options were removed and replaced with a goal free task. It also asked them to explain what they see (self explanation principle)</p> <p>Spot the potential error</p> <ul style="list-style-type: none"> A video follows which shows a simulated encounter in hospital between a doctor and nurse. Which errors do you see? <ul style="list-style-type: none"> Incorrect dose calculation Incorrect dispensing Incorrect administration Incorrect weight calculation Incorrect communication 	<p>Spot the potential error</p> <ul style="list-style-type: none"> A video follows which shows a simulated encounter in hospital between a doctor and nurse. Can you spot any potential for error? Think about what you would do in this situation.
<p>Worked example principle – A question was replaced with a video demonstrating how to work out a dose using resources. Audio narration was offered (modality principle)</p> <p>How to calculate doses using the BNF by weight (A demonstration follows on the next slide)</p> <ul style="list-style-type: none"> Omeprazole, oral, 18 month old, 10 kg for reflux. <ul style="list-style-type: none"> Look up Omeprazole Confirm indication – reflux disease Confirm route – by mouth Confirm age – in range of 1 month – 2 years What is the solution? 	
<p>Split attention principle – integration of different sources of information spatially and from different multimedia sources</p> <p>Drug administration to Children</p> <ul style="list-style-type: none"> A neonatal brain is large relative to its body size. Muscle bulk is low. This can affect drug distribution GFR does not reach adult levels until 1 year of age, impacting on drug clearance Liver metabolism is not linear, affecting drug metabolism 	<p>Differences between children and adults</p> 

Figure 1. Examples of modifications made to the intervention that were guided by cognitive load theory

clinicians who are responsible for significant programmes of continuing education, in the way that tools such as Moodle have allowed online learning to become widely used.

There are several limitations to this work. Whereas we have applied a number of theoretical elements to this design, it is difficult to ascertain how each element has contributed to the effectiveness of the intervention, and this will need further investigation. The design was of e-learning versus no intervention, and so it is not possible to comment on the effectiveness of the intervention compared with other interventions. In addition, no attempt has been made to assess whether such design

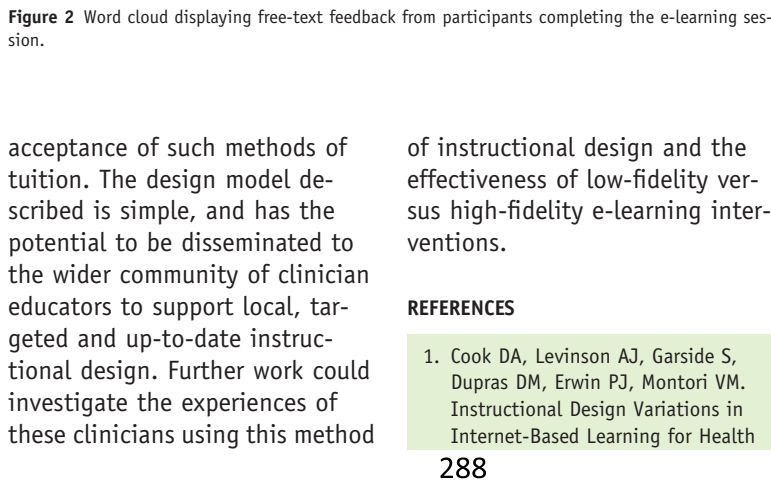
methods are acceptable or usable by clinician educators. Future work reporting the ease with which clinicians can apply these methods and the quality of such interventions is needed. Additionally, comparing e-learning that has been constructed using a low-fidelity approach to an intervention designed using a high-fidelity approach would further investigate the issue of effectiveness versus practicality.

In summary, a low-fidelity approach to design in medical education can successfully overcome many of the barriers to the introduction of e-learning interventions. This method offers perceived advantages to learners, as well as allowing levels of interactivity that are required for the

This approach has overcome many of the previously identified barriers to e-learning

acceptance of such methods of instruction. The design model described is simple, and has the potential to be disseminated to

educators to support local, targeted and up-to-date instructional design. Further work could investigate the experiences of these clinicians using this method.



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When shifting context: the role of context dynamics in educating and understanding handover

Morris Gordon

'The environment is everything that isn't me'

Albert Einstein

The father of modern physics chose a concise and surprisingly existential notion to understand the world around him. He evocatively views the universe that he spent his life trying to quantify as separate and external to the individual. In pondering this notion, I draw on my secondary school level education in physics, which although limited, gives me sufficient insight to understand that Einstein cannot be seeking to remove the individual from their environment. Indeed, I believe he is emphasising that the individual exists within the physical world and, as such, we should always attempt to understand how we can impact and be impacted by the wider external world. This viewpoint successfully frames two different understandings of context within medical education. In this issue, Pimmer *et al.*¹ choose to

align themselves with the view that context is actively produced from interactions between individuals and their environment, rather than viewing context as a distinct well-defined bubble surrounding learners. As such, their insightful research is able to produce a framework that highlights factors influencing learning in a specific context and the different roles that learners assume while achieving that learning. For its development, this model was framed in the context of doctor-to-doctor consultations. Such interactions are indeed common and will mostly occur in the context of, or result in, handover of care.² Handover of care describes two activities that simultaneously occur in undefined and variable measures: the transfer of information and the passing of responsibility.³

Context is actively produced from interactions between individuals and their environment

Handover of care offers both a challenge and an opportunity to educators. The challenge offered is the need to educate staff on how to handover effectively and efficiently. Even though shift-based working has rendered handover a staple of daily life, there is great

variation in educational provision, largely due to the varying perceptions of what handover should look like (the reference standard) and how such education should be constructed.⁴ Previously published work to design such education is limited, both in terms of quantity and quality.⁵ More importantly, these works focus on 'what' such education should offer, while offering little guidance as to 'how' such learning can occur.

The limitations of the literature are partly a reflection of the complexity of the task and partly a lack of true insight into how handover occurs from a psychosocial perspective. A recent study investigated this issue through a qualitative analysis of considerable amounts of observation and proposed several handover patterns.⁶ Each handover pattern constitutes a systematic way of participating in the care transfer process and the authors suggest these are heavily influenced by context, which in turn influences the quality of handover. If this research is considered in the light of the framework for contextual learning proposed by Pimmer *et al.*,¹ clear parallels can be seen.

Within health care, learning and clinical practice are symbiotically

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entwined, giving rise to the importance of situated learning theory in medical education.⁷ As context clearly influences learning, it is just as apparent that clinical behaviour is also influenced by context. In the undergraduate environment,^{8,9} curriculum factors (schedules, learning objectives) have previously been identified as key contributors to an understanding of contextual learning. In the postgraduate setting, Pimmer *et al.*¹ filled the void left by the lack, or perceived lack, of curriculum factors with an interplay of organisational, individual and situational factors forming the 'workplace curriculum'. Given that handover is a paramount activity for safe patient care,² innovative new approaches that are mindful of contextual dynamics of learning in both the undergraduate and postgraduate workplace setting are needed. This can ensure skill acquisition before and during transition to clinical practice, with several examples already reported.^{10,11}

As context clearly influences learning, it is just as apparent that clinical behaviour is also influenced by context

Handover of care also offers an unparalleled opportunity to educators. Handover is a fixed forum for learning that occurs within the busy work schedule. No two handover meetings are identical, but handovers can be multidisciplinary, multiprofessional, interruption free and senior clinician led. This combination of potential contextual variables is too precious a resource to be wasted. Such handover encounters offer almost limitless potential for educators who are constantly struggling to deliver education, often citing a number of barriers to such clinical teaching. Indeed, as context is a key

variable affecting education, recognition of contextual factors that are conducive to the delivery of such education suggests that handover is a premium opportunity to support all manner of effective learning.

Innovative new approaches that are mindful of contextual dynamics of learning in both the undergraduate and postgraduate workplace setting are needed

Just as learning how to handover is heavily influenced by contextual learning factors, learning during handover is inextricably influenced by these same factors. Therefore, educators who have been investigating the learning potential of handovers have suggested that clear organised planning must take place to address these factors and to maximise the potential of each specific encounter.¹² Similar contextual barriers to learning as identified by Sanfey *et al.*¹³ have been found, such as timing and the perceptions of learners. In line with the principles of situated cognition,⁶ learning during handover occurs and is influenced by a dynamic interaction of the learners' capacities and attitudes, as well as other key contextual factors relevant to any specific handover. As such, an understanding of contextual dynamics is key in achieving such learning in an efficient and effective manner.

If we once again consider Einstein's view of the world, the environment is everything apart from the self. As such, context influences not just learning, but doing. When a complex task such as handover is inspected, the two are embedded and intertwined. Health care involves constant interprofessional handover of information and each encounter can be framed as a learning opportunity, as well as a

responsibility to offer effective handover to facilitate patient care. Consideration of contextual dynamics can support both the quality of handover and inform educators in maximising the potential to learn during handover.

Consideration of contextual dynamics can support both the quality of handover and inform educators in maximising the potential to learn during handover

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A better hammer in a better toolbox: considerations for the future of programme evaluation

Kathryn Parker

I suppose it is tempting, if you only have a hammer, you tend to see every problem as a nail

Abraham Maslow (1966)

Known as the law of the instrument, the metaphor does not cast a poor light on the hammer, but on our over-reliance on it. This concept is currently applicable to the field of programme evaluation in health care education. Currently, the four-level, outcomes-driven Kirkpatrick model is the dominant model used to evaluate health care education programming. Noble and rigorous pursuits to improve the use of this model include the paper in this issue by Schonrock-Adema and her colleagues.¹ However, we have become over-reliant on this limited outcomes-driven model, which leads to the query; are we to continue to improve our use of Kirk-

patrick (build better hammers) or do we expand our thinking, and thus our 'toolbox', to understand how complex programmes work to bring about both intended and unintended outcomes? I argue that we need to do both.

Currently, the four-level, outcomes-driven Kirkpatrick model is the dominant model used to evaluate health care education programming

Allegiance to the Kirkpatrick model is understandable. Undeniably influenced by the works of Ralph Tyler, the culture of programme evaluation in 1959 was one that valued measureable, pre-determined outcomes as the means of rendering judgement on the merit or worth of an educational programme. Formal public education evaluation efforts valued knowledge test scores to measure if short-term learning outcomes were achieved. This practice of programme evaluation no doubt influenced evaluation efforts of Kirkpatrick in the private sector.

Dixon brought the model to evaluating health professions education

and in the last 35 years the model has become ingrained in the culture of evaluation of health care education programming. To date, the model has been used to evaluate hundreds of health care education programmes and the measurement at all four levels is still considered the reference standard in programme evaluation.²

Although not Kirkpatrick's original intent, the model's shortcomings lie in its conceptualisation as causal; that outcomes at each level can predict outcomes at the so-called 'higher and more valuable' levels. With this conceptualisation, the model is flawed. Recent work in the field of organisational development found that changes in Level 3 outcomes were better predicted by factors external to the training itself.³

Challenges with this model have been known for some time, so it is perhaps not surprising that efforts continue to improve it; arguing that Level 1 should measure motivation and engagement rather than reaction,⁴ methods to measure Level 1 can be improved¹ and Level 3 should measure performance rather than behaviour.⁵

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Limitations of poster presentations reporting educational innovations at a major international medical education conference

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Background: In most areas of medical research, the label of 'quality' is associated with well-accepted standards. Whilst its interpretation in the field of medical education is contentious, there is agreement on the key elements required when reporting novel teaching strategies. We set out to assess if these features had been fulfilled by poster presentations at a major international medical education conference.

Methods: Such posters were analysed in four key areas: reporting of theoretical underpinning, explanation of instructional design methods, descriptions of the resources needed for introduction, and the offering of materials to support dissemination.

Results: Three hundred and twelve posters were reviewed with 170 suitable for analysis. Forty-one percent described their methods of instruction or innovation design. Thirty-three percent gave details of equipment, and 29% of studies described resources that may be required for delivering such an intervention. Further resources to support dissemination of their innovation were offered by 36%. Twenty-three percent described the theoretical underpinning or conceptual frameworks upon which their work was based.

Conclusions: These findings suggest that posters presenting educational innovation are currently limited in what they offer to educators. Presenters should seek to enhance their reporting of these crucial aspects by employing existing published guidance, and organising committees may wish to consider explicitly requesting such information at the time of initial submission.

Keywords: *patient safety; non-technical skills; human factors; adverse events*

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Background

Quality is a key concern in all fields of medical research. Within clinical medicine, there is a very clear hierarchy of research methods, with higher level methods likely to contribute more to the wider 'clinical truth'. Through work by international organisations that promote systematic review methods, such as the Cochrane Collaboration, evidence can be consistently synthesised to support evidence-based medicine and enhance patient care.

In the world of medical education, the situation is far more complex and challenging. An article in the *British Medical Journal* several years ago sparked an active debate regarding the nature of quality within medical

research (1). The authors concluded that research lacks methodological rigour. This led to responses from scholars in the field within the pages of this journal (2) who were concerned that medical education research 'cannot be viewed in such a uni-dimensional way', and that evidence should not be viewed in hierarchies of quality but should be selected like colours in a rich tapestry. Eva (3) describes this as 'an endless oscillation between promoting the evolving empirically grounded approach and the associated criticisms of the accumulated findings', concluding that quality in medical education research should be based on our understanding of the problems, rather than on whether or not a particular

research methodology has been adopted. Questions such as ‘how’, ‘why’, and ‘when’ education is effective are increasingly being sought from researchers (4).

The ‘Best Evidence Medical Education’ (BEME) collaboration has endeavoured to address such issues and has produced materials for data extraction that seek to view quality in a multi-dimensional manner. Other than supporting evidence synthesis, such materials support the view that quality should not be based on a single arbiter and offer insights into gold standard elements of reporting educational innovations.

Whilst such ideas surrounding the reporting of medical education research are clearly widespread in the literature, it is unclear how much this debate is influencing those who are reporting on research. We set out to assess the quality of poster presentations describing educational innovations at a major international medical education conference from a multi-dimensional perspective.

Methods

At the 2012 Association of Medical Education in Europe (AMEE) International Conference 2012 in Lyon, there were 636 poster presentations in English (5). A random sample of 50% of these was selected for inclusion in the assessment process. Presentations reporting a new innovation or method were included and data extracted using a *pro forma* (Appendix 1). The studies included were analysed in four key areas: reporting of theoretical underpinning, reporting of instructional design methods, describing of resources needed for introduction, and, finally, the offering of materials to support dissemination.

Each of the first 15 posters was assessed by two authors to assess concordance, which was 75%. The discrepancies were analysed, and assessment of a further 10 posters gave 88% concordance in the major assessment items. The remaining posters were evaluated by one author each. Any concerns regarding decisions were discussed between the authors and a consensus was reached.

Results

A total of 312 posters (49%) were assessed. One-hundred and forty-two posters were excluded as they did not report a new educational innovation. This included 7 audits, 72 cross-sectional surveys, 14 narratives, 5 opinion pieces, and 44 service evaluations.

One hundred and seventy poster presentations were included within the analysis. Seventy of these (41%) described their methods of design, 56 (33%) gave details of equipment, and 49 (29%) described resources required. Sixty-one (36%) offered further resources to support dissemination of their innovation. Thirty-nine studies discussed theory or conceptual framework underpinning their work. The remaining 141 (77%) made little, if any, allusion to any such elements; they did often mention

relevant literature, which may have implied an orientation to an appropriate framework, but this was not explicitly stated.

Discussions

Poster presentations at international medical educational conferences enable the dissemination of descriptions of exciting innovations, even if the work has not become the focus of a full-scale research project. In this small study, it has been found that such reports are often lacking in key areas that may be associated with ‘quality’ in the context of educational research.

Before discussing these findings further, it is important to make clear that the authors recognise that the very element we have sought to assess is, by its very nature, not as simple as three or four criteria, as discussed above. In addition, such judgments are also subjective, with the perspectives of the reader often influencing the perceived quality of the research. Nevertheless, it is difficult to overlook that over half of the posters describing innovations offered no details regarding the resources or methods of design. Many focused on whether their intervention was effective, offering data regarding acceptability, changes in attitudes, or changes in knowledge or skills. However, given the relatively small scale or early stage of most of the reported developments, the authors believe that details facilitating dissemination of these, often impressive, innovations should be prioritised over the description of low-powered quantitative outcomes.

The lack of details regarding the theoretical orientation or the consideration of appropriate conceptual frameworks was the starkest finding. These play an essential role in identifying the nature of educational problems and in formulating solutions or designing studies. They help clarify and magnify the issues at hand. The use of frameworks allows authors to be mindful of the assumptions and foundations of their work and makes the process transparent for the reader. For those without an educational background, this may be a new concept, but it is key for informing those reviewing such work and to support future research. In many cases, it is likely that the details are available but simply not presented.

Whilst considering these findings, it must be noted that this is a small study based on a single conference, and only a sample of posters were reviewed. Also, whilst checks were made for concordance, not all presentations were reviewed by two authors. In addition, the authors have focussed on studies reporting educational interventions, but clearly there are many other worthwhile forms of research and innovation that have not been considered within this definition. Finally, our definitions and judgements are ultimately subjective, though given the magnitude of our respective findings, they most likely provide an appropriate approximation.

Conclusions

These findings suggest that posters presenting educational innovation are currently limited in what they offer for educators. Presenters should seek to enhance their reporting to include these important elements. In addition, conference organising committees may wish to consider explicitly requesting such information at the time of initial submission to support the useful dissemination of these works to their attendees.

Conflict of interest and funding

The authors have not received any funding or benefits from industry or elsewhere to conduct this study.

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Appendix 1: Assessment of poster presentations – AMEE 2012

Which session was this poster from (highlight in bold)

2W Posters: Career Choice
 2X Posters: The Education Environment
 2Y Posters: Continuing Professional Development
 2Z Posters: Outcome Based Education
 2AA Posters: Clinical Skills
 2BB Posters: Written Assessment
 3W Posters: Simulation
 3X Posters: Research and Evidence Based Medicine
 3Y Posters: Postgraduate Training 1
 3Z Posters: Problem Based Learning
 3AA Posters: The Student in Difficulty
 3BB Posters: Clinical Assessment
 4W Posters: Faculty Development
 4X Posters: Selection
 4Y Posters: Postgraduate Training 2
 4Z Posters: Curriculum Development
 4AA Posters: Clinical Teaching 1
 6V Meeting: AMEE Simulation Committee
 6W Posters: The Teacher and Evaluation of the Teacher
 6X Posters: Basic Sciences
 6Y Posters: The Doctor as Teacher/Training the Surgeon
 6Z Posters: Curriculum Development 2
 6AA Posters: Clinical Teaching 2
 6BB Posters: Feedback and Online Assessment
 7W Posters: The Student as Teacher
 7X Posters: Professionalism
 7Y Posters: GP Education, Mentoring and Postgraduate Education
 7Z Posters: Curriculum Evaluation
 7AA Posters: Communication Skills
 7BB Posters: Teaching and Learning Methods and Students' Learning Styles
 8W Posters: eLearning Case Studies 1
 8X Posters: Interprofessional Education
 8Y Posters: Health Promotion and Public Health
 8Z Posters: Community Oriented Medical Education
 8AA Posters: Lectures and Learning Resources
 8BB Posters: Student Engagement and the Student as Teacher
 9W Posters: eLearning Case Studies 2
 9X Posters: Leadership/Management
 9Y Posters: Reflection, Clinical Reasoning and Critical Thinking
 9Z Posters: Team Based Learning/Case Based Learning
 9AA Posters: Selection and The Student and Resident in Difficulty
 9BB Posters: Students
 10W Posters: Patient Safety
 10X Posters: Ethics and Empathy

10Y Posters: Work Based Assessment
 10Z Posters: Curriculum Evaluation and Electives
 10AA Posters: Active and Student Centred Learning
 10BB Posters: Assessment

Was the poster reviewed or just abstract review? (delete as appropriate) Poster Abstract

What type of work does this describe? (highlight in bold as appropriate)

RCT / Before and after trial / Action based / case control / Cohort / - **PLEASE CONTINUE**

Opinion / Audit / Service evaluation / descriptive / Narrative - **NO FURTHER INFORMATION REQUIRED**

Is relevant educational theory or general theoretical underpinning discussed with this presentation? YES – (please give details) / No

Are resources, design methods and equipment needed described? YES (give details) / No / N/A

If yes, please state on a scale of 1–5 how useful this is, 1 being limited and not of great benefit, 5 supporting widespread replication.

If the presentation could potentially be disseminated, are materials given to support this? YES (give details) / No / N/A

If yes, please state what type or give details below:-

Handout material (not relevant if just poster handout or summary) / Links for download / Example materials shown

If yes, please state on a scale of 1–5 how useful this is, 1 being limited and not of great benefit, 5 supporting widespread replication.

Appendix 3

Statement regarding candidate's independent work

Scholarly research, particularly systematic reviews, are typically team endeavours. This is often a necessary part of the research in order to reduce bias, an inherent part of the systematic review methodology. Systematic review teams also need to be comprised of subject specialists and subject methodologists for example information search experts, statisticians and economists, who each bring a unique and valuable contribution to the systematic review. This team approach is therefore reflected in the majority of the papers included for consideration as the research study would not have taken place without each team member's participation. However the candidate has made a unique and independent contribution in each of the papers – and it is this contribution which should be under scrutiny. These contributions are specified below and confirmed in the statements of the co-authors that will be signed in the final submission of this thesis (appendix 3).

Study	Independent/Unique Contribution	Joint Contribution
Paper 1: Gordon, M., Findley, R. (2011). Educational interventions to improve handover in health care: a systematic review	Designed the protocol, led the completion of the review, led the writing of the manuscript and submission process	Completed search, data extraction and analysis with Rebecca Findley
Paper 2: Gordon, M. (2013a). Training on handover of patient care within UK medical schools.	Wholly independent work.	
Paper 3: Darbyshire, D., Gordon, M., Baker, P. (2013). Teaching handover of care to medical students.	Integrated the theoretical elements of handover model into educational package, led writing of these elements of manuscript, contributed to and edited all versions of manuscript.	Daniel Darbyshire conceived the project, led the project and delivered the teaching. Paul Baker commented on drafts of the script
Paper 4: Gordon, M., Catchpole, K., Baker, P. (2013). Human factors perspective on recent medical graduates'	Conceived the study, wrote the protocol, led ethical approval process, carried out the data collection and analysis, led the writing of the manuscript.	Paul Baker completed coding of data and analysis with Morris Gordon and contributed to the final writing. Ken Catchpole gave input regarding human factors perspectives on the manuscript and analysis

prescribing behaviour: Implications for educators.		
Paper 5: Gordon, M., Darbyshire, D., Baker, P. (2012). Educational interventions to improve patient safety: A systematic review.	Designed the protocol, led the completion of the review, led the writing of the manuscript and submission process	Completed search, data extraction and analysis with Daniel Darbyshire, Paul Baker commented on drafts of the review and the final document.
Paper 6: Gordon, M., Bose-Haider, B. (2012). A novel error feedback system to enhance paediatric prescribing.	Design of study, data analysis and interpretation and carrying out of the study. Led the writing of manuscript	Bratati Bose Haider conceived the idea for the study, commented on drafts of the protocol and manuscript
Paper 7: Gordon, M., Holt, K., Lythgoe, J., Mitchell, A., Hollins-Martin, C.J. (2013). Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals.	Conceived, designed and implemented the TOSCE within the university setting, led the data collection, analysis and the manuscript write up.	Co-authors supported the carrying out of the TOSCE process and commented on drafts of the paper
Paper 8: Gordon, M. (2013b). Non-technical skills training to enhance patient safety.	Wholly independent work.	
Paper 9: Gordon, M. (2013c). Building a theoretically grounded model to support the design of effective non-technical skills training in healthcare: The SECTORS model	Wholly independent work.	

Appendix 4

Letters confirming author's contributions

Flat 4 Red Lodge

Oak Lane

Sevenoaks

Kent

TN13 1UH

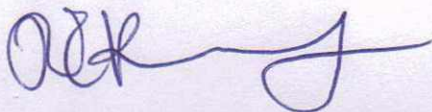
31st July 2012

To Whom It May Concern,

Re: Contributions to the paper "Educational interventions to improve handover in health care: A systematic review"

I am writing to confirm that Morris Gordon conceived the project, wrote the protocol, completed the search and analysis, and led the write up. I, Rebecca Findley, commented on drafts of the protocol, completed the search and analysis, and commented on drafts of the write up.

Yours sincerely,

A handwritten signature in blue ink, appearing to be 'R Findley', with a long horizontal flourish extending to the right.

Dr Rebecca Findley

To whom it may concern:

Darbyshire D, Gordon M, Baker P. 2012. Teaching handover of care to medical students. Clinical Teacher.

In relation to the research described in the above paper, I am writing to confirm that Morris Gordon's unique contribution the project was to apply the handover model of care to support educational design and to apply appropriate pedagogy to support this design process, as well as supporting and contributing to all stages of manuscript synthesis. Daniel Darbyshire conducted the content analysis of qualitative data and managed the project overall at all stages. Paul Baker was jointly responsible for the manuscript writing.

Gordon M, Darbyshire D, Baker P. 2012d. Educational interventions to improve patient safety: A systematic review. Med Educ 46:1042-54

In relation to the research described in the above paper, I am writing to confirm that Morris Gordon's unique contribution the project was to conceive the project, lead the writing of the protocol and manuscript and manage the project overall. He was jointly responsible for the data collection, extraction and analysis.

Sincerely

A handwritten signature in black ink, appearing to be 'D. Darbyshire', with a large loop at the start and a long horizontal stroke at the end.

Mr Daniel Darbyshire
MBBS PGDip MRCS FHEA

Department name

3rd Floor
3 Piccadilly Place
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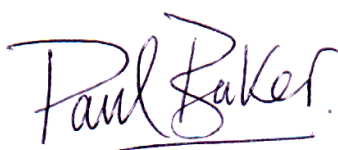
1st October 2013

To whom it may concern,

RE: Gordon M, Catchpole K, Baker P. 2012. Human factors perspective on recent medical graduates' prescribing behaviour: Implications for educators. Advances in Medical Education and Practice.

In relation to the research described in the above paper, I am writing to confirm that Morris Gordon's unique contribution the project was to conceive and design the protocol, lead the data collection and analysis, support educational design and to apply appropriate pedagogy to support this design process, conduct the content analysis of qualitative data and manage the project overall. He was jointly responsible for the data analysis and the manuscript writing.

Yours sincerely,



Professor Paul Baker
Director of Foundation Training

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Our ref:- BBH/JS/Gordon

Typed:- 7/10/2013

To Whom It May Concern:

RE: Gordon M, Bose-Haider B. 2012e. A novel error feedback system to enhance paediatric prescribing. International Journal of Risk and Safety in Medicine, 1;24:207-14.

In relation to the research described in the above paper, I am writing to confirm that Morris Gordon's unique contribution the project was to lead the writing of the protocol and manuscript and manage the project overall. He was responsible for the data collection and analysis.

Yours sincerely



Dr Bratati Bose-Haider, MD, FRCP (London), FRCPC, DCH (London), DCCH
Consultant Paediatrician-Community Child Health
Clinical Director – Children's Directorate

To whom it may concern,

RE: **Gordon M**, Holt K, Lythgoe J, Mitchell A, Hollins-Martin CJ. 2012f. Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals. Journal of Interprofessional Care, Oct 3

I can confirm, that Morris Gordon's unique contribution to the project was to conceive the project, lead the writing of the protocol and manuscript and manage the project overall. He was jointly responsible for the data collection and analysis. We value his commitment and continued support.

Yours sincerely,

KMHolt

Kathleen Holt MSc, PgDip, BSc (Hon), RM, RGN

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4th February 2013

To whom it may concern,

Re the paper:

Gordon M, Holt K, Lythgoe J, Mitchell A, Hollins-Martin CJ. 2012f. Application of the team objective structured clinical encounter (TOSCE) for continuing professional development amongst postgraduate health professionals. Journal of Interprofessional Care, Oct 3. [Epub ahead of print]

In relation to the research described in the above paper, I am writing to confirm that Morris Gordon's unique contribution to the project was to conceive the project, lead the writing of the protocol and manuscript and manage the project overall. He was jointly responsible for the data collection and analysis.

Yours Sincerely



Prof Caroline J Hollins Martin
PhD MPhil BSc PGCE RMT ADM RGN RM MBPsS

Appendix 5

Presentations at scientific meetings

- 1) Gordon, M. (2012). Building a theoretical model to support non-technical skills training in healthcare: The SECTORS model. Presented at the Association for Medical Education in Europe annual scientific meeting, 27 – 29th August 2012. Lyon, France.
- 2) Gordon, M. (2012). Improving handover of care through education: A theoretical model. Presented at the Association for the study of medical education annual scientific meeting 16-18th July 2012. Brighton, UK.
- 3) Gordon, M. (2012). Educational interventions to enhance non-technical skills in healthcare. Presented at the Association for the study of medical education annual scientific meeting, 16-18th July 2012. Brighton, UK
- 4) Gordon, M. (2012). A novel educational intervention on handover of care to support patient safety in gastroenterology practice. Presented at Digestive Disease week. 19 – 23rd May 2012. San Diego, USA.
- 5) Gordon, M., See, L., Bose-Haider, B. (2012). Error awareness to enhance prescribing in Paediatrics. Presented at the Royal College of Paediatrics Annual meeting. 19 – 23rd May 2012. Glasgow, Scotland.
- 6) Gordon, M., Naidoo, K., Thomas, A., Akobeng, A. (2011). Osmotic and stimulant laxatives for the management of functional childhood constipation. Presented at the British society of paediatric gastroenterologists, hepatologists and nutritionalists annual trainees meeting, 5th Oct 2011, London, UK
- 7) Gordon, M., Chandratilake, M., Baker, P. (2012). A short educational interventional to improve paediatric prescribing: An RCT. Presented at the Association for medical education in Europe annual scientific meeting, 25 – 27th August 2011, Vienna, Austria.
- 8) Gordon, M. (2012). Training in handover of care: The situation in UK medical schools. Presented at the Association for the study of medical education annual scientific meeting, 20-22nd July 2012. Edinburgh, UK
- 9) Gordon, M., Chandratilake, M., Baker, P. (2012). A short educational interventional to improve paediatric prescribing: An RCT. Presented at Association for the study of medical education annual scientific meeting, 20-22nd July 2012, Edinburgh, UK.
- 10) Gordon, M., Chandratilake, M., Baker, P. (2012). A low fidelity but high quality e-learning intervention to improve prescribing: pedagogical and theoretical underpinning.

Presented at the Association for the study of medical education annual scientific meeting, 20-22nd July 2012. Edinburgh, UK

- 11) Gordon, M., Naidoo, K., Thomas, A., Akobeng, A. (2011). Osmotic and stimulant laxatives for the management of functional childhood constipation. Presented at the Digestive Disease week. 7 – 10th May 2011. Chicago, USA
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