Introduction

Newborn babies in the Neonatal Intensive Care Unit (NICU) often require numerous radiological examinations during their first weeks of life¹. Due to the increased sensitivity of newborns to ionising radiation, it is important to reduce the radiation dose where possible without compromising image quality. NICU is one of the most critical areas for dose optimisation, as it has the youngest patients, who often require multiple imaging exams². Neonates are maintained in the incubator and warmer systems to ensure a well-regulated, stable and protective environment, which also reduces the chance of infection. Carver and Carver suggested that opening the incubator may change temperature within the incubator which can adversely affect the neonate³. To perform radiographic imaging of neonates, a mobile radiography system is used together with an image receptor (IR). The radiographer can place the neonate directly onto the IR or use the built-in tray/slot; both these methods have their benefits and limitations⁴. Placing the neonate directly onto the IR results in an image with minimal magnification and allows for simple positioning and collimation checks. In addition, there are no objects between the neonate and the IR resulting in limited additional attenuation from other structures. However, placing the IR in the tray eliminates unnecessary movement of the neonate during imaging and therefore minimising the risk of accidental displacement of catheters, endotracheal tubes or other support devices. It also has potential benefits from an infection control perspective. When the IR is placed within the tray, it makes judgements regarding collimation and alignment more difficult, and also the radiation beam must pass through the extra thickness of the mattress and the IR holder, which reduces beam attenuation and consequently detector dose ^{1, 2, 5, 6}. A further variable is the presence or removal of the incubator canopy (lid). This is typically left in place, but provides further reduction in beam attenuation and consequently, it is necessary according to Rizzi and colleagues, to increase the exposure factors⁶.

As seen above, issues with incubator imaging are often acknowledged within the literature. However, limited evidence is available to allow standardisation of this type of imaging. Little is known about the effect of incubator design on image quality and radiation dose. Many assumptions are made regarding the need for modification of acquisition parameters to compensate for placing the IR within the tray⁶. A review of current literature is required to explore the optimal methods for imaging a neonate within an incubator and the consequences of incubator design on image quality and radiation dose.

Method

A systematic review was carried out following guidance provided by the Cochrane Collaboration⁷.

Eligibility criteria

Articles were included if they were written in English and explored radiation dose and/or image quality in relation to neonatal incubator imaging. If studies explored neonatal incubator imaging but did not consider or make reference to incubator design and the consequential effect on technique (attenuation, tray, mattress) then they were excluded. In other words, the effect of the incubator on imaging must be the primary focus of the included studies. All relevant study designs were permissible with the exclusion of ideas, opinions, case studies and editorials. Only studies published after 2004 were included, that was due to technological advancement both in radiographic equipment and incubator design.

Sources

To ensure all relevant published studies were identified, a wide range of databases were searched including: Medline via Ovid (2004 to present), Pubmed (2004 to present), Science Direct (2004 to present), Cumulative Index to Nursing and Allied Health (CINAHL) (2004 to present) and the Cochrane Library Database (2004 to present). In addition, the reference list of each relevant article was searched for additional publications in accordance to the eligibility criteria.

Search strategy

A search strategy was performed for each individual database, this included keyword terms, synonyms, and the AND/OR qualifiers. The "Medical Subject Heading" (MeSH) was used to help identify related keywords which enabled the development of the key terms for searching (**Table 1**)

Study selection and data extraction

Following the search strategy, duplicates were removed and the remaining studies were screened by two independent reviewers using the title and abstract in conjunction with the eligibility criteria. Both reviewers met to compare findings; any differences in reviewers' judgements were resolved through discussions until a consensus was reached. The included papers were then screened for full text inclusion against the eligibility criteria by the same two independent reviewers. The quality of each study was assessed using modified questions (to account for phantom studies) from the Critical Appraisal Skills Programme Oxford UK (CASP) diagnostic checklist⁸.

The CASP diagnostic checklist was then applied to all eligible studies for assessing the quality and presence of bias in the included papers. Each article was provided with a score from 0-7. If the answer to a question was 'yes' it was scored 1, but if the answer to a question was 'cannot tell' or

'no' a score of 0 was awarded for that question. The result of this second phase of screening was the same as previously where the two reviewers debated until consensus was reached.

Due to the limited literature identified on incubator imaging during the search strategy, all studies identified were included within the review regardless of quality scoring. This was to ensure that all relevant literature was included. The quality of these studies were, however critically evaluated with their outcomes heavily scrutinised within the review analysis.

<u>Results</u>

The PRISMA flow chart (**Figure 1**) summarises the literature review search results⁹. Following the initial search, 84 studies were identified, 24 were duplicates with the remaining 60 proceeding for screening. Following screening, 25 papers qualified for full text review and confirmation of eligibility (**Figure 1**). Upon extraction, both reviewers agreed that on closer inspection that 18 of the papers did not meet the inclusion criteria. Although these 18 papers explored image quality and/or radiation dose of neonates within incubators, they did not consider the impact of incubator design on image quality and radiation dose. Two of the remaining seven articles were conference abstract papers and following deliberation between the reviewers, these were included as they did meet the inclusion criteria.

Overall, seven relevant articles were included within the review. The studies were of average quality with CASP scores ranging from 2-5 out of a possible 7 (**Table 2**). The reviewers had no disagreements with the scoring of article quality. Five of the seven papers were published within the last 10 years, with the remaining two papers published between 10-15 years. These seven papers accounted for 99% of the studies found within the search of literature (only 1 study was identified prior to 15 years).

All studies identified were different in terms of research question and the methodology used; therefore comparison of outcome measures was difficult. There was wide variation between the attenuation values recorded for different incubator components, however this was expected owing to methodological differences in how attenuation was calculated in terms of units used as well as which incubator components were considered (**Table 3**).

Jiang and colleagues² considered the attenuation of the mattress and mattress support individually but not the canopy, whereas Mutch and Wentworth⁵ along with Rizzi and colleagues⁶ explored the attenuation of the canopy and then the mattress and mattress support combined (but not individually). Rattan and Cohen¹⁰ compared the attenuation of four different comfort pads/mattresses but did not consider the incubator canopy nor mattress support. Both studies from Del Rio^{1, 11} considered attenuation and made reference to the reduction in radiation dose reaching the IR, however no information was provided on which incubator components were considered and no numerical values were available regarding the stated reduction. This was due to the studies being conference abstracts. Slade and co-workers¹² did not consider attenuation values but instead retrospectively explored differences in image quality between direct exposure and tray exposure which indirectly reflects attenuation impact. Owing to the above methodological differences, there was a wide variation in recorded attenuation values for incubator components ranging from 12%-72%. These values are influenced by methodology differences but also they are influenced by the make and manufacturer of the incubator, however this was difficult to quantify as only two studies specified the type of incubator used^{2,5}. In addition, the studies whom provided attenuation values for various different components of incubator design (individual components and combined) calculated the percentage difference or percentage reduction between a direct exposure (without any attenuator) in comparison to exposures with various different incubator component in-between the X-ray tube and image receptor. These calculations were obtained at the surface the image receptor or phantom for each scenario using different units such as ESD^{1,11} and exposure index¹⁰ and therefore it is difficult to compare these attenuation values reliably due to these methodological variations.

Six of the seven studies were phantom based studies who all found that incubator components reduced beam energy hence the amount of radiation reaching the IR if placed in the incubator tray **(Table 3)**. This reduction was correlated with image quality in five studies, with Del Rio and Jiang^{1,2} suggesting reduced image quality when using the incubator tray in comparison to Mutch and Wentworth, Rizzi et al. and Slade et al. ^{5,6,12} who found no significant difference in image quality. Three of the five studies used a Leeds Test Object TOR phantom^{1,5,6} which is designed for routine quality control to quantify the degree of threshold contrast in each image. A Leeds Test Object does not resemble clinical imaging and therefore this method may not always be suitable for evaluating different imaging systems or imaging techniques, since their contrast could behave differently to the contrast of clinically relevant details with changing acquisition parameters¹³.

Jiang et al.² on the other hand used an objective measure of image quality which was contrast to noise ratio (CNR). CNR has been used successfully as a measure of image quality in various optimisation studies ¹⁴⁻¹⁷. In comparison to SNR, CNR takes into consideration the effect of noise on our ability to distinguish objects within the image because visibility depends on contrast (the difference between signals). A highly exposed image may have a high SNR but show no useful information on that image¹⁸. According to the study by Jiang et al.², CNR increased by 28-36% when removing the mattress and support tray from the primary beam but whether this increase in CNR would impact visual image quality using human observers is unknown. It must also be remembered that CNR does not include the display and observation steps of the imaging process and therefore does not truly reflect clinical processes. The study by Slade et al.¹² was the only study to use visual grading analysis (VGA) with a criteria-based scoring system on actual neonatal chest images. However, this study did not consider radiation dose and was limited by numerous confounding variables such as radiographer practice variation, equipment variation, neonatal size and weight variation which is seen by the fact that most X-ray examinations performed using incubator tray for the study were on very premature neonates in comparison to direct exposures performed on larger neonates. This means that comparisons within this study were flawed.

The effect of incubator components on image quality has been considered previously, however consideration must be given to radiation dose. Although the seven studies reported that incubator components reduced/absorbed X-ray beam intensity, there was limited evidence on whether this required an increase in exposure factors. The report by Rizzi and colleagues⁶ was the only study which suggested increasing exposure parameters to accommodate for the increase in beam attenuation when using an incubator tray, however this recommendation was based on an assumption rather than evidence of any correlation with image quality.

Balancing radiation dose and image quality is the forefront of optimisation as sufficient image quality is required for the lowest possible radiation dose. National legislation exists¹⁹ together with national and international guidelines ²⁰⁻²² recommending the importance of reducing radiation dose whilst maintain image quality. These national and international guidelines predominantly focus on traditional methods of imaging and do not expand to more unconventional imaging situations such as incubator imaging. When considering radiation dose there are many methods (direct and indirect) which can be used to estimate radiation dose (examples DAP, IAK, ESD, E). Within the studies reviewed, three used detector dose or radiation dose at the surface of each incubator component in order to assess attenuation ^{2,5,6}. Detector entrance exposure (DEE) unit is not a universally accepted dose quantity and has limited use in optimisation studies. It is also not cited in radiation protection reports such as those from the International Commission on Radiological Protection (ICRP)^{22, 23}. From a radiation protection perspective, detector dose does not consider the risk to the patient and it is also not fully understandable in terms of its correlation with image quality therefore it must be carefully interpreted. The study by Rattan and Cohen¹⁰ used exposure index as a metric to reflect attention and dose reduction but again exposure index is a controversial quantity due to its lack of standardisation and needs to be considered carefully especially in terms of how it translates into clinical practice. Only one from the seven articles calculated effective dose¹¹ which

considers the associated risk of the exposure to the neonate and yet this was the study by Del Rio and colleagues whereby only the abstract was available and therefore did not disclose any numerical data/statistics to support the assumption that using the incubator tray as oppose to a direct exposure increases radiation risk.

Another factor that makes it very difficult to compare the studies under review is the acquisition parameters used within them (Table 4). A variety of different tube potentials and current time product combinations were used as well as various SIDs. Currently there are no set guidelines for neonatal chest imaging within an incubator, with the exception of the European Commission²⁰, however, they do not consider neonatal incubator components and design and were also based on film-screen. The studies under review have therefore either used parameters based on local current practice or have followed the recommendations of the European Commission despite their limitations. Although the European Commission did not consider incubator components and the difference between direct and tray exposure when recommending acquisition parameters, they have within the same document made a generic statement regarding the importance of using low attenuating materials for imaging to allow for reduction in patient dose for example table tops and grids²⁰. This is reinforced by work from Mutch and Wentworth⁵ and Jiang and colleagues² who also recommend within their studies that manufacturers need to consider the thickness and construction of incubator support, mattress and canopy and to consider alternative materials that are more radiolucent to ensure minimal beam attenuation. Yet again as suggested by Tugwell and colleagues²⁴, manufacturers tend not to specify the density and construction of the materials and components used for various medical equipment which makes it difficult to compare and explore this issue further. Mutch and Wentworth found that construction and material across incubators are similar with most of the attenuation caused by the mattress support⁵. However, Jiang argues that the attenuation of comfort pads vary between different makes of incubator, even by the same manufacturer². These conflicting findings may be based on the method used to evaluate image quality as small changes in image quality may be more apparent in objective measures such as CNR in comparison to visual changes witnessed by human observer ^{25,26}.

Discussion

An informative systematic review has been performed identifying seven articles that consider incubator design and their influence on image quality and radiation dose when imaging neonates. Although the quality of the studies varied owing to methodological flaws in each piece of work, the findings within these studies are still important and highlight an unconventional area of imaging requiring further standardisation and optimisation. All studies found a reduction in beam energy

reaching the IR however there was considerable variation in terms of how much attenuation and the impact this reduction had on image quality and radiation dose risk to patients. This reduction in beam energy reaching the IR *will* have an impact on image quality as there is a reduction of photons reaching the IR, however, whether this is significant and impacts on visual image quality is a question yet to be fully answered. All studies failed to correlate their findings with visual image quality in addition to data on the radiation risk associated with incubator imaging. Perhaps the limited evidence on visual image quality relates to most studies using a physics phantom for image quality evaluation instead of either an anthropomorphic neonatal phantoms or control clinical trials which would evaluate clinical practice more accurately. The seven studies therefore are limited in their practical implications in terms of translation into clinical practice.

Another factor to consider when synthesising the results of this review is that imaging equipment has changed over recent years due to healthcare demands, technological advances and safety regulations and therefore it is important to conduct experimental work that not only simulates clinical practice but uses up to date and current technology employed in clinical practice. None of the seven studies within the review used direct digital radiography; only CR was used and therefore this needs to be explored further using technology that is becoming wide spread in clinical practice.

When taking into account incubator design and components, and how these features impact/differ between direct exposure and tray exposure, attenuation is not the only factor to consider. The difference in object to image distance (OID) will also vary as seen for trolley imaging²⁴. None of the seven articles explored this increase in OID and calculated the difference or evaluated impact on magnification and geometric unsharpness. Mutch and Wentowrth did however make an assumption based on the inverse square law that the difference in OID between direct exposure and tray exposure may have accounted for one-fifth of the reduction see in IR dose within their study⁵. In theory, the closer the object being imaged is to the IR (reduced OID), the less the magnification, and the better the geometric sharpness^{27, 28}. To overcome this issue, a slight increase in SID is required which will reduce magnification but also reduce radiation dose to the patient²⁹. However, this may not always be possible for incubator imaging as there are restrictions to increasing SID e.g. incubator height, radiographer height and the portable machine design ^{24, 30}. Tugwell et al. also highlights the importance of the radiology department being involved in the procurement stages when considering and purchasing new imaging equipment such as incubators²⁴. It is important that incubator height can be lowered to ensure maximum SID can be achieved which also allows for collimation to be closed to the area of interest as more area is covered with increased SID due to beam divergence.

Limitations

Owing to the limited studies available on incubator imaging identified from the search strategy, the study quality threshold was potentially compromised and therefore both lower quality studies and conference abstracts were included within the review. The aim of this systematic review was to identify all evidence relevant to the research questions and this may sometimes necessitate the inclusion of 'grey literature' and those of lower quality. Even though these articles may be deemed of lower quality, their findings are still relevant but need to be considered more carefully. A clearly defined search strategy was established prior to review and the decision to include conference abstracts was based on recommendations within the literature ^{33,34}. Conference abstracts potentially contain a lot of information and when considering the limited literature on this subject, the inclusion of this information was both important and justified. Furthermore, the potential contributions of grey literature to systematic reviews are becoming increasingly more apparent.

The safety of the neonate when comparing direct and tray X-ray exposures was not explored within any of the included studies and therefore no conclusions were drawn as to the benefits of tray exposures when compared to those undertaken with direct contact to the neonate. Previous, historic studies, have demonstrated hypoexemia³¹ and bradycardia^{12,32} when moving and handling neonates but this needs to be explored further, especially in terms of its relationship with radiographic imaging.

Conclusion

The literature clearly demonstrates that with existing incubator designs, the X-ray beam is attenuated considerably when the image receptor is placed in the incubator tray as oppose to directly behind the neonate. However, this attenuation is not well correlated with both the radiation dose risk to the neonate and the resultant image quality .This is confusing and poses challenges when defining best clinical practice. Within the literature there is limited visual evaluation of image quality using anthropomorphic phantoms together with limited evidence on effective dose and the risk associated with the exposure of a neonate within an incubator.

Current studies on incubator imaging have been radiology led, with a focus on radiation dose, attenuation and image quality. However, there needs to be a more holistic multi-disciplinary

approach to investigating the numerous factors that could affect neonates during radiographic imaging. A larger clinical study is required that considers not only the radiological aspect of incubator imaging but also the safety considerations from a nursing perspective (moving and handling, infection control) together with the medical aspect e.g. diagnostic yield. What is optimal from a radiology perspective may be outweighed by other associated risks/benefits. Within radiology, an anthropomorphic phantom-based study estimating effective dose as well as evaluating visual image quality is warranted to more fully explore the numerous variables/factors associated with incubator imaging.

References

 Del Rio V, Satta L, Fanti V. Radiologic imaging of the newborn inside the incubator. Radiation dose and image quality. Abstracts of the 9th National Congress of the Associazione Italiana di Fisica Medica. Physica Medica 2016; 3: e71–e96

2. Jiang X, Baad M, Reiser I, Feinstein K, Lu Z. Effect of comfort pads and incubator design in neonatal radiography. Pediatr Radiol *2016* 46(1): 112-118

3. Carver E, Carver B. Medical Imaging: Techniques, Reflection & Evaluation. 2nd ed. Philadelphia: Churchill Livingstone; 2012

Ehrlich R, Coakes D. Patient Care in Radiography: With an Introduction to Medical Imaging. 9th ed.
 Missouri: Mosby; 2016

5. Mutch SJ, Wentworth SD. Imaging the neonate in the incubator: an investigation of the technical, radiological and nursing issues. Br J Radiol *2007;* 80: 902–910

6. Rizzi E, Emanuelli S, Amerio S, Fagan D, Mastrogiacomo F, Gianino P, Cesarani F. Optimization of Exposure Conditions for Computed Radiology Exams in Neonatal Intensive Care. Open Journal of Radiology 2014; 4: 69-78. doi: 10.4236/ojrad.2014.41009

7. Higgins JPT, Green S, editors. Cochrane handbook for systematic reviews of interventions version
5.1.0 [updated September 2018]. The Cochrane Collaboration; 2018. Available from: http://handbook.cochrane.org [accessed 11.10.18].

8. Critical Appraisal Skills Programme (CASP). 2013. CASP Diagnostic Checklists. Available from: https://casp-uk.net/casp-tools-checklists/[Accessed January 2019]

9. Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-Analyses: The PRISMA Statement. PLoS Med 2009; 6(7): e1000097. doi:10.1371/journal.pmed1000097

10. Rattan AS, Cohen MD. Removal of comfort pads underneath babies: a method of reducing radiation exposure to neonates. Acad Radiol *2013;* 20: 1297–1300

Del Rio V, Satta L, Fanti V. Radiologic imaging of the newborn inside the incubator. part
 risk estimation . Abstracts of the 9th National Congress of the Associazione Italiana di Fisica
 Medica *In: Physica Medica 2016; 32, e71–e96.* http://dx.doi.org/10.1016/j.ejmp.2016.01.259

12. Slade D, Harrison S, Morris S, Alfaham M, Davis P, Guildea Z, Tuthill D. Neonates do not need to be handled for radiographs. Pediatric Radiology 2005; 35(6):608-11. DOI: 10.1007/s00247-005-1414-x

Kupinski, MA. Evaluation and Image Quality in Radiation-Based Medical Imaging. In C. Grupen, I.
 Buvat (Eds.), Handbook of Particle Detection and Imaging (pp. 1083-1093). Berlin: Springer-Verlag;
 2012. DOI. 10.1007/978-3-642-13271-1_43

14. Hess, R., & Neitzel, U.Optimizing image quality and dose for digital radiography of distal pediatric extremities using the contrast-to-noise ratio. *Rofo*, 2012; 184(7): 643-9. doi: 10.1055/s-0032-1312727

15. Mori M, Imai K, Ikeda M, Iida Y, Ito F, Yoneda K, Enchi Y. (2013). Method of measuring contrastto-noise ratio (CNR) in nonuniform image area in digital radiography. *Electronics and Communications in Japan,* 96(7), 32--41. DOI: 10.1002/ecj.11416

16. Goenka AH, Herts BR, Dong F, Obuchowski N, Primak AN, Karim W, Baker M. Image Noise, CNR, and Detectability of Low-Contrast, Low-Attenuation Liver Lesions in a Phantom: Effects of Radiation Exposure, Phantom Size, Integrated Circuit Detector, and Iterative Reconstruction. *Radiology:* Volume 280: Number 2—August 2016

17. Kim H, Park Ch, Chae H, Lee SM, Goo JM. Impact of radiation dose and iterative reconstruction on pulmonary nodule measurements at chest CT: a phantom study. Diagn Interv Radiol. 2015 Nov-Dec; 21(6): 459–465

 Vladimirov, A. Comparison of image quality test methods in computed radiography. (MSc Thesis), University of Tratu, Estonia. 2010; Retrieved from: http://dspace.utlib.ee/dspace/bitstream/handle/10062/15191/Vladimirov_Anatoli.pdf;jsessionid=80 A1A82F275CF25DA0B99383FFB3DACB?sequence=1

19. Ionising Radiation((IR)[ME](MedicalExposure)). (2018). The ionising radiation (medical exposure) regulations 2000.Statutory instrument. Available from:

20. European Commission (1996) European guidelines on quality criteria for diagnostic radiographic images in paediatrics , Report EUR 16261EN

21. International Atomic Energy Agency. (2009). Justification of Medical Exposure in Diagnostic Imaging. Proceedings of an International Workshop. September. Brussels: IAEA. Retrieved online from: http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1532_web.pdf 22. International Commission on Radiological Protection (ICRP). (2007). The 2007 recommendations of the ICRP on radiological protection, publication 103. *Annals of ICRP*, 37(2-4), 1-332.

23. International Commission on Radiological Protection. (2005). Basis of dosimetric quantities used in radiological protection'. Draft for discussion by Task Group of ICRP Committee 2. Available from: http://www.icrp.org/docs/physics_icrp_found_doc_for_web_consult.pdf

24. Tugwell-Allsup J, England A, Hogg P, Legg JS. Challenges Associated With X-ray Imaging of Stretcher-Bound Patients. Radiol Technol 2017;89(2):159-172.

25. De Crop A, Smeets P, Van Hoof T, et al. Correlation of clinical and physical-technical image quality in chest CT: a human cadaver study applied on iterative reconstruction. *BMC Med Imaging* 2015;15:32. doi:10.1186/s12880-015-0075-y

26. A. Meijer, A, Buissink C, Hogg P. Radiation dose, image quality optimisation, the use of new technology y in medical imaging. (OPTIMAX 2017) Oslo, Norway; 2017. Retrieved from: http://usir.salford.ac.uk/id/eprint/46104/7/OPTIMAX%202017%20ed.pdf [Accessed 12/06/2019]

27. Bushong S. *Physics, Biology, and Protection. Radiologic Science for Technologists*. 10th ed. Missouri: Elsevier; 2013.

28. Fosbinder R, Orth D. *Essentials of Radiologic Science*. Philadelphia: Lippincott Williams and Wilkins; 2011.

29. England A, Evans P, Harding L, Taylor E, Charnock P, Williams G. Increasing source-to-image distance to reduce radiation dose from digital radiography pelvic examinations. Rad Tech 2015; 86(3): 246-56.

30. Gleeson C, Spedding R, Harding L, Caplan M. The mediastinum – is it wide? *Emerg Med J.* 2001;18: p. 183-185.

31. Long JG, Philip AG, Lucey JF.) Excessive handling as a cause of hypoxemia. Pediatrics 1980; 65:203–207

32. Danford DA,Miske S, Headley J et al. Effects of routine care procedures on transcutaneous oxygen in neonates: a quantitative approach. Arch Dis Child 1983; 58:20–23

33. Paez A. Gray literature: An important resource in systematic reviews. J Evid Based Med 2017; 10(3):233-2.

34. mahood Q, Van-Eerd D, Irvin E. Grey literature in systematic reviews: a practical approach to searching and including in systematic reviews. In: Bero L, Montgomery P, Robinson K, Pigott T, Krause K. Bringing Evidence-Based Decision-Making to New Heights. Abstracts of the 2010 Joint Colloquium of The Cochrane and Campbell Collaborations; 2010 18-22 Oct; Keystone, USA. John Wiley & Sons; 2010.