Salford
Integrated Care Partnership

TOOLKIT

DEVELOPING DIGITAL APPLICATIONS IN HEALTH CARE

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INTRODUCTION

Co-creating and engaging patients with a mobile App to enable greater self-management for people with long term conditions: a toolkit

The purpose of this toolkit is to provide a 'how to' manual for projects which aim to engage patients in co-creating and implementing Apps for the self-management of long-term conditions.

- This toolkit is based on experience gained together with the wider literature during a project to customise, deploy and evaluate an App to support the self-management of long-term conditions using Multiple Sclerosis (MS). The App in question was a mature, CE-marked product, LINCUS. MS is an ideal condition to select as an exemplar as:

- MS has a broad range of symptoms and features, and many are common to other long-term conditions, including; fatigue, co-morbid depression and anxiety, physical and cognitive deficits, which can present both acutely and worsen progressively.

- MS most commonly presents between the ages of 20-40 years, which matches that of digitally native technology users better than many other common long-term conditions that have a later onset.

The project was conceived as a co-creation project working with people living with multiple sclerosis (PwMS), Health Care Professionals (HCPs) and other stakeholders to customise an App to the satisfaction of its intended users and link with relevant patient information provided by the MS Trust. The customised App was deployed as a pilot project to 51 PwMS for up to 6 months. The project was funded by Salford Clinical Commissioning Group (CCG) (LC21-19).

The following foregrounds the stages the project passed through from which lessons can be learnt.

1.
PRE-DEVELOPMENT

Before beginning the project, it is essential to gauge potential interest amongst stakeholders and scope its development. For example, we conducted focus groups with patients and health professionals as follows:

- 2 x MS patients with different grades of disability.
- 1 x MS health professionals.

Supplementing the focus groups with semi-structured interviews with patients (we did over 40) helped establish an appetite for using a digital App and provide a long list of design requirements that stakeholders feel would be useful in helping patients and clinicians to manage the patient's condition efficiently and effectively between clinical appointments. This includes, for example:

- Improving patient control over their data and data use such as: a digital diary for recording pattern of illness, or, accessing information about 'norms' associated with their help when considering their type of condition, other conditions and other life factors, the results of blood tests; provision of information on other support services e.g., social services, citizens advice, wheelchair services, benefits etc.
- The ability to manage relationships between health care professionals and people living with MS – such as: receiving key information about a patient and / or their priorities before they arrive for their appointment, or, giving patients; access to the right professional at the right time, the ability to foster personal/trusted relationships and enhance the sense that they are being 'looked after' and supported, timely reassurance/advice regarding efficacy of new medicines or contextualising evidence of the latest 'miracle' cure.

Establish the Partnership

Partnerships are important to combine knowledge and 'know-how' in an inter and transdisciplinary framework to drive sustainable innovation and adoption. This project was delivered via a partnership with representation from patients, clinicians, academia, industry and the third sector. Working in this way can be an advantage in the context of a health and social care landscape characterized by fragmentation and isolated clusters that can be the major obstacle to the adoption and diffusion of technological innovation.

An example of Partner Organisations and their roles includes*:

- Hospital Trust

Neurology Department Consultants and Nurses
Research and Innovation Team
Governance
To act as study sponsor
Liaison with Ethics Committee
Delivery
To deliver the project on a day to day basis
Digital team
Project Management / Software Testing /
Liaison with Finance Department re contracts

- Academic Partner

Research Team who designed the study
Write the Project Evaluation.
Potential, with Research Passport to also deliver elements of the study.

- Software company

Supplier who develops, maintains, and manages the App.
Customisation of the platform so that it could be used with MS Patients as part of this study.
Delivery of End User Training Prior to Go-Live for all members of the team.
Ensuring all Project Team Members have the correct level of access within the App Platform.

- Patient Charity

Provision of trusted content, over 130 Approved Articles related to Multiple Sclerosis and its various Symptoms.

Meta Tagging of the articles prior to upload into the content library within the Lincus Platform.
Patient Representative.
Ensuring full patient representation and opinions were factored into the customisation of the Lincus Platform, creation of Project Collateral and all aspects of the Project.

* for research projects, all staff with delegated responsibilities are required to undergo Good Clinical Practice (GCP) training, prior to commencing any study activities.

Establish the Project Board

The project Board should include at least one representative from each of the partner organisations. One partner should be the lead partner, who is responsible for co-ordination and bringing the project to fruition, in this case the hospital Trust was the lead partner with the Neurology consultant leading this Board.

Agree appropriate resources

The resources needed to implement a project of this nature should not be underestimated. A key learning from this project has been the need for a dedicated and wide-ranging project team with clinical, academic, industrial, patient, third sector, R&I and digital project management stakeholders, to enable a medical device study of this type.

The key resources should include project management: this should be a dedicated resource for the duration for the project; and project specific research assistants in the clinical setting. It is important not to underestimate the time involved in key elements of the project such as patient engagement, onboarding and retention. Consideration should be given to recruiting clinical staff, such as MS Specialist Nurses, for example, who have knowledgeable and trusted relationships with patients and can therefore facilitate the onboarding and engagement process. Staff with direct experience of the patients are able to provide contextual information which will help decide which patients to recruit and/or how best to recruit them.
For example, they are aware who has mobility difficulties and who are in employment (and are therefore unavailable at particular times).
If there is a need to change key personnel during the project, then time should be allocated for a proper hand over. This is particularly important to ensure that elements that have been agreed at the outset of the project are carried through to each stage and by each partner. It is also important to ensure that there are appropriate records of each stage and requirement of the project and these are handed over for continual reference. If contractors are utilised, ideally they should be available for at least the expected duration of the project, and, ideally, with funding to anticipate any reasonable delays.

Agree Project design

The project design should be agreed at the outset with all the project partners. The design needs to allow sufficient time for customising and deploying the App; trialling the App with an appropriate number of users and a final evaluation stage. Slippage needs to be built in and a plan B may need to be in place in case of unforeseen eventualities (such as a pandemic or winter bed pressures).

For example, in a project running for 12 months we designed the project in 3 stages:
Months 1-3 – assessing stakeholder needs, customising, user acceptability testing and deploying the App
Months 4-9 – trialling the App
Month 6 – interim evaluation
Months 9-12 – final evaluation stage

However, following a project pause due to restrictions in place to the COVID pandemic, followed by necessary changes to recruitment methods and ethics delays we reworked the project timeline to:

Months 1-3 – customising the App
Months 4-11 – deploying and trialling the App
Months 10-12 – evaluation stage

Ethics and governance approvals

It is important to understand the various approvals needed and at which stage when planning the project and build contingencies into the project timeline to accommodate these.

If a project involves an academic partner and the NHS, it is likely that University ethics approval is secured as well as NHS ethics approval. It is important to determine the order of these approvals. For example, in this project, University approval needed to be secured before we could apply for NHS ethics. Within NHS Trusts there will also be a specific procedure to follow and will be dependent on the process at each individual institution. The Integrated Research Application System (IRAS) is a single system for applying for the permissions and approvals for health and social / community care research in the UK. Once a research application is confirmed as valid, it usually takes approximately 4-6 weeks to complete the checks before a decision letter is issued.
Depending upon the nature of the project and evaluation, there are different levels of approval. This can include HRA approval, full IRAS approval and MHRA approval. Sufficient time (and a contingency) should be built into the project plan to accommodate these approvals.

In addition to ethics approvals, in digital projects, it may also be necessary to secure local approval regarding information governance issues. For example, for this project we needed to prepare Data Protection Impact Assessments (DPIAs), Data Sharing Agreements, Contracts (E.G., development and service level agreements) and Clinical Safety Case Reports (CSRs), technical assurance (As a minimum this should include; pen testing certification, DTAC compliance, Cyber Essentials (https://www.ncsc.gov.uk/cyberessentials/overview)) in conjunction with the local Project Team and the supplier to be presented and approved by a Trust board responsible for these issues.

A key identified issue regarding generation of digital patient data on a device, is how this is integrated into the patient's (electronic) health record. This will be a site specific consideration based on the digital maturity of the organisation deploying the tool and the ability of an electronic patient record system to consume view only or structured data feeds, as well as the chosen software supplier's ability to provide APIs. If there is a desire for structured data to be incorporated, this must form part of the decision-making matrix at supplier selection, in line with the receiver's digital strategy and capabilities.

Devices (which can include Apps) may be subject to MHRA approval. In this case as the App was a mature product which already had been through device approval, and the App was being used within the specified approval parameters, no additional approval was needed, however confirmation about the status of previous approval was required.

Linking with the R&I department at Trust level and digital governance structures, on an ongoing basis, to determine what is required and how to proceed is key to success.

Consideration should also be given to research design and operating in a digital environment. A simple way of recruiting patients would often be in a face-to-face clinic. Research assistants can explain the project to patients whilst they are waiting for an appointment and take the opportunity to take consent, and even onboard to the device, as appropriate. If clinics take place by video or telephone, other methods need to be considered to inform patients about the project, provide information, take consent, and onboard. To maximise recruitment and engagement a broad range of strategies should be incorporated into the research design and ethics approvals.

These issues can be improved by:

- Ensuring there is plenty of time allocated to submitting a formal application to the Ethics Committee. Allow time for the substantial amount of work in writing the formal application, confirming the study methodology and preparing the formal project documentation prior to submission. (e.g., Patient Information Sheets, Consent Forms).

- Consulting with patients regarding the patient information leaflets. They can help check for clarity and that the requirements of the design are appropriate and the information accurately conveys this.

- Ensure that the widest possible project stakeholder representation, eg clinical, academic, patient, supplier and third sector are available to attend the ethics committee meeting and answer any questions.

- Allowing time for amendments following an ethics meeting and a potential resubmission.

Establish a Patient Advisory Group

Engaging patients throughout the project is key to success. Patient advisory groups (PAGs) are seen as fundamental to the project success. The purpose of this group is twofold (i) it serves to offer a forum for peer-to-peer support as the project unfolds and (ii) provides feedback, via the patient representative, to the wider project team. The PAG should be resourced and supported as appropriate.

2.
CO-DESIGN THE APP

Co-design, involving both professional staff and patients, is essential to ensure that the App is relevant to the needs of the patients using the product and ensure that the app is accepted and used in clinical practice. Letting patients discuss the design of the device with their peers will provide valuable feedback for customising the device to meet their requirements.

For example, we deployed a co-creation process involving people living with MS, along with representatives of the study partnership, to collaborate to customise a mature generic health self-management tool, to enable people with MS to self-manage their condition.

This involved 10 MS patients from an MS clinic, the consultant neurologist leading the study team, an academic researcher (as an observer); a representative from the MS Trust; and, the MS patient representative on the study team. The latter's participation was particularly productive as he, spontaneously, agreed with the other PwMS to establish a private facebook group for the MS patients to continue discussing the App outside of the planned co-creation process. This was a facility that proved invaluable at this stage in that it served as a 'back channel' process that delivered more insight from the patients on required design specifications for the App.

Online workshops facilitated by the technical partner can be used to 'walk through' the design and functionality of the App. Care should be taken with the 'walk-throughs' to ensure they are not too long, cover each aspect of the App to the participants, enable sufficient feedback and interaction from patients to comment on the design and function for ease of use and suitability for their condition.

To supplement the 'walk-through' sessions a dialogue between all participants, but particularly between the clinical staff representative and the patients is productive. Patients can suggest design alterations to better suit their condition and what they feel are more likely to sustain their use of the App. Clinicians can promote changes that might prove beneficial to the time spent with patients in clinic. Iterative development of the App with the supplier is the ideal and should be expected by all stakeholders.

It is important to be aware that this may produce a list of design specifications that are not feasible to implement within the project time frame and budget. One way of addressing this is to ask all participants to prioritise each suggested specification by allocating a score of between 1 (nice but not necessary) and 10 (absolutely necessary). This can be supplemented by further discussion with the patients. For example, PwMS were enabled, via the private Facebook group, established by the MS patient representative, to discuss the strengths and weaknesses of each specification freely within their own forum and without any mediation.

To ensure that a feasible list of design specifications is produced that is based on patient priorities, the scores for each patient can be aggregated but the patients' rankings be provided separately. This ensures that the patients' priorities, the users of the App, are given precedence. This ranked list can be used by the technical supplier to assess if the specifications are within the scope of the agreed contract and its development time.

A final iteration of the co-design process should be run with the re-specified device and the patient group. This should help additional issues to come to light prior to deployment, such as repetitious questions. It is a false economy trying to save time on this part of the project. Getting this aspect right is likely to pay off later with increased patient retention.

3.
HCP ENGAGEMENT

Alongside patient engagement, staff engagement is crucial to successfully embed digital devices into institutions.

Involving Health Care Professionals in the project team helps to ensure they appreciate the merits of the project, however a more wide-ranging project, that for example, aimed to integrate the device into existing institutional systems would require extensive consultation and ongoing communication with the relevant staff.

Backfill of clinical time in order to realise these projects is crucial, particularly in the post-Covid pandemic environment where backlogs are the norm. This is likely to require long-term commitment to expand staff numbers to enable innovation projects to be piloted alongside “business as usual”. Anticipating and streamlining the requirement for Good Clinical Practice (GCP) training is also crucial.

4.

PATIENT ENGAGEMENT RECRUITMENT & RETENTION

The task of recruiting patients and then maintaining their use of the App is an essential but challenging aspect of this type of project.

Consideration needs to be given to how the patients will be recruited, what information they will be given about the study and how they will consent. If face to face recruitment is a possibility, patients can be recruited at relevant clinics, providing the opportunity for questions and discussion.

If clinics are conducted over the telephone or online, it is important to determine an efficient way of ensuring that patients receive all the required information and have an opportunity to ask questions and consent prior to being enrolled in the study. Email, including E consent, is one option, providing the hospital systems facilitate this method (and patients read the emails).

Sending information packs by post with follow up telephone calls by research staff is a further option, as is hand delivery of information packs but very time consuming and not always fruitful. This approach may be hampered by internal post systems, availability of staff at the same time as patients and missing information in Royal Mail.

Managing consent via telephone can also be laborious and difficult to keep track of, to ensure that records are maintained, consent can be granted over the telephone and signed by the team member on the patient's behalf and a copy posted back to the patient. Or the patient can sign and post it back to the research team.

Once consented, onboarding patients to the study needs to be carefully considered. As well as conveying the technical information that patients need to use the App, it is important that patients understand why they are using the App and the benefits that it will bring to them. The marketing industry consider a good 'onboarding', that is, explaining to the user how to use the App, is critical and can result in up to a 50% increase in user retention for the App in question. For a project aiming to improve self-management, communicating how to use the App is not sufficient; patients need to be clear why they are using the App, the benefits to them and their health. This should not be conducted over the phone and ideally would be run as an interactive group session (either virtually or face-to-face),where patients can use the App and ask questions; a group session enables patients to bounce ideas off each other.

Recruitment and engagement could be improved by:

- **Fully exploiting appropriate digital avenues for recruiting patients.**

For example, a QR code. could be sent via email, if patient email is available, or printed on a leaflet to be distributed at clinics for patients to peruse. Scanning the QR code would provide further study information and, if the patient consented to, download the App to the users' phone, and they could then create a username and password. Social media containing the QR code could also be used either from the hospital site or amongst patient groups to generate interest in the study.

- Considering hard to reach groups

The method above could well exclude those lacking in digital confidence. As such, specific, targeted methods and resources must be applied if the socio-economically disadvantaged or digitally illiterate are to be included in any such project. Examples might include conducting face-to face workshops in their locality, a local library, and make it more of a social event, with mutual support.

- Trusted relationships

This emphasises the importance of trusted relationships in patient recruitment. This might involve, using the MS Nurses to build upon their relationships with patients or exploiting the doctor – patient relationship and perhaps develop online videos of the consultants and nurses explaining the value of the patients' involvement in the project.

- Incentivise the patient

The latter point underlines the importance of incentivising the patients. Why should they participate? The benefits to patients of their involvement – even if these are deferred benefits– should be explained clearly in the patient information leaflet, the consent and onboarding process. Such benefits would include providing an online journal for the patient to consider aspects of the their condition, accessing timely information relevant to them, preparing for and facilitating upcoming consultations and prioritising their goals for clinical encounters.

- Agree anticipated pattern of useage of the device

Research suggests that patients are more likely to engage with health Apps at significant times in their disease journey. Therefore it is reasonable to assume that patients will differ in terms of how and when they interact with the App. This should be anticipated by the HCP.

- Reduce participant 'burden'

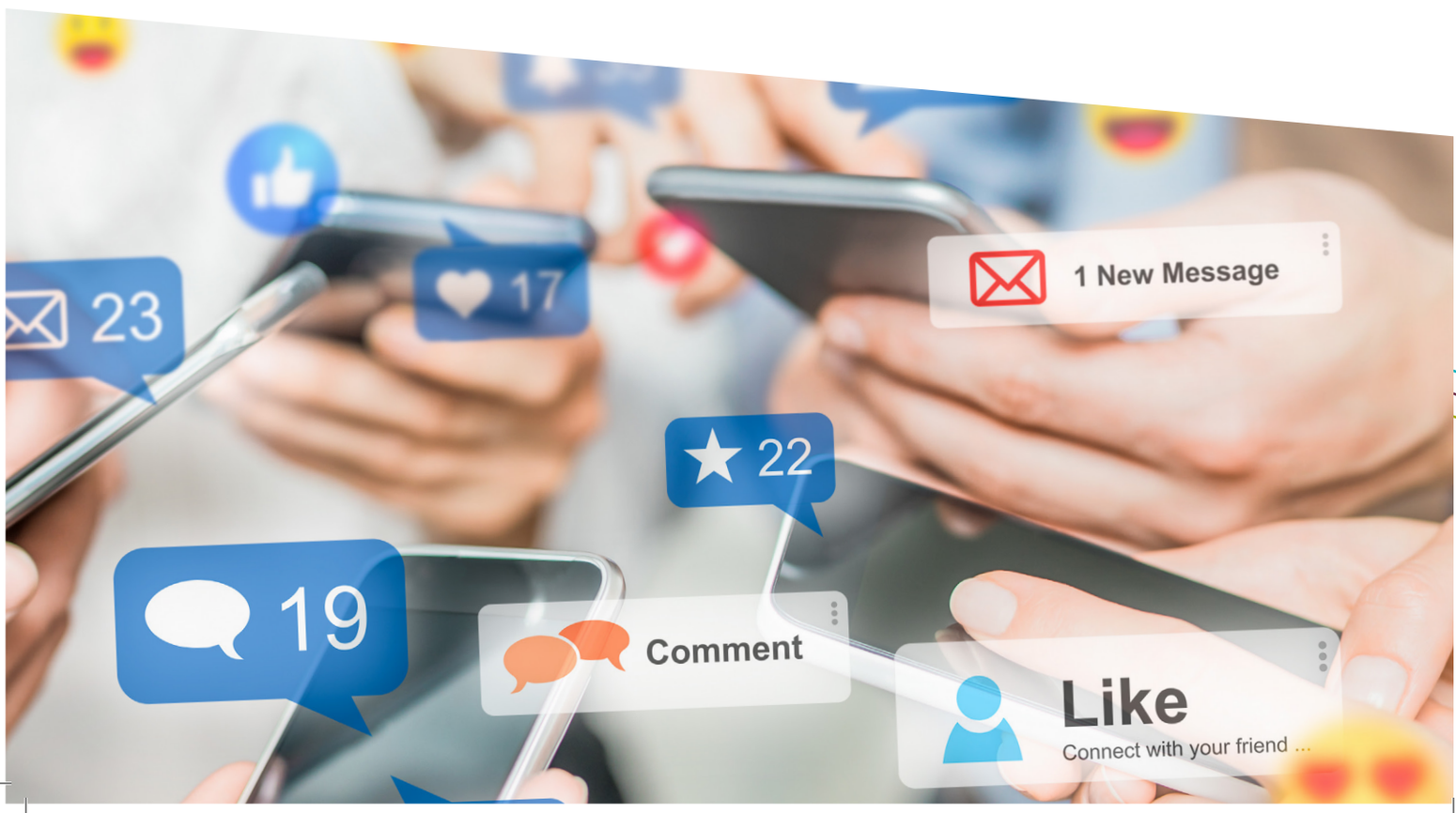
This is largely a design consideration but, if done well and ideally co-designed (see below) with participants, can increase patient retention with the App. So, avoiding questions that appear repetitious and making the App sensitive to the requirements of the intended user group. For example, designing the App to facilitate oral instruction for people living with MS may be appropriate, where coordination, sensory and visual deficits may be present.

- Use real time data

The App, or mobile device, should provide onboard metrics that monitor usage of the device in real time. Monitoring this data should enable the project team to identify those patients who are not using the device and contact them to offer support if required and a reminder of upcoming consultations for example.

- Use the Patient Advisory Group (PAG)

If this group is working successfully it can serve as an important support mechanism for patients and thereby help to promote retention.



SUMMARY

Utilising all of the above strategies is likely to improve the chances of success in deploying a new health App, although there may well be condition-specific factors that are also crucial and should be anticipated.

Supporting Literature/Resources

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