York Health Economics Consortium

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Providing consultancy and research in health economics for the NHS, pharmaceutical and health care industries since 1986

NICE

Evidence Guide for Apps Developers: Study Designs Including Applied Examples for Apps

Evidence for Evaluation Purposes: Report

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Abbreviations

CCA	Cost consequences analysis
MOST	Multiphase Optimisation Strategy
NIB	National Information Board
NICE	National Institute for Health and Care Excellence
RCT	Randomised controlled trial
SMART	Sequential Multiple Assignment Randomised Trial
TBSA	Total burn surface area

Section 1: Introduction

This guide aims to support app developers to understand and create the evidence required to demonstrate the health and care benefits of their apps. For some apps, evidence will be needed in order to be considered for independent evaluation at Stage 4 of the NHS app assessment and endorsement process [1]. The outcome of Stage 4 evaluation will facilitate adoption of the most beneficial, high value apps by the NHS and social care. Other users of evidence will include commissioners and health care professionals to help inform their local decisions on adoption of apps.

It is recognised that this is a rapidly evolving field and that the model and tools that are currently being created and explained in this guide will evolve over time, incorporating new approaches and methodologies and so this guide will be subject to regular review.

The context for this guide is that decisions on adopting innovative technologies into the NHS and social care services are based on a health technology approach. This involves a structured approach to reviewing, and appraising clinical and patient research findings to aid the delivery of optimum care to patients and other service users.

Where the words “app” or “apps” are used in this document these are shorthand for digital applications, which may include a mobile app, a web-based application or in certain cases a digital service. The evidence should measure the performance of the software, related components such as face-to-face appointments, dedicated websites and the platform. Evaluation will consider the intervention package and not the app in isolation from these components.

The layout of the document is:

- Section 2 sets out an approach to define the research question;
- Section 3 sets out the criteria used in evidence-based decision making to inform adoption decisions within the NHS;
- Section 4 sets out detailed questions for each criterion;
- Section 5 suggests developers may supplement primary evidence by conducting a literature review to identify existing evidence on similar apps or in the general topic area.

Section 2: Defining the Research Question

A good starting point when thinking about collecting evidence about new interventions is to define the scope of the challenge or question that is being addressed. In this guide, we have referred to this as defining answerable research questions. These are best structured using four elements, with the acronym PICO:

- 'P' , the person, patient or population in question;
- 'I', the intervention;
- 'C', the comparison or control;
- 'O', the outcomes considered.

It is recommended that the app developer should first define the scope of the research question using 'PICO'. The process requires the following steps:

a) Describe the characteristics for the Population of potential users of the app. Factors to consider include:
  - Who are the potential users? These could include patients, health and social care professionals, carers and members of the public;
  - What will be the level of adoption and use of the intervention and will this vary by user group?
  - Will users have a specific diagnosis or disease and if so, is severity important?
  - Does the app address specific health risk factors such as age, smoking, obesity, sedentary lifestyle?
  - Are any subgroups anticipated to have different outcomes? Relevant characteristics could be age, gender, ethnicity, co-morbidities and disability;
  - What is the appropriate setting? For example an app providing oral hygiene information to all primary school children will have a different reach to one recommended by dentists.

b) Describe the Intervention, which includes the app, any associated components, platform(s) and connections to other systems and the intended use of the app, including the setting and the desirable level of usage of the app to be effective;

c) Describe the Comparator(s). In other words, how is the service or function of your app currently provided by the health and care system? For example, this may be an existing health and social care provision or another digital service. It is important to describe what happens now because this is what your app will be compared to;

d) Define what Outcomes you expect to change as a result of using the app. It may be useful to group these under headings such as:

- Safety. This will include any adverse effects which could arise as a result of using the app (e.g. if the app is for a diagnostic test, consider the accuracy of the app and its impact on false positives and false negatives compared to current practice);
- Clinical benefit. This will include any clinical endpoints, which are expected to change as a result of using the app. Examples of clinical endpoints include reduced incidence of depression, reduced blood pressure or improved glucose control, improved health-related quality of life;
- Resource use. Will using the app reduce the number of NHS attendances, examinations or tests required by users? Will it reduce the need for social care support? What will be the impact of increasing usage of the app on NHS and social care professionals e.g. will they use information from the app to inform decisions? If so, will this replace current sources or be additional to these?
- NHS and social care costs and savings. What will be the costs to the NHS of users adopting the app e.g. staff training, staff time to manage the information from the app or to purchase equipment to connect to it. Will service re-design be required? Are these one-off costs or will some costs recur? What is the value of the resources saved?
- User and others. What is the impact of the app on the well-being of the user? Will the user be able to participate more in employment and community activities? Is it more convenient for the user and the service than the comparator? What will be the costs to the user of the app? Will other costs be incurred? What about the value of potential savings to the user from e.g. fewer face-to-face appointments?

The reason why app developers need to think about these elements is that these are the key questions to be considered and supported by appropriately evidence as part of the independent assessment at Stage 4 of the NHS app assessment and endorsement process [1]. The benefit to the app developer of thinking about the research questions and investing in the production of evidence to support their claims is that the health and care system is enabled to make informed decisions on adopting new technologies where the value and benefit has been clearly demonstrated and where there is an appropriate level of evidence to support this, that has been subject to independent evaluation.

More guidance on how to develop a scope using PICO is available from the NICE (National Institute for Health and Care Excellence) Medical Technologies Evaluation Programme Methods Guide [2]. An example of a PICO for the Mersey Burns app, a case study, is provided at Appendix A.

Section 3: Criteria Used in Evidence-Based Decision Making

Evidence-based decision making in the NHS and social care systems requires a structured appraisal of the best evidence in the context of NHS and social care resources available and overall policy.

This section presents six criteria that may require to evidence at Stage 4 of the NIB (National Information Board) Evaluation Framework and a series of questions for each criterion. The latter are designed to help:

- An app developer identify the evidence that is required to inform decisions;
- Commissioners to identify the key questions for which they may expect evidence to be available;
- Evaluators to appraise the evidence generated by the developer to inform the decisions of commissioners.

When addressing each criterion the developer must compare the app intervention to current practice. It is the additional benefits, costs and savings compared to current practice that are important to commissioners.

For some apps all criteria may be important, for other apps a developer may be able to demonstrate that specific criteria do not apply to their app. Hence not all developers will be required to provide evidence on all criteria, rather the evidence required will be proportionate to the potential impact of the app on each criterion and the risk of such impact occurring.

3.1 SIX CRITERIA TO INFORM ADOPTION DECISIONS

Crossing the Quality Chasm: A New Health System for the 21st Century [3], from the Institute of Medicine outlined six aims which are designed to foster innovation, provide care that is evidence-based and that meets users' needs. These have been widely adopted within the NHS and are:

a) First health and social care must be safe. Hence, an app intervention should be able to demonstrate that it reduces, or has no impact on, the risks to patients and carers from harm, compared to current practice;

b) Second, health and social care must be effective. Hence, an app intervention should be able to demonstrate it improves the health of users, or has no impact on this compared to current practice. If there are no clinical benefits, then the app must be able to demonstrate benefit in some of the remaining categories;

c) Third, health and social care must be patient/user-centred. Hence, an app intervention should be able to demonstrate that patients/users find it useful, that it improves outcomes relevant to them and enhances their health and social care experience, compared to current practice;

d) Fourth, care must be timely. Hence, an app intervention should be able to demonstrate it reduces, or has no impact on, unnecessary delays for patients in the health and social care system and may increase the likelihood that each patient receives prompt attention, compared to current practice;

e) Fifth, the health and social care system must be efficient. Hence, an app intervention should be able to demonstrate it can reduce, or not change, the need for, and hence cost of, resources required to deliver high quality patient–centred care, compared to current practice. If it costs more, this must be justified by benefits across other criteria;

f) Sixth, health care must be equitable. Hence, an app intervention should be able to demonstrate there are minimal barriers to its use arising from a patient's disability, age, race, ethnicity, gender, sexual orientation, and religion or belief[1].

The next section sets out some research questions, which aim to help apps developers produce the evidence required on these criteria. These are typical of the lines of enquiry which will take place at Stage 4. However not all apps will be required to provide evidence of impact for each criterion. For example, low risk apps, particularly where they are additional to a current services, such as the Brush DJ case study may not be required to conduct clinical safety studies.

[1] For a full list of protected characteristics go to the Equality Act 2010, available at https://www.gov.uk/guidance/equality-act-2010-guidance [4]

Section 4: Detailed Research Questions for Each Criterion

This section provides some questions to guide developers on the type of evidence required to inform robust evaluation of an app intervention.

4.1 SAFETY OF AN APP INTERVENTION

In this section, only clinical safety is considered. Aspects of safety related to information governance, information security and the application of clinical risk management approaches to Health IT Systems are addressed in a sister document which refers to the standards required by Health & Social Care Information Centre [5].

Where there is a risk that an app could cause potential harm to a user then evidence is required on the absolute risk of such an outcome occurring. This risk also needs to be compared to the risks with current practice. Such harms are usually referred to as adverse events, or side effects. Often such effects are mild but occasionally they are severe.

1. Has patients' and/or clinicians' feedback been invited specifically on potential harms?

Quantitative studies such as randomised controlled trials (RCTs) may not detect adverse events. Such trials are often of short duration, include small numbers of patients and exclude patients with very severe disease or comorbidities. Hence, regulatory authorities such as the Medicines and Healthcare products Regulatory Agency, European Medicines Agency and United States of America Food and Drug Administration, encourage people to report all suspected problems or incidents relating to any healthcare product. Such reports, usually from individual patients and clinicians, are vital information to identify previously unknown safety issues. Clinicians also take steps to identify harms, for example through use of audit data.

App developers should encourage such feedback in order to identify potential issues as early as possible; clinical studies alone are unlikely to detect all potential harms to patients and users.

2. If there is the potential for harm, what studies have been conducted to estimate the incidence rate of adverse effects and to examine the likely range of their severity, and what do these studies show?

Safety studies can take several forms including cohort studies and case series. These usually have a longer duration than a RCT and ideally have a comparator arm. They are often pragmatic studies and set in routine clinical practice.

The function of the app intervention may determine the type of study required; for safety studies, there is no single gold standard.

3. Has any post-launch evidence been collected to show the safety of the app intervention in the real world?

Apps that collect outcome data as part of their functionality may be better placed to address this than other types of app intervention. App developers may also seek to incorporate safety outcomes data collection. Register studies can be used for the systematic collection of data on safety. Other forms of 'post market surveillance' on safety include collecting reports of possible safety problems from users (and encouraging these submissions through reporting systems).

4. If the app intervention provides information on a clinical indicator e.g. blood glucose level or alcohol content in blood, or makes a calculation with clinical consequences (such as a medication dose), then there are safety implications to getting this wrong. Therefore, the app developer should be able to demonstrate that the app is measuring or calculating what it is intended to do, is doing so consistently and accurately and any subsequent actions recommended by the app intervention are the same as those provided by the gold standard measurement, for matched individuals. This is also part of effectiveness and is therefore also covered in 4.2.

Answering such questions requires developers to undertake accuracy studies to show how the app measurement, reporting and advice functions compare to current practice, and whether it does so in a repeatable, consistent manner. A diagnostic test accuracy study, comparing a diagnostic test of interest to an existing 'gold standard' diagnostic test is an example of an accuracy study test design.

4.2 CLINICAL EFFECTIVENESS OF AN APP INTERVENTION

Evidence of effectiveness is required to show that an app has the potential to do more good than harm, bringing benefits to users and/or the health system.

Study designs in this domain need to focus on generating evidence on the impact of the app intervention on clinical and well-being outcomes. Where desired outcomes improve in comparison to current practice, the app is said to improve clinical effectiveness. A key factor influencing effectiveness is whether the app is used in accordance with recommended practice (which should be described). The drop-out rate with the use of apps in practice is higher than the rate for most other medical interventions. Thus, how the app is used in practice and the impact of that on health outcomes should also be considered here.

5. Is there evidence to demonstrate that the mechanism of action, or theory of behaviour change adopted in the app, associated components and platform is clinically effective?

The answer to this question should identify the theoretical underpinning for the app intervention, identifying any guidelines, theories of change, and/or existing evidence, which provide support that the proposed mechanism of action will lead to good patient/user outcomes.

6. Are results available to show the app changes behaviour as anticipated?

Several forms of quantitative study designs are appropriate to address this question including RCTs, cohort and accuracy studies. Before developing a quantitative study, it may also be of value to undertake qualitative work to explore patients' and clinicians' perspectives of the benefits and drawbacks of the app intervention, and to gain an understanding of how it is actually used in practice. The findings from such studies are likely to give valuable insights into how and why the app is used, and will also help shape the questions in later quantitative studies. They may also guide the choice of the most appropriate and relevant outcome measures for the intended benefits. (See case studies from OWise and GDm-health on the benefits of pre-studies to shape an RCT).

7. Have the individual components within the app intervention been optimised to enhance patient/user outcomes?

Best practice recommends that studies are undertaken to identify the optimal mix of components within an app intervention [6]. One way this can be done is using a framework derived from engineering known as Multiphase Optimisation Strategy (MOST) or Sequential Multiple Assignment Randomised Trial (SMART). Once the app intervention is optimised, further trials, typically RCTs, are still required to identify the relative clinical benefits.

8. What is the expected direction and magnitude of the effects of the app intervention on clinical outcomes, compared to current practice, and how have these effect sizes been established?

An app developer might seek to demonstrate that the app is clinically equivalent to current practice, also described as non-inferior, or may seek to show the app leads to better outcomes than current practice (is superior). In each case, the comparative effects should be measured. Robust measurement may require use of an RCT, designed to reduce the risk of bias. An RCT is the gold standard trial design for evaluating relative effectiveness, but other designs including cohort studies and case series may provide sufficient evidence to inform an evaluation, provided that potential biases can be adequately addressed.

Some apps, for example, those designed to improve the efficiency (reduce resources required) of a clinical pathway or those designed to improve the patient/user experience of care, are likely to still need to demonstrate there will be no loss in effectiveness relative to current practice.

9. Has any post-launch evidence been published to show the effectiveness of the app intervention in the real world?

RCTs and other quantitative studies are conducted in a sample population; evaluators and others must infer whether the results from this sample apply to the whole population of interest. Relevant factors include the criteria used to include and exclude people from entering the study and the size of the study. Additional evidence can be provided by 'real world' studies, which collect evidence of outcomes from patients/users using the intervention in a natural environment. Apps that collect outcome data as part of their functionality may be better placed to conduct such research than other types of app intervention. App developers may also seek to incorporate outcomes data collection to support the ongoing generation of evidence both on effectiveness and on safety. Cohort designs and register studies are often used for this 'real world' data collection.

10. Do real world studies show the app is used with the frequency required or for long enough to achieve the effectiveness results anticipated?

The outcomes from RCTs and other study designs which require users to adhere to a protocol are unlikely to be replicated in natural settings where users can opt for different adherence patterns. Hence, the evidence required for this aspect is likely to come from real world studies of how the app is used in practice, with key indicators including frequency of use and dropout ratios, including reasons for the same. Study designs could be either qualitative or quantitative. If length or frequency of usage is likely to impact on clinical effectiveness then then the relationship will need to be explained. Ideally developers will collect data on usage on an on-going basis and may be able to incorporate the automated monitoring of usage into their app design.

11. What is the impact on patients' quality of life and other patient-reported outcomes and how has this been measured?

For apps which are designed for use by patients, it is important that app developers measure outcomes which are relevant to them and which reflect the impact of the app on their health and wellbeing. Using validated questionnaires can demonstrate the impact of using the app on generic health outcomes (using, for example, the EQ-5D questionnaire) or disease specific outcomes such as Patient Reported Outcome Measures (PROMs). Hence, app developers should ideally provide evidence using such tools (likely to be incorporated into evaluations using RCT, cohort or case series designs).

4.3 PATIENT/PERSON CENTREDNESS OF AN APP INTERVENTION

Demonstrating an app intervention is person-centred can draw on several sources of evidence. For example, evidence may relate to the usability of apps, identifying how user/patient involvement was influential in developing and refining the app pre-launch, and how their feedback informs further enhancements to it. Such involvement may take the form of observations, interviews, focus groups, questionnaires and more structured user testing.

Capturing the patient experience when using the app is also important evidence and some examples of Patient Reported Experience Measures (PREMs) are provided in a sister document.

Also relevant to decision makers is the potential economic impact for the users of the app intervention. For example, an app intervention may reduce the number of appointments required at a diabetes or warfarin clinic, saving users travel time, time off work and related costs. On the other hand, it is possible that some apps may incur costs for the user (independent of their cost to the health service).

12. What is the expected impact on the wider well-being of users and others (e.g. carers and family)?

The answer to this question should identify the anticipated wider benefits to users, who may or may not be patients, and any other groups who may be impacted, such as carers and family members. Developers should consider a holistic definition of well-being including:

- Control by the individual over day-to-day life including the provision of care and support;
- Participation in work, education, training or recreation;
- Social and economic well-being;
- Domestic, family and personal relationships;
- The individual's contribution to society.

(Definition of well-being taken from Section 1 of the Care Act 2014, available from The Stationery Office at: http://www.legislation.gov.uk/ukpga/2014/23/section/1/enacted).

These wider benefits are harder to measure, although there are some validated scales for measuring aspects of wellbeing and constructs such as self-efficacy or social support. App developers may choose to specify what the anticipated wider benefits are, even if there is no empirical data to support these. If they are able to provide evidence it could come from a variety of study designs, both qualitative and quantitative.

13. What usability testing has been conducted with end users?

Evidence should discuss the findings of usability testing, and the role of users in developing and updating the app intervention and consider factors such as expected variance in the frequency and intensity of use with the app. Developers may also want to include details of how the app incorporates guidelines and/or theory in relation to best practice in app usability design.

4.4 TIMELINESS OF CARE WITH AN APP INTERVENTION

Some apps have the potential to change clinical care pathways, for example, offering services which might otherwise have been delivered on a face-to-face basis or combining the app with fewer face-to-face interventions than current practice. Such changes may alter the timescale for patients to receive appropriate care. Hence, it is important for the developer to describe the potential impact of the app intervention on the current patient pathway. Ideally, this will be informed by expert opinion from relevant clinicians who are more familiar with pathways and how to achieve changes to these. Evidence on reduction in NHS inputs may come from economic studies, which are described in a sister document. Other evidence on timeliness and impact on current pathways could come from a variety of study designs, both qualitative and quantitative.

The relevant research questions are:

14. Does the app intervention change how and when users access health or social care?

If yes, describe the anticipated changes, with supporting evidence for these where available. Developers should also aim to capture changes which may occur which are not intended.

4.5 VALUE FOR MONEY OF AN APP INTERVENTION

The commissioning decision will be informed by evidence on the potential costs and savings offered from adopting the app. The form of analysis required at Stage 4 is anticipated to be cost consequences analysis (CCA). CCA is already used by NICE when judging the value for money of medical technologies and public health interventions. CCA presents estimates of the impact of a new technology, compared to current practice, on:

- Health outcomes for users. Usually several measures are adopted such as change in risk factors, impact on subsequent clinical events and health-related quality of life;
- Health and social care professionals. Examples include potential changes in workload and patient mix, different clinical care pathways, different ways to get information and advice;
- Health and social care system. This seeks to capture the impact of the app intervention on the usage and associated value of individual health and social care resources.

The evidence required on health outcomes should come from the same sources as adopted for clinical effectiveness (questions 5 to 11).

Evidence of impact on healthcare professionals may be from intervention studies as for clinical effectiveness, but could also be drawn from descriptive or qualitative analyses including surveys, interviews, and focus groups. Factors to consider include whether the app intervention is fast and easy to use in clinical settings, whether it provides useful advice quickly, and whether quality patient care can be maintained or improved but with less staff input. The baseline for measuring benefit against will usually be the current clinical or social care pathway. Information about NHS pathways for a wide range of conditions is published by NICE and available at http://pathways.nice.org.uk/.

Evidence of impact on the health and social care system could come from economic studies alongside RCTs. However, these studies will only provide information on the resources required/saved for a small population, over a limited timeframe and in a protocol-driven setting. Hence, further work will be required to generalise these results to the potential population using the app. Relevant factors may be whether the frequency and intensity of usage is anticipated to decline (or increase) over time; whether the wider population will use the app intervention in the same way as that defined in the trial protocol, and if the clinical pathway in the trial is representative of normal care. Hence, the associated research questions are:

15. What are the anticipated benefits to users from the app intervention?

16. What impact will the app intervention have on NHS and social care professionals?

17. What impact will the app intervention have on other NHS and social care resources?

18. What is the value of the change in staff and other resources?

19. What proportion of the population identified in your PICO (Section 2) do you anticipate will use the app intervention in years 1, 3 and 5 (this should be expressed as % of population and in absolute numbers)?

20. What proportion of users do you anticipate will stop using the app each year?

21. What are the cost consequences for users and others?

Evidence should include the expected cost to users of the app over say a year. This should include training, and anticipated maintenance and updating costs.

User feedback, or well-designed studies, may enable developers to estimate potential savings to users and others from factors such as avoided journeys and less time off work, whilst increased independence may enable carers to have greater leisure time and reduce social care support.

22. What are anticipated annual costs and savings to NHS and social care from adopting the app at years 1, 3 and 5?

4.6 EQUITY OF AN APP INTERVENTION

Members of the National Information Board are committed to promoting equality and eliminating unlawful discrimination. Moreover, an apps developer providing services to users of health and social care must comply with equality laws. In order to discharge its responsibilities the [evaluation body/NICE] requires to ask whether any groups with protected characteristics may be put at a disadvantage relative to others if the app was adopted in the health and social care sector. Thus, the research questions explore factors impacting on using the app intervention and whether its use may increase or reduce access to health and social care. Factors to consider are:

- Limitations related to physical attributes such as size, visibility and comprehensibility of buttons and symbols, or associated with platforms, or from rules on when the app can be used;
- Whether the app intervention may reduce current barriers to users accessing quality healthcare e.g. by reducing need to take time off work to travel or reducing the costs required to access care;
- Whether the app may raise barriers to users seeking to access quality care. This could arise if apps users were afforded different prioritisation to services based on subjective factors.

The evidence to answer these questions may come from intervention studies, (for example, from details of characteristics of recruited users), usability studies, ongoing data collection of user characteristics through the app itself and from user of clinical feedback and opinion elicited from interviews, focus groups or questionnaires.

Hence the associated research questions are:

23. Are there any groups in the target population who might not be able to access or use the app as intended?

24. Will the app remove any current barriers to accessing services?

25. Will the app give rise to potential barriers to accessing services?

Exploring issues of equity does not require any specific study design; rather evidence on these aspects could be an outcome to adopt under any study design. For example, evaluating what has worked well and why, using results from quantitative studies, may well give insights into barriers that prevent an app intervention performing as anticipated. User feedback in real time, or through specific qualitative studies, will also provide relevant information on functionality which some users struggle to understand or use.

Section 5: Other Information Required by Decision Makers

In addition to primary evidence, many decision makers, particularly those undertaking a formal evaluation similar to those conducted by NICE for medical devices will require that submissions of evidence also document the conduct of, and findings from, a literature review targeted on the research question (i.e. a review of published studies which have evaluated similar interventions). This will be as informed by the PICO characteristics.

Findings from literature searches can be useful to app developers, particularly at the development stage. They can be used to support the theoretical basis underpinning the concept, which informs the app's development by exampling evidence that the theory is effective in delivering the desired outcomes. Developers can learn lessons from studies of other similar tools.

The developer may find an existing systematic review which has already collated and synthesised all existing research evidence. In some cases this may be accompanied by a meta-analysis which has combined the results from multiple studies which have evaluated sufficiently similar interventions to all an estimate of an overall effect size across the studies combined, compared to defined comparators. However, results from meta-analyses are only of value if the methodology adopted was robust and studies are sufficiently homogenous that findings can be meaningfully combined. Generalising findings from such reviews to the specific context of the app under development hence builds on existing evidence and is more likely to deliver an effective app than other approaches. If the systematic review is accompanied by a meta-analysis then the findings on the absolute value of the effect size and its variability should inform study design, particularly sample size and recruitment [7, 8].

Literature searches can also be targeted to provide information on the population of interest, comparators, existing clinical pathways, relevant patient and clinical outcomes and existing economic evidence in the topic area. All such aspects will inform an evaluation strategy for the app.

NICE require a literature search to be conducted for two main reasons. Firstly, to ensure that a comprehensive evidence base is available to the Committee when making recommendations and secondly, that all information is available for subsequent modelling or synthesis. Other evaluators are likely to have similar requirements.

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APPENDIX A

Example of PICO Using Mersey Burns App

Population	Adults or children with recent burn injuries. For use in acute care settings and remotely e.g. in emergency departments or ambulances where no burns specialists are available. Subgroups include those aged over 70 years and infants.
Intervention	Mersey Burns mobile application, which calculates the percentage area of the body affected by a burn and uses this to calculate the fluid resuscitation requirements.
Comparators	Traditional paper chart and calculator methods using Lund and Browder charts to estimate total burn surface area and Parkland formula to calculate fluid requirements.
Outcomes	Outcome measures to be considered include: • Accuracy and variation in calculation of fluid resuscitation; • Propensity for error for different subgroups; • Accuracy and variation in calculation of total burn surface area (TBSA); • Time taken to complete calculations; • Adverse events; • Costs of app; • Resource use in NHS settings; • Morbidity; • Mortality; • Ease of use; • User satisfaction.