Improving health outcome for young people with long term conditions: the role of digital communication in current and future patient-clinician communication for NHS providers of specialist clinical services

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Scientific summary

Our overall research question is "What are the effects, impacts, costs and necessary safeguards for digital clinical communications for young people living with long term conditions and engaging with specialist NHS providers?" The research focuses on young people (age 16-24 years) with long term health conditions (e.g. diabetes, cystic fibrosis, sickle cell) as they tend to disengage from health services resulting in poor health outcomes. It will investigate whether and how their engagement can be improved through the use of digital clinical communication (direct patient-clinician communication with clinical content) and so improve health outcome. Young people are prolific users of digital communications (e.g. email, text messaging, social media, web portals) and use it for health care. As such, young people using the NHS present the best current opportunity for understanding how, why and with what effect digital clinical communication can be used by NHS providers. Many NHS clinicians and young people have started unofficially using digital communication; this research will learn from these innovators. We expect this research will prompt a rethink about the way the NHS uses digital media for clinical communication and the implications of this for information governance. It will inform policy and commissioning of NHS services for young people with long term conditions and guide the deployment of digital clinical communication across specialist NHS care more widely.

There is public interest in digital clinical communication and informal use within the NHS. The scientific literature which includes many technology or disease specific systematic reviews, suggests its use may improve health outcome. We seek to address identified evidence gaps: what is important to patients and clinicians, cost and resource use, risks and harms, and understanding the active ingredients and their link with outcome. Many reviews suggest research is undertaken across disease areas.

Our research has two aims: A) to evaluate the impacts and outcomes of digital clinical communications for young people living with a long term condition; B) to provide a critical analysis of the use, monitoring and evaluation, of digital clinical communications by NHS providers.

Our objectives are:

1) To engage young people, including those with long term conditions in the implementation of the research.
2) To evaluate and synthesise published evidence on the use of digital clinical communication by health professionals with young people with long term conditions that informs future policy and practice.
3) To identify from patients, clinicians, clinic support staff and managers the issues, concerns, opportunities and solutions for the use of digital clinical communication in the NHS for a variety of clinical conditions, their expectations of it, their perspectives on the function of the communication, and issues concerning patient safety, quality of communication, patient-clinician trust, medico-legal issues, ethics, work load and configuration, training, and policy development and its dissemination.
4) To investigate the impact of digital clinical communications on health outcomes for young people with long term conditions and on their engagement with, and use of, health services. Health service engagement includes routine outpatient appointments (monitoring), between appointment contacts (advice and support at the time of need) and emergency care use (unexpected/unpredicted needs).
5) To describe the cost of implementation and on-going provision of digital clinical communication and how it varies across different clinical conditions, to understand the value of this service to patients and clinicians, to understand the cost of up-scaling in the NHS.
6) To explore the use of an outcome measure for future cost-effectiveness studies which can be used across disease areas to capture the impact of digital clinical communication on engagement with health care.
7) To develop and disseminate guidance for NHS providers and commissioners on policy, procedures, service management and payback in return for investment, guidance on which clinical areas are most likely to benefit; and to consider the need for and design of future cost-effectiveness research.

Patient and Public Involvement

To inform the implementation of the project we will run 'Warwick Young Researcher' projects, engaging school pupils to undertake mini-research projects to capture the perspectives of their peers on questions related to the research. We will undertake a similar activity with young people aged 19-24 years.

Literature review

We will i) review potential generic measures available to assess the impact of digital clinical communication, ii) review the use of digital clinical communication in the UK and iii) summarise relevant legal, ethical and policy issues. We will also undertake six rapid scoping reviews on topics identified during data analysis. An example might be, a systematic review for evidence related to a specific type of participant, intervention and outcome.

Case studies

We will identify 60 clinics providing NHS care to young people with long term conditions, some that use digital clinical communication and some that do not. From these we will sample up to 20 clinics for diversity of clinic setting, disease and technology use. In each clinic we will collect data to understand what works for whom, where, when and why, and data for exploring cost, value, ethics, safety and impact. Data will include policy documents, non-participant observation field notes, interviews with approx. 15 patients and where appropriate parents/carers and with approx. 15 clinic staff. NHS staff will extract data about clinic patient attendance, A&E attendance, and emergency hospital admission. Analysis will use the following approaches: qualitative case study approach, a before-after analysis, cost-benefit and willingness-to-accept analysis, ethical policy analysis, safety and risk analysis, and qualitative thematic analysis related to impact.

Synthesis of results and consensus meeting
Results of work packages will be synthesised for presentation to a consensus meeting including young people, specialist service providers and national stakeholders. Policy recommendations will be developed.

Dissemination of results and policy recommendations will be to all NHS commissioning and providing organisations and to stakeholder organisations.

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Background and Rationale

Our overall research question is "What are the effects, impacts, costs and necessary safeguards for digital clinical communications for young people living with long term conditions and engaging with specialist NHS providers?" The research focuses on young people with long term health conditions as they tend to disengage from health services resulting in poor health outcomes. It will investigate whether and how their engagement can be improved through the use of digital clinical communication (patient-clinician communication about clinical issues using digital technology) and so improve health outcome. Although people of all ages are starting to use these technologies in their health care (1-7), young people are the most prolific users of digital communications (8) including its use for health care (9). As such, young people using the NHS present the best current opportunity for understanding how, why and with what effect, digital clinical communication can be used by NHS providers within appropriate clinical, and information governance standards. We expect this research to inform the policy, planning, provision and commissioning of NHS services for young people with long term conditions and to guide the deployment of digital clinical communication across specialist NHS care more widely. This research is timely as clinicians and young people are already using digital communication outside of the NHS information governance framework. Through this project we can learn from these innovators at a time when there is public pressure for the NHS to provide digital clinical communication and technology solutions are becoming available. We seek to discover how the NHS embrace digital communication in all its variety and use it to the benefit of the young people for whom it provides care.

Our proposed research involves four work packages: Patient and Public Involvement activity; literature review; case studies; and finally synthesis and a consensus conference. We have chosen this approach in order to learn from the small number of established systems for digital clinical communication for young people in the NHS, and from the informal, unregulated development of this means of communication between clinician and patient that, according to our NHS colleagues, is now common. At the end of our project we will consider whether a future clinical trial of digital clinical communication is needed, and the form of generic outcome measure appropriate for such a trial.

The proposed project focuses on young people (age 16-24 years) who have long term conditions such as diabetes, cystic fibrosis, sickle cell, liver disease, thalassemia, schizophrenia and other conditions that require engagement with specialist (secondary or tertiary) clinical services, are costly to the NHS and where improved health care engagement has potential to improve health outcome and reduce NHS cost now or in the future. For example, improved adherence to treatment may reduce inpatient admissions currently, or reduce complications later in life. Our focus is on digital communication systems that are usually used in an asynchronous manner such as email, text messaging, social media and web based patient portals but also those used in a synchronous manner such as Voice over Internet Protocol (VoIP) (e.g. Skype and Google Talk) as VoIP can simultaneously transmit voice and other media such as text and images. We are concerned with NHS providers of specialist clinical services, including NHS Trusts and other organisations commissioned to deliver specialist care on behalf of the NHS. There is evidence that the health and health care of the young people requiring specialist clinical services is sub-optimal, as we explain in the next section, and that many clinical teams are already using digital communication with young people in an attempt to improve this situation.

<u>The health and health care of young people living with long term conditions</u>

Young people living with long term conditions are vulnerable to service disengagement and this endangers their long term adult health. Elliott et al (2013) state that 1 in 5 children under 16 have to take medicines on a long term basis (10). It is possible to extrapolate this to those beyond 16 years on the basis that many long term conditions do not go away (e.g. diabetes) and those that do may take some time to resolve (e.g. anxiety). There are 25,000 under 25's living with Type 1 diabetes in the UK (11). Approximately 20% of children will have a mental health problem, most commonly anxiety and depression, in any given year (12). There are 9,000 people living with cystic fibrosis in the UK (13) and many of these will be under 25 years old. Transition from paediatric to adult services has become an increasing focus for the NHS in recent years with Department of Health guidance published in 2008 (14). Poor transition can lead to disengagement from health services and poorer health outcomes (15-17). Watson et al (2000) (18) showed that 35% of young renal transplant recipients had lost their transplants by 36 months after transfer to adult renal care and there is a large peak of graft loss between the ages of 20-24 years. The National paediatric diabetes audit report 2010-11 (19) found that in England and Wales, the number of 20-24 year olds having their HbA1c measured dropped by >5% compared to the number of 10-19 year olds. The health outcomes for young people compare poorly with those for an adult population with the same condition (20). With sickle cell disease, during the period of transition to adult services, regular attendance at outpatient clinics and adherence to medical regimens, in particular penicillin prophylaxis, declines (21-23). This is a worrying trend especially because it is estimated that 25% of deaths reported in young people are linked to infection and poor compliance with penicillin prophylaxis (24). This represents a substantial health burden for young people and their families and an economic burden for the NHS. Reasons for disengagement with health services include psychosocial factors and, for some conditions, the impact of hormonal changes on the condition itself. Service level factors affecting young peoples' engagement include poor patient-clinician communication, inflexible access to people and information, lack of person-centred health care and the need for continuity and relationship development (25-27). The age group at the focus of this study are transitioning into adulthood. Those aged 16-18/19 years tend to be more supported by parents than those who are older but are transitioning between paediatric and adult services. Those who are 19-24 years old are less supported by parents and are a very mobile age group, whilst establishing themselves as adults with long term conditions. Several studies report requests for email, text and social media communications with their health care team (25, 28). In the next section we give examples of digital clinical communication with young people with long term conditions in the NHS.

Digital clinical communications with young people living with long term health conditions in the NHS

Clinicians working with young people are aware of and are often using digital clinical communication. During our NIHR funded Programme Development Grant we engaged with clinic based projects providing digital clinical communication to understand their challenges and research needs. These included projects working with young people with bipolar (29) and diabetes (30). Since then we have identified other examples of the use of digital clinical communication. For example, the liver transition clinic at King's College Hospital, London, sees 450 young patients each year and recently surveyed 50 of them about communication with the clinical team. Of the 50 patients, 18 had contacted the team by email and 4 by text. The team had made contact with 14 of them by text and 13 by email. We have more anecdotal reports through our NHS collaborators of informal use of digital clinical communication: collaborator Barker uses email to guide his young respiratory patients through accessing services, and Musumadi uses text and email for maintaining contact with young sickle cell patients. We are also aware of local initiatives to develop patient portals and apps. For example, University College London Hospitals NHS Foundation Trust runs a patient portal for its clinic of 381 children and young people (aged up to 19 years) from an ethnically mixed area of London. The portal allows young people/parents to set the agenda for their next clinic appointment, upload glucose measures, and receive tailored information. University Hospital Coventry and Warwickshire NHS Trust is currently developing a patient portal for young people with diabetes in transition to adult services. Co-applicant Musumadi is developing an app for sickle cell patients. It is clear to us that clinicians are using digital clinical communication and we can identify them for this study. Next we consider the policy context in which these innovations are occurring.

The policy context

The research is timely in relation to the UK and EU policy agenda. In 2012 the European Commission announced its 'Action Plan to address barriers to the full use of digital solutions in Europe's health care systems' (31). Nationally, government policy on clinical information is to improve access to information (32) and the on-going Caldicott 2 review is seeking the appropriate balance between protection of personal information and sharing of information to improve care (33). Government policy is to have systems in place for digital clinical communication by 2015 (32). One aspect of this is the NHSmail 2 project (34).

NHS Trusts use digital communication infrastructures such as NHSnet email, send appointment reminders by text message and run websites and social media for providing information. Press reports suggest the NHS should go beyond this and provide digital clinical communication (35-37). Professional regulating bodies have issued cautious guidance to their members on its use or are intending to update relevant guidance (e.g. Royal College of Nursing, British Medical Association, General Medical Council) (38-42). The Medical Protection Society advises clinicians to check with their employer about safeguards (43). These safeguards are currently absent, as demonstrated by a recent informal web-based survey by one of our team (Matharu). This found that of 30 West Midlands NHS Trusts none had a policy for clinical use of email, and only three such policies were identified among NHS Trusts in England. Using NHSnet the sender and receiver can be assured that information is secured but when a clinician sends an email to a patient the email goes outside this secure environment. The formal retention of digital clinical communications with patients currently relies on the forethought and vigilance of individual clinicians. Significant events relating to digital clinical communications which have compromised patient care and safety have been identified (44, 45) including within some co-applicant's Trusts. The few NHS Trusts that provide information about how patients can email staff require consent for email communication (46). Clinicians have expressed interest in web portals for patients and there is on-going NIHR supported research on their use for data collection and intervention delivery. However, integration of these into NHS Trust IT systems and day to day clinic activity is not straightforward. Solutions also need to be flexible to the changing technologies available and their uptake in the population served by the NHS. There is on-going NIHR research on telephone consultations with children, transition to adult services, clinical communication, supporting self-management and adherence. None of this research examines the use specifically of digital clinical communication, and how the lessons from the research can be embedded in this communication medium. There are many questions emerging from patients, clinicians, Caldicott Guardians and NHS IT systems managers, about patient safety, ethics, medico-legal issues (47), including security (48), health care costs and clinical and organisational impacts of these new types of clinical communication. In the next section we outline the existing evidence for the impact of digital clinical communication on health outcome and the unanswered questions and evidence gaps that reviewers have identified.

Evidence for the impact of digital clinical communication on health outcome

In the last two decades a wide range of digital communication systems have been developed in relation to health.There is a large research literature, including several dedicated peer review journals and many reviews. In this section we discuss systematic reviews of evaluations of digital clinical communication and long term conditions. We exclude the delivery of health promotion or disease prevention information and the delivery of clinical interventions where these are distinct from the on-going patient-clinician interaction. Some reviews are focused on a specific technology e.g.(49-51), and others specify both disease and technology e.g.(52). There are reviews that focus on the nature of the content of the communication, such as symptom reporting before a first appointment or between appointments e.g.(53) or the communication of diagnostic tests e.g.(54). Most reviews include studies from across all ages, except our own reviews on diabetes and mental health (55, 56) that focus specifically on young people.

Evidence of the effectiveness of digital clinical communication from systematic reviews is equivocal although all reviews reporting effects found either in favour of the intervention or no differences when compared to usual care. No trials reported poorer outcomes in the experimental digital communication arm. It is difficult to ascertain what contributes to positive effects on health outcomes where these are found, as the findings of the included trials demonstrate considerable intervention and population heterogeneity and varying effects from trial to trial. Research quality issues muddy this picture with an almost unanimous finding from review authors of poor intervention reporting alongside varying methodological quality of included studies. The reviews found study populations to be generally more educated with higher socio-economic status than population norms (52, 57, 58). Several reviews found patient engagement with health care providers increased and this was assessed by access data, contact data or health care professional

workload data e.g.(50, 55, 56, 59). In a further consideration of the possible impact of this increased engagement, Verhoeven et al. (2010) (60) reviewed 90 trials of synchronous and asynchronous communications in diabetes care(60). They found asynchronous communications led to greater improvements in glycaemic control and self-care outcomes, with synchronous interventions being more user friendly and more cost effective for patient and provider. Combined interventions led to greatest quality of life improvements. Alongside these positive findings were negative impacts. Depression increased, parental relationships deteriorated and information overload was reported in some included studies. In summary, the evidence continues to have much uncertainty contained within it despite considerable research endeavour. However, the reviews highlight priority topics for future research to fill gaps in the evidence. We discuss these priority topics in the next section and identify those which our proposed research will address.

Evidence gaps identified by the existing systematic literature reviews

In response to HS&DR panel feedback we have undertaken a review of current systematic reviews on the topic of digital clinical communication to ensure we fully understand the evidence gaps identified by review authors. There are a very large number of reviews on the broad topic of digital communication use in health care. To inform our proposed research area, we considered review evidence if a) it investigated asynchronous and/or synchronous interactions and communications between patients and clinicians using digital communication technologies, b) the review had been published from 2010 onwards as older reviews were unlikely to capture the types of digital communication usage patterns commonly experienced today, and c) it included children and young people or young adult populations only or as well as older adults OR it concerned a condition commonly affecting young people. Seventeen published reviews were identified and their recommendations and justifications for future research were identified. We included one review from 2009 because of its focus on training and support for health professionals. Table 1 presents the list of research priorities topics identified along with details of the reviews and whether or not our proposed research tackles the priority.

Our proposed research tackles many of the priority topics identified by the reviews. Of the 17 reviews, nine indicated the importance of understanding what was important to patients, public and clinicians. Eight reviews identified cost as a priority for future research on digital clinical communication. Specific areas of concern were health care resource use by patients and health professional workload. Several reviews reported increased communication with patients when digital communication was in use and this led to concerns about the costs of meeting patient demand (56, 57). One of our own reviews (56) identified health professional training and on-going support as a potentially hidden cost because health care professionals may not be as confident, nor as socialised, in the use of these technologies as their younger patients. Given the information security, confidentiality and privacy issues related to digital clinical communication, reviews indicated the importance of exploring this area in the process of developing broader policy guidelines. Verhoeven et al. (2010) (60) found the effect sizes of these interventions had remained static over the 16 year period covered by their review, despite increasing normalisation of the technologies across the populations and emphasis on higher quality research designs. They suggested greater involvement of the target population in the development of these interventions might result in greater effect sizes. They suggested co-design of interventions with the target population. As our proposed research does not seek to design an intervention, this particular approach is not appropriate, but our response to this identified priority is to include extensive participation in the proposed research from young people. Several reviews felt that it was time to develop an evidence base across conditions and clinical contexts. A concentration of evidence was found in a number of the more common long term conditions such as diabetes and asthma. As there were many commonalities across long term conditions it was suggested it would be timely to expand the evidence to broader service areas (53). There was an explicit message surrounding the need for a deeper understanding of these interventions, the moderators and mediators of change and the theoretical basis for assuming effectiveness and how all this links to desired outcomes. This suggests the need for qualitative research which can identify how, where and why these interventions work as proposed in our study, and for a more generic approach with measures used across populations to enable moderator and mediator analysis to be possible. Our proposed research seeks to identify or draft a generic measure for future use. Specific outcomes of interest for three review teams related to determining the impact that the frequency of contact digital communication technologies offer, on A&E attendance, hospitalisations and clinical outcomes. The need to explore any impact on the patient-clinician relationship including how patients and clinicians negotiate health needs and health care, was also mentioned, linked to the use of qualitative research methods. Finally, for several teams, there was recognition that the majority of research to date had been undertaken in more affluent, educated and ethnic majority populations and there remain many unanswered questions relating to equity of access in more diverse populations. Our research will tackle a number of the priority topics identified by the systematic reviews. As suggested by a number of reviews we will study digital communication technology as it is currently being used, in its various technical forms, and its use with patient groups with a range of clinical conditions including those more common among ethnic minority groups such as sickle cell. In the next section we describe our inclusions and exclusions for our proposed research and the reasons for these, before presenting our aims, objectives and research questions for our four work packages.

Priority topics for future research identified in systematic reviews	**Number of reviews recommending research on the topic**	**Does current research proposal tackles topic**	**Review reference**
Factors important to patients, public and clinicians	9	Yes - for patients and clinicians	(49, 52, 54-57, 60-62)
Cost and/or cost effectiveness/resource use	8	Yes	(49, 50, 53, 56, 57, 61, 63, 64)
Research to identify moderators, mediators, active ingredients, theoretical basis for intervention and link with outcomes (MRC framework).	6	Yes – qualitatively	(49, 53, 59, 61, 65, 66)

Response harms and risks (including privacy and data security)	5	Yes	(49, 54, 57, 59, 61)
Qualitative research designs	4	Yes	(54, 57, 59, 60)
Research generic to multiple long term-condition populations such as use of generic scales or outcomes of interest, measures to facilitate meta-analysis and/or comparisons across conditions e.g. health economics, medication use, quality of life and service engagement	4	Yes - to the extent of developing a generic measure for future validation and use	(50, 53, 59, 64)
Need for research to inform policy and practice in a range of digital communication aspects to inform implementation/roll out	3	Yes	(53, 54, 63)
Impact of contact and increased contact on A&E attendance, hospitalisation and clinical outcomes	3	Yes – case based	(56, 60, 63)
Health care professional- patient relationship within this digital communication context	3	Yes – via interviews	(54, 58, 67)
Broaden socio-economic and ethnic diversity of research to assess access and inequalities and uptake/usage.	3	Case studies will include conditions common in ethnic minorities	(52, 57, 58)
Telephone counselling vs email counselling	1	Not specifically although case studies may include examples	(57)
Function of communication (e.g. timely advice) in digital communications rather than technological mode of communication	1	Yes	(59)
Focus on widely used digital communication intervention not just future focussed.	1	Yes	(64)
Effects of age on use, impact, outcome	1	No – proposal is focused on young people	(56)
Patient and clinician training and preparation	1	Yes	(55)
Use in symptom monitoring	1	Case studies may include this use	(55)
Investigation of the motivational/fun elements of health technology toys	1	Not specifically although this may be mentioned during data collection	(53)
Smart phone applications to support web based interventions	1	Case studies may include this	(60)
Content of communication	1	Yes, via interviews	(61)

Table 1 Summary of the research priorities identified in 17 systematic reviews of digital clinical communication relevant to young people with long term conditions

Digital clinical communication – study inclusions and exclusions

The digital communication technologies

We have chosen not to specify a specific technology for the study in order to future proof the study and to avoid limiting the utility and validity of the results. The digital communication ecosystem is rapidly changing (68). For example, a few years ago applications for second generation mobile phones did not exist and they will probably be replaced by something else soon. Twitter and Facebook are major providers of social media in the UK (69) at present but a few years ago MySpace was on the ascendancy. People are using many communication channels and are doing so in a patterned way. They use different channels to interact with different groups of people on different subjects, for different purposes, and in different communication technology architectures (e.g. in terms of anonymity, spontaneity, trust, expertise, relationships and timing). The use of communication channels also evolves. For example, Twitter was initially used primarily for broadcasting, but is now often used for communicating between individuals or within small groups (70). We propose that the selection of communication channels, groups and messages is interactive and path-dependent. The starting point tends to reflect peoples' existing social networks and access to digital communication media. However, the way one individual uses these media influences others. These patterns continue to evolve both in an evolutionary way and with unanticipated step changes, for example when new media, services or devices become available. These patterns of communication in turn influence the uptake of opportunities for patient-clinician communication. If a young person has to use an unfamiliar medium and communication pattern in order to communicate with their clinical team, they are less likely to try it out. For example, a web based portal may not be used by young people who mostly communicate via a social media platform. A secure email system may not be used by young people who mostly use text. We will test our propositions in the research. However, a number of patient portals have been launched but have failed due to lack of use, including NHS HealthSpace, a now defunct website launched in 2007. An advanced version of the website offered access to 'Communicator,' a facility allowing patients to have secure email contact with their GP. Despite heavy Government investment, uptake of both HealthSpace and Communicator was very low and the site closed in December 2012 (71). Our aim is to study the use of digital clinical communication via whatever medium is current at the time of the study and to draw out results that are transferrable across technologies.

We will include asynchronous communication technologies such as email, text messaging, social media and web based patient portals. We will also include synchronous technologies such as Voice over Internet Protocol (VoIP) (e.g. Skype and Google Talk) which can simultaneously transmit voice and other media such as text and images. Currently, these systems usually use the internet or mobile phone infrastructures with crossover between these infrastructures. If other digital communication technologies come into common use during the project we will include them if we identify clinics where they are used for clinical communication. We are not intending to include technologies that provide a service that is all but the same as a telephone consultation as there is a large body of evidence on clinical telephone consultations.

The clinical communication

Our research is concerned with communication between patients and specialist (secondary or tertiary care) clinicians/clinic teams who have already been in contact with each other in the clinical setting. Our focus is on systems of communication where there is, or is potentially, communication in both directions – patient to clinician and clinician to patient. We are not including specifically the delivery of therapeutic interventions via digital communication media (72) such as cognitive behavioural therapy (73) nor are we including digital communication that solely involves the delivery of information on disease prevention and health promotion (74). Where the use of a digitally delivered intervention or the delivery of disease prevention and health promotion information forms part of on-going patient-clinical team communication, they will be included.

We have chosen not to limit our case studies to one condition. Recommendations from the findings of four systematic reviews (50, 53, 59, 64) on digital clinical communication relevant to young people with long term conditions, suggest that there is now considerable condition specific evidence regarding disease impacts and outcomes and it is now the right time to look across conditions. The reviews identify priorities for generic study: 1) data security and patient confidentiality 2) self-care/health management outcomes e.g. medication concordance 3) health care usage and costs from the health care provider and the patient perspective and 4) stakeholder service satisfaction. Other priorities identified in recent systematic reviews (52, 57, 58), such as the need to understand uptake and usage across a more diverse population than current evidence allows, can also be studied by taking a generic approach. We will however aim to focus on conditions where the potential to improve health outcome for young people through improved engagement with health care is high, for example where there is a need for frequent monitoring or treatments or complex treatment changes, and where there are significant potential savings to the NHS either in the short term through improved health care or in the long term through prevention of costly complications.

Our 'Patient and Public Involvement' activity with young people undertaken prior to submitting this proposal, suggests that the comparison across different diseases of the use of digital clinical communication will provide important insights. The need to understand the nuances around patient confidentiality is one example. A young person with diabetes may choose to share information about their condition with friends so that the friends know what to do if they become unwell. If they lend their mobile phone to a friend and a text arrives with advice about their insulin dose, this may be acceptable to the young person. In contrast, a young person with a mental health condition may not tell friends about this and will not want to risk receiving a text from their clinical team when lending their mobile phone to a friend – or at least will ensure such texts divert directly into a folder the young person can view when alone. In the next section we detail our study aims, objectives and research questions before describing our research approach and methods.

Aims, objectives and research questions

The research has two aims. The first is to evaluate the impacts and outcomes of digital clinical communications for young people living with a long term condition. The second aim is to provide a critical analysis of the use, monitoring and evaluation, of digital clinical communications by NHS providers.

The overall research question for this proposal is "What are the effects, impacts, costs and necessary safeguards for digital clinical communications for young people living with long term conditions and engaging with NHS providers?" Our proposed research involves four work packages: 1) Patient and Public Involvement activity; 2) literature review; 3) case studies and 4) synthesis and a consensus meeting (see figure 1). The patient and public involvement activity will inform the implementation of the other work packages. The results of the synthesis and consensus meeting will be disseminated to NHS care providers to inform their policy and practice development. The objectives are as follows:

1) To engage young people, including those with long term conditions, in the implementation of the research. (Work package 1)
2) To evaluate and synthesise published evidence on the use of digital clinical communication by health professionals with young people with long term conditions that informs future policy and practice. (Work package 2)
3) To identify from the perspective of patients, clinicians, clinic support staff, clinical and IT managers and information governance specialists the issues, concerns, opportunities and solutions for the use of digital clinical communication in the NHS for a variety of clinical conditions; their expectations of it, their perspectives on the function of the communication, and issues concerning patient safety, quality of communication, patient-clinician trust, medico-legal issues, ethics, work load and configuration, training, and policy development and its dissemination. (Work package 3)
4) To investigate the impact of digital clinical communications on health outcomes for young people with long term conditions and on their engagement with, and use of, health services. Health and clinical outcomes of interest will be those specific to the clinical setting of each case study. Health service engagement includes routine outpatient appointments (monitoring), between-appointment contacts (advice and support at the time of need) and emergency care use (unexpected/unpredicted needs). (Work package 3)
5) To describe the cost of implementation and on-going provision of digital clinical communication and how it varies across different clinical conditions, to understand the value of this service to patients and clinicians, to understand the cost of up-scaling. (Work package 3)
6) To explore the use of an outcome measure for future cost-effectiveness studies across disease areas. (Work package 3)
7) To develop and disseminate guidance for NHS providers and commissioners on policy, procedures, service management and payback in return for investment, guidance on which clinical areas are most likely to benefit, and to consider the need for and design of future cost-effectiveness research. (Work package 4)

The research questions for work packages 2-4 are as follows. In work package 3 data collection will be undertaken for a range of research questions clinic by clinic and then analysed from a range of disciplinary perspectives. We describe the research questions for each analysis package.

Concerning the UK NHS provision of digital clinical communication for young people with long term conditions:

Work package 2, literature review (Lead: Sutcliffe)

- What generic outcome measures are available to assess the impact of digital clinical communication? (Lead: Sturt)
- How and for what purpose is this form of communication taking place (or not) in the UK? (Lead: Atherton)
- What is the ethical, legal, policy and governance framework for digital clinical communication? (Lead: Matharu)
- What is the evidence in the literature to support, refute or add value to the case study findings? (Lead: Sutcliffe)

Work package 3, case studies (Leads: Griffiths and Sturt)

- Analysis package 3.1 (Lead: Griffiths)
  - What works for whom, where, when and why?
- Analysis package 3.2 (Lead: Palmer)
  - How is impact on health status of patients currently evaluated?
  - Using existing clinical data, what is the impact on health status of patients?
- Analysis package 3.3 (Lead: Madan)
  - What value do patients place on digital clinical communication?
  - What are the direct resource use implications for the NHS of implementing it?
  - How does the direct resource use vary when used with different patient groups?
  - What are the resource implications for scaling up in the NHS?
- Analysis package 3.4 (Lead: Slowther)
  - What concerns do patients and clinicians have about confidentiality in relation to digital clinical communication?
  - How does this form of communication affect the patient/clinician relationship and the clinician's duty of care?
  - What regulatory framework is needed to reassure patients and clinicians regarding its use?
- Analysis package 3.5 (Lead: Sujan)

- What are the significant risks to patient safety associated with the use of digital clinical communication in the context of supporting young people with chronic disease?

- Analysis package 3.6 (Lead: Sturt)
  - In future, how can its effectiveness be measured across health conditions?

Work package 4, synthesis of results from the above research questions and consensus meeting (Leads: Sturt and Griffiths)
- What are the risks to patients and to NHS specialist care providers from its use?
- What policy and procedural changes are needed for gaining benefit and limiting harm?
- In which clinical areas is benefit most likely, and how is benefit most likely to be achieved?
- What future evaluation is needed and how should it be undertaken?

Research Plan (See Figure 1)

Independent Study Steering Committee

The Independent Study Steering Committee will meet three times, at 6, 12 and 18 months to review project progress. The Steering Committee will be set up following NIHR guidelines and consist of an independent chair, two representatives of the patient and public perspective (preferably one with experience of having a long term condition as a young person and one with experience of caring for a young person with a chronic condition, a clinician with experience of providing specialist health care to young people with chronic conditions, an academic with experience of organisational/social science research in health care settings, a statistician and a health economist.

Project Management Group

The Project Management Group will be formed of all co-applicants, research fellows and administrators, an additional five Patient and Public representatives including three young people and two parents/carers of young people and collaborator Tewary, a general practitioner from a commissioning group. We will also seek representation from the Health and Social Care Information Centre to maintain links with NHS information technology developments. We will advertise for Patient and Public representatives through the Universities/User Teaching and Research Action Partnership (UNTRAP)(75), and existing young people's research user groups such as that run by Cathy Street at Rethink Mental Illness. UNTRAP has a membership of over 200 service users and carers from diverse backgrounds, supports the users (75) and provides training (6 full days training accredited for 10 CATS points at level 3 or 4 through the Centre of Lifelong Learning at University of Warwick). Co-applicant Fraser will lead any selection process during this recruitment. From our initial exploration of interest we have identified a parent of a young person with a long term condition, Clare Martin who has already agreed to join. The Project Management Group will meet six times during the project and be chaired by a Patient/Public representative. At each meeting the leaders of each work package and sub-package will present plans, progress and any initial results for feedback from the group members. Group members will also actively engage with analysis and advise on dissemination. Patient/Public representatives will be invited to participate in dissemination activities.

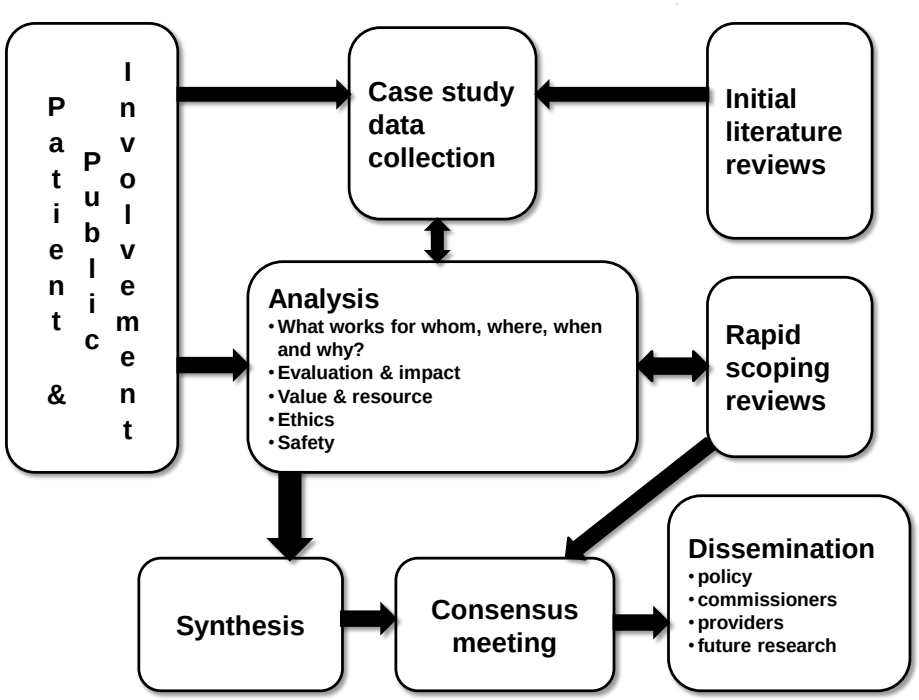

Figure 1 Flow diagram showing links between research activities

Work Package 1: Public and Patient involvement (Lead Griffiths and Sturt)

Deliverables: 1.1-1.2 two reports from young people aged 14-18 years; 1.3-1.4 two reports from young people aged 19-24 years. Reports will be based on research undertaken by young people among their peers to inform the implementation of the research.

Our work in this area over the past four years has involved patients and the public through the Warwick Diabetes Research and Education User Group, The Warwick Young Researchers project, and individuals living with a long term condition such as co-applicant Joe Fraser. We have refined our Patient and Public Involvement activity over this period. Research team members have a published record of sustaining user involvement. We have presented at conferences with Patient/Public representatives on many occasions, most recently with two young researchers involved in our NIHR programme development grant at the INVOLVE 2012 conference.

Our research proposal is highly relevant to young peoples' interests and it is essential that we capture their ideas, views and concerns on a number of detailed issues. Our main vehicle for this is the Warwick Young Researcher project. This uses an established infrastructure to engage secondary school pupils in research. The pupils get an extra curricula experience that will broaden their knowledge of health and research and will contribute significantly to their personal statement or CV. Their schools get an enriched curriculum for their students, the LYNCs research team gains input from the young people. Collaborator Robinson runs the Warwick Young Researcher project and engages with approximately 30 schools per year stretching from Barnsley (Yorkshire) to Guildford (Surrey). Robinson ensures a variety of schools are involved including special needs schools, and within these, students with a diversity of background and ability. We will ask each young person to undertake survey, interview or focus group research with their peers on one of the following topic areas.

1) Development of propositions to inform case study design (see work package 2): Why do young people with long term conditions want to contact their clinical team digitally? Why do they choose to use a particular digital medium?
2) Recruitment and research design: Are we asking young people the right questions in the right way? Which young people would we miss out? What would young people like to ask health professionals about digital clinical communication? Which patient reported outcome measure is appropriate for use across a wide range of conditions (informed by literature review 2.1)?
3) Analysis and dissemination: Is our analysis capturing the messages and themes communicated by young people? Are young people saying what we think they are saying? What are the important messages from our research for clinicians, commissioners and policy makers?

We will undertake two Warwick Young Researcher projects, the first on topics 1 and 2 and the second on topic 3. Each stand-alone project involves a day visit to Warwick University of up to 20 pupils (age 15/16 to 18/19 years) from 10 schools. They receive training in research methods, develop their own questions from our suggested topics, and write a protocol for collecting data from peers usually, but not always using digital media (a web based survey, focus groups using VoIP, interviews via social media). Back in school, and with their teachers' support, they execute their mini-research project over a few weeks. Each young researcher canvasses the opinions and ideas of other people in their school or friendship group, therefore broadening the community of young people with whom we consult. Although not all the young people will have a long term condition themselves, our previous experience of this approach suggests most are close to someone who does. The young researchers return to the university for a further day when they analyse their results and write a report. In order to capture the voice of 19-24 year olds we will run similar projects for young adults aged 19-24 years (10 people each event). We will recruit through university societies to attract students, through UNTRAP, through local broadcast media and YouthNet (76) to attract other young people including those in and not in employment. As young people increasingly look for opportunities to enhance their skills and employability we are confident that we will engage equally successfully with this age group. The materials and expectations will be suitably adjusted for the different age group. Evidence from all the projects will be synthesised and presented at Management Group meetings for discussion.

Work package 2: Literature reviews

Research questions: Using published peer reviewed research literature and grey literature this work package will seek to answer the following research questions concerning the UK NHS provision of digital clinical communication for young people with long term conditions:

- What generic outcome measures are available to assess the impact of digital clinical communication?
- How and for what purpose is this form of communication taking place (or not) in the UK?
- What is the ethical, legal, policy and governance framework for digital clinical communication?
- What is the evidence in the literature to support, challenge or add value to the case study findings?

Deliverables: 2.1-2.3 By three months into the project, reports addressing each of the first three questions to inform the implementation of case studies (work package 3), with updates during the project. 2.4 By the consensus meeting, reports on six scoping exploratory reviews on issues arising from case studies.

Review 2.1 We will identify systematic reviews of the use of digital clinical communication and through these identify intervention studies. We will undertake supplementary searches to find additional studies published since the systematic reviews. We will search these studies for any patient reported generic outcome measures used. We will use rigorous, transparent methods for identifying the literature. We will be iterative in the development of our search methods, through undertaking hand searching, grey literature searching (e.g. google scholar) and checking reference lists and citations of key papers to identify the available outcome measurement tools. We have access to highly skilled information specialists who are familiar with bibliometrics, developing complex search strategies and identifying literature using methods other than through electronic databases. We will review the outcome measures

identified by seeking evidence of the development or evaluation of the measures. We will exclude measures aimed at non-English speaking populations and measures where we are unable to identify any evidence of reliability or validity. Using the COSMIN checklist (77) we will assess each measure for the methodological quality of development studies, measurement properties, and interpretability and generalisability of the measurement results. Data extraction will be checked by a second researcher and disagreements resolved through discussion. We will summarise the findings in a form accessible to the Management Group and to young people engaging in Patient and Public Involvement activities.

Review 2.2 This exploratory literature review will identify reports of the use of digital clinical communication by specialist NHS providers in the UK. We will search both peer review and grey literature. The review will alert us to potential case study sites.

Review 2.3 The NHS based members of the research team will collate relevant ethical, legal, policy and governance documents and summarise them to inform case studies.

Review 2.4 In the nine months of the project prior to the consensus meeting we will undertake up to six rapid scoping reviews. The topics for review will be identified during analysis of the case study data. The reviews will aim to find evidence that supports or challenges or in some other way adds value or a wider dimension to the case study findings and places the case study findings in a wider research context. The exact inclusion and exclusion criteria for each of these reviews will be determined by the results of the case studies and consultation with the Management Group. For example, we may seek to evaluate clinical trial evidence for a specific type of participant (e.g. diabetes), intervention (e.g. mobile phones), outcomes (e.g. reduction in HbA1c). In this fast changing field it may be necessary to extend the existing review of factors that promote or inhibit the implementation of e-health systems (78). If social media are found to be important we may extend our own theory based review of their use (79) and the recent systematic review (80). Another possibility is a review of qualitative evidence. Each review will summarise the available literature from the previous five-year period in tables with a narrative synthesis and discussion of findings. The team are highly experienced in undertaking this type of rapid scoping review and have a range of templates to help combine large and fragmented bodies of research in a coherent and economical way.

Work package 3: Case studies

Research questions and Deliverables – these are presented in the analysis section below.
The protocol for this work package has ethical approval (see details on title page)
Study design

This is a mixed methods case study design. Qualitative methods include interviews and non-participant observation of practitioners and patients communicating in 20 specialist clinical settings. Quantitative data, aggregated at the case level (non-identifiable patient data), will be collected on a range of clinical outcomes meaningful within the case and across cases. For each participating clinic, data collection will be undertaken as far as possible within one episode of field work to minimise disruption and maximise engagement. The detailed design of data collection will be informed by the Patient and Public Involvement activities and modified based on advice from the Management Group. We will seek to describe the use of digital clinical communication from the perspective of all the stakeholders in the clinic (patients/clinical staff/support staff/managers). First we describe the case study approach we will use and that is particularly relevant for the research question 'What works for whom, where, when and why?' We then describe the range of data collection methods that will be used during field work in each clinic to answer the whole range of research question for this work package.

A case study, as defined by Robert Yin (81), is 'an empirical inquiry that investigates a contemporary phenomenon in depth and within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident' (page 18). The 'contemporary phenomenon' we propose to study is the use of digital clinical communication, and the 'real-life context' is the NHS, in particular specialist care provision for young people with long term conditions. A case study approach is of particular value for asking our research questions: 'What works for whom, where, when and why?' and 'How is impact on health status of patients currently evaluated?' A first step in a case study is to develop propositions to suggest what to study (81). Our propositions include the following: 1) young people use or would use digital clinical communication in preference to other means of communication with their clinical team as this fits with their day to day mode of communication; 2) digital clinical communication is used by clinicians to promote the engagement with health care of young people with long term conditions with the aim of improving their health outcome, even if it puts at risk other aspects of clinical service provision (e.g. record keeping). These propositions suggest where to look for evidence to answer our research questions – the young people and the clinical teams. Thus our unit of analysis will be the young person with a long term condition in communication with their clinical teams (i.e. young person-communication-clinical team). This unit of analysis is embedded in the wider clinic and the technology through which the communication is conveyed. The clinic is selected as a case for study within the context of the NHS and contemporary society (81). Data collection will also be guided by existing theory concerning the implementation of innovation in particular the Comprehensive Framework for Implementation Research (CFIR)(82) and Normalisation Process Theory (NPT) (83, 84). We will use these theories to sensitise us to the areas to explore in data collection and the initial structure of our observation and interviews. For example, in the CFIR the domain of intervention characteristics includes stakeholder's perception of the advantage of implementation of the intervention, its adaptability, the potential for testing the intervention on a small scale, and its complexity. Similarly, NPT suggests questions such as whether the intervention fits within the overall goals of the organisation. However, we will not be constrained by these theories and will actively seek other relevant data.

Identification of potential clinics for study sampling
We will study specialist clinics (or clinical teams who provide mostly outreach services) providing NHS health care to young people (aged 16-24 years) with long term conditions which have and have not used digital clinical communication. Sixty sites will be identified from publically available literature, by the project management group particularly the Public and Patient representatives, and through posing questions on internet for a aimed at young people with chronic conditions. From the 60 sites, 20 will be recruited. The lead clinician/manager of each potential clinical site will be contacted by letter and phone to explain the study and seek their agreement to an initial telephone interview. During the initial telephone interview we will ask about the nature of the clinic and the use of digital clinical communication to inform our sampling. We will also seek agreement to participation in the study if their clinic was to be sampled, and seek information on barriers to participation (e.g. upcoming move of clinic location). We will then sample from the clinics that have agreed to participate.
Site inclusion criteria are:

- specialist care for young people with long term conditions
- long term conditions currently expensive to the NHS
- Interest in the use of digital communications to a minimum, moderate or large extent

Sampling will be based on achieving diversity in these three areas alongside geographical location and regional or district specialist clinics, degree of integration of the digital clinical communication within the routine work of the clinic based on an estimate of the proportion of clinic staff using it, type of technology used, duration of innovation and age group served. We will sample clinical sites so that each is different from the last on one or more of these criteria.

We aim to recruit up to 20 clinics to study but recruitment will stop when we have included a diversity of clinics and we reach data saturation. We will also consider the need to collect data to provide contrasts between clinics for analysis. For example, if a clinic is actively using digital clinical communication for advising patients on changing medication regimes, we would aim to recruit a clinic that undertakes similar clinical activity but not using digital clinical communication.

Site recruitment
The lead clinician or manager for each clinic included in our sample will be notified and asked to confirm they are still prepared to participate in the study. A timetable will be prepared with the lead clinician/manager of:

- Date for briefing clinic staff members about the study, for example, during a clinic staff meeting at least four weeks before field work
- Start and end date of field work
- Draft timetable of data collection to maximise opportunity for data collection and minimise disruption to the clinic
- Provision of local policies and guidelines of relevance to the research questions

The lead clinician/manager will be asked to provide the contact details of a clinic staff member with whom the research team should liaise day to day about the field work. The research team will arrange to attend a staff meeting to explain the project and answer any questions.

The research team will provide the following:

- Participant information sheet about the study for distribution to all clinic staff members (including those unable to attend the briefing). These will be made available prior to the commencement of field work.
- Posters about the study to be displayed in the clinic for both staff and patients to see for the duration of the fieldwork

Participant recruitment

Recruitment of clinic staff for interview and informed consent

During the clinic field work we will sample health professionals working in the clinic who use or would potentially use digital clinical communication (nurses, doctors, professions allied to medicine) and administrative, managerial and technical staff who provide support, including IT manager and Information Governance specialists. Sampling will be purposive for diversity of experience and opinion about digital clinical communication within each case study. We will aim for data saturation for each clinic and expect to interview up to 15 clinic staff. In some clinics the number needed to reach saturation may be as low as 4 or 5. Clinicians may decline to be interviewed despite the clinic being a case study site. Study information sheets will be distributed before commencement of observation fieldwork and again at commencement. Written consent will be obtained at the beginning and confirmed at end of each interview with clinicians.

Recruitment of patients for interview and informed consent
Patients (and where appropriate patients' parent/carer/household member – based on patient choice and parent/carer/household member involvement with illness management) will be invited for interview. Prior to the commencement of the field work in a clinic, the research team will discuss with NHS research staff recruitment of patients for interview. A Research Nurse from the relevant NIHR Clinical Research Network will then identify the patients due to attend clinic during the field work and patients who are considered under the care of the clinic but do not attend clinic. The Research Nurse will send a study information sheet by two weeks before the field work commences in that clinic, to the identified patients. This will be sent by post or, if the clinic communicates with them by email, email will be used. Patients who are willing to be interviewed will be asked to text or email their decision to a

dedicated study phone number or email address. Those who have not responded after one week will be contacted by the Research Nurse to remind them about the study, usually by phone, text or email, if the clinic keeps these contact details, or if not by post. Those who agree to interview will be given either an appointment time for interview that fits with their clinic attendance (e.g. after their blood test and before seeing the doctor) or arrangements will be made for telephone/Skype or email/Facebook (and similar) interview, whichever is preferred by the patient. Consent will be taken by the researcher undertaking the interview before the interview commences. Where an interview is held over the telephone, consent will be taken verbally and a dated note made by the researcher in their field. Patients will be offered a thank you token of a £20 High Street voucher. During interview the patient will be asked about the study team interviewing their parent/carer/household member (e.g. girl/boyfriend or wife/husband). The patient will make the decision as to whether they are willing for the parent/carer/household member to be interviewed. If they are willing, they will be asked to pass a participant information sheet to the parent/carer/household member and to provide their contact details for the Research Nurse. The Research Nurse will contact the person identified by the patient and seek their agreement to be interviewed. These interviews will usually be by telephone or email unless the person identified is going to be at clinic during the fieldwork. Consent will be collected as for the patient. Although phone and email interviews might not give as rich data as face to face, we will offer a choice to encourage participation. Interview length is likely to range from a 45 minute face to face interview after clinic through to one email exchange. Guided by clinic staff, we will purposively sample for current users, past users and non-users of digital clinical communication, patients from localities with low socio-economic indicators and patients from ethnic minorities. As well as digital communication users, we will aim to recruit for interview patients who are or might be excluded from the use of digital communication media due to lack of resource, due to disabilities or because they do not want to use them. Where necessary we will employ an interpreter to assist with communication at recruitment and for undertaking interviews for people unable to communicate in English. We will aim for a diversity of patients and data saturation within each clinic and expect to interview up to 15 patients or patient/parent/carer/household member dyads. Where patient and parent/carer/household member are both interviewed, we will interview them separately if they agree.

Data Collection

Documentary analysis
With the assistance of each clinic's lead clinician/manager, we will collate current policies and procedures. The research team will familiarise themselves with these documents before commencing field work and the documents will be used in analysis. We will ask the clinical lead/manager to tell us about any reported incidents or adverse events related to digital clinical communication that have occurred in the previous three years. The clinical lead/manager may refer the research team to a member of hospital staff who has access to this information. A member of the research team will read the reports and make field notes about the nature of the incidents but will not record any identifiers.

Non-participant observation
Fieldwork will vary from 3 to 12 clinic working days depending on the size of the clinic and the extent of usage of the digital clinical communication. Throughout the time at the case study site the researcher will observe how the clinic functions and ask clarifying questions guided by an observation proforma. Clinic staff will be shadowed for up to two hours at any one time and up to four times during data collection to observe different types of clinic activity. This may include observing clinical consultations. The focus of observation in clinical consultations is the clinic staff member. All patients attending appointments during the fieldwork period will be alerted to the presence of the researcher, directed to the wall poster information informed that the researcher is observing some consultations and asked that if they prefer for the researcher not to be present during their clinical appointment to inform the receptionist, the clinician or the researcher.

Observation data will include: who uses digital clinical communication, where, when, why and for what purpose, frequency of digital clinical communications, and the length of time spent dealing with these communications. Dated and structured field notes will be taken but the notes will not include identifiers. Where notes are about specific people, they will be identified with a number. The researcher undertaking the field work will at all times be clearly identifiable by wearing a badge or T-shirt. After each two hour observation period the researcher will spend at least one hour completing their field notes and reviewing the data. Based on this review the researcher may suggest alterations to the planned observation timetable to enhance the collection of data. This will be discussed with the clinic lead and any affected clinic staff.

The researcher will keep a separate paper sheet for recording names of staff and patients and contact details where this is necessary for continuing data collection, for example arranging an interview. This sheet will be kept confidential at all times. It will be kept at the clinic site and when not in use it will be kept in a locked cabinet. A back up copy will be stored on an NHS computer. After data collection is complete this sheet will remain with the NHS Trust of the clinic in a locked cabinet until the project is complete.

Collection of impact data
The researcher will establish during clinic observation, how any use of digital clinical communication is being or could be evaluated for its intended objectives. If a clinic has evaluated their use of digital clinical communication, we will seek access to this evaluation. If not, with the clinic team, we will plan a retrospective evaluation using available data. For example, if the purpose of using digital clinical communication was to reduce emergency admissions for clinic patients, we will extract data on emergency admissions from before and after the use of the digital clinical communication. If the purpose of the digital clinical communication was to improve concordance with treatment or monitoring regimens then we will seek data that reflects this (for example, a routinely used clinical indicator). If the purpose was to improve access to advice and support at the time of need, we will assess whether this is taking place

and any impact on emergency admissions or A&E attendance. The evaluation plan will include: time frame (before and after initiation of use), data relevant to objectives (e.g. A&E attendance, blood test results), time points (e.g. annual data), clinic denominator (young people recurrently in contact with clinic team). The following data will be collected for all clinics included in the case study for before and after initiation of the use of digital clinical communication (or for non-user clinics, over a similar period of time as for user clinics): Did Not Attend rates (excluding first appointments), emergency hospital admissions and Accident and Emergency Department attendance rates. Where a clinic caters for adults we will limit the data to patients aged 16-24 years. The evaluation design will be discussed and agreed with the clinic lead clinician/manager. The research team will then initiate data retrieval by the relevant NHS Information Service Managers. This data will not include patient identifiers and will be provided to the team in aggregate form.

Collection of economic data about the digital communication system
We aim to establish the direct cost involved with the development, implementation and day-to-day running of the technology used in the case study sites for digital clinical communication. We will determine, at each site, the extent to which the development, implementation and maintenance of technology has been managed internally, or commissioned from external specialists. For internally managed activity, we will identify the appropriate person with oversight (e.g. IT director, practice manager) to ascertain the staffing and equipment costs associated with these activities, and determine whether there were specific challenges or design features that were particularly costly to accommodate. We will also investigate costs associated with externally commissioned activities.

Semi-structured interview content (staff, patients and parents/carers)
Interviews will usually be brief (up to 45 minutes), audio-recorded, and focused on the experience of using digital clinical communication. Interviews will be individual interviews or group interviews (up to six people interviewed together). In advance, interviewees will be asked to bring to the interview examples of recent digital clinical communications (anonymised) and critical incidents as examples to inform interview discussion. These examples will not be given to the research team by health professionals. Patients may choose to give the researcher these examples. Parents/carers/household members may choose to give the researcher these examples if they are examples of communication that they, themselves, had with the clinical team.

In clinics where digital clinical communication is in use interviews will cover the following:
- intended objectives of using digital clinical communication and whether or not they have been achieved
- digital clinical communication actually used, why it was used and in what context
- understanding of the nature of privacy and confidentiality in the context of digital clinical communication
- understanding of the clinician's duty of care and the patient-clinician relationship, including responsibility for care/self-care in this context.
- features of the digital clinical communication system, the content of the communication and any contextual factors that contribute to its successful/unsuccessful use
- perceived risks (patient safety, ethics, data storage)
- costs and benefits (patient experience, staff work experience, unintended consequences, impact on other services, financial costs and savings, evaluated health outcomes)
- future implications from greater use of digital communications
- needs or experience of training for using digital communication with patients/clinicians

Within each interview we will also use a variation of the critical incident technique for both when digital clinical communication did and did not work well: tell me about a situation where the digital clinical communication did/did not work well for you; what happened (unfolding); what was the result (consequence); how did you cope (mitigation); what could have happened (worst credible effect)?

To investigate the impact of digital clinical communication on staff workload, in interviews with staff, we will attempt to capture ways in which digital communication has increased their workload, or allowed them to work more efficiently. We will ask participants to quantify this impact as far as possible.

The interview topics will be adapted for use in clinics where there is partial use or past use of digital clinical communication. Where it has not been used, interviews will seek to explore currently used processes of communication between clinicians and patients, attitudes to digital clinical communication and reasons for not using it, implications of greater use of digital communications including training needs. We expect to reach data saturation rapidly in these clinics.

The interviews will be an opportunity to expose any generic measures identified in literature review 2.1 to clinicians and young patients to ascertain to what extent the success or not of their digital service is captured by these outcome measures. If no generic measure has been found through literature review or if cumulative case study analysis identifies that existing measures are not viewed as adequate, then the interview and observational data will be used to develop items for a new generic scale to capture the impact of digital clinical communications.

We will investigate the value patients place on digital clinical communication using a willingness-to-accept approach (85). Within the semi-structured interviews, patients will be asked to consider the hypothetical opportunity to receive payment (cash or vouchers) as an alternative to using the digital communication system, and indicate how much they would need to be offered to forego use of the system.

We will be asking health care staff to talk about practices that may be contravening NHS current Information Governance guidance. To collect rich data we will emphasise the confidentiality of the research data and that we are collecting data from many clinics so it will not be possible to identify specific clinics/staff from our research report. We will have an ethical protocol in place for considering breaches of Information Governance policy and professional standards. We do not expect to take action for activity that we find is common practice but will be alert to serious breaches of policy and professional standards. We will steer a careful path here as clinicians using digital clinical communication will be rich sources of data for the project. We will ensure transparency of ethical process.

Data management
All qualitative data will be given an identifier, typed up/transcribed and during this process anonymised. NVivo software will be used to manage this data. Retrospective quantitative clinic data will be retrieved by members of the health care provider data management team and provided in an aggregate, anonymised form.

3.5 Analysis To guide the reader through our analysis plans we describe our analysis in relation to each of the research questions to be answered through the case studies. However, there is overlap between analysis packages and each analysis package will inform the others as they all form part of the same case study. Throughout analysis we will use standard techniques for quality checking including qualitative coding by independent researchers and investigation of outliers / non-standard responses.
Although the analysis packages will be led by specific team members, analysis protocols, interim analysis and penultimate analysis results will be considered and discussed by the whole team. Qualitative analysis will be concurrent with data collection to ensure data collection ceases when data saturation is reached.

Analysis package 3.5.1
Research question: What works for whom, where, when and why?
Deliverable: 3.5.1 Analysis addressing the research question including logic models to assist policy makers and planners, for example, 'If we do this ….then that ….in this context but not in that one'
Analysis process: Given the research gaps identified related to the need for generalizable evidence across disease areas, we will focus analysis on the commonalities across the health conditions such as communication about medication or communicating results of investigations or symptom reporting or health service navigation, as one review (60) called it "the function of the communication". Following Yin's case study approach (81) we will use the following analytical strategies 1) testing propositions developed early in the study from Patient and Public Involvement activity and early data collection where propositions are possible explanations of outcome; 2) using both quantitative and qualitative data where the quantitative data describes the outcome and qualitative data is used to explain the outcome; and 3) seeking rival explanations. We will have a large volume of data for analysis. We will follow the advice from Pawson (86) to probe our developing findings particularly where they are 'most fragile ……where doubt provides us with pressing rival theories to account for a particular finding, which we can then proceed to test' (page 107). These general strategies will be implemented in the following way with data collection and analysis proceeding concurrently. A) Propositions about the use of digital clinical communication will be developed from the Patient and Public Involvement activities and from analysis of data from the first clinics studied. These propositions will inform further data collection and will be used in the subsequent analysis process. Data will be examined for evidence to support propositions so they continue to be considered as possible explanations, or refute propositions so they are excluded as possible explanations, or to provide alternative explanations. The data examined will be both the qualitative data and the qualitative 'outcomes' data (analysed in analysis package 3.2 see below). Explanations will be constructed, following the realist evaluation approach, as configurations of context, mechanism and outcome (87). (Illustrative example - context: mental health team working with young people in deprived inner city locality with high rates of admission for psychosis + mechanism: SMS messages remind young people about medication and young people can report side effects = outcome: reduced rates of admission). B) As data collection proceeds initial possible explanations identified will be compared with evidence from subsequent data and cases, and revised. This will continue until we are finding no new data/patterns of data (data saturation) and so no evidence for revising the explanations further. C) Of particular value for informing policy and practice is the development of logic models. This brings together explanations as a chain of events that starts with an intervention (e.g. use of email to communicate with patients) and through intermediate steps (e.g. improved self-care or reduced support from parent) produces a final outcome (improved health or not). The aim is not to produce one logic model but a number of alternative models.

Analysis package 3.5.2
Research questions: How is impact on health status of patients currently evaluated? Using existing clinical data, what is the impact on health status of patients?
Deliverables: 3.5.2.1. A summary of how the impact of digital clinical communication on patient health status is currently measured at a clinic level. 3.5.2.2. An evaluation of the impact of the use of digital clinical communication for each clinic included in the case study where this form of communication is used. 3.5.2.3 A comparison of the rates of 'Did Not Attend', emergency hospitalisation and Accident and Emergency Department attendance for each clinic population, between clinics to establish trends and exceptions, and with nationally published rates for these clinic populations. With clinic agreement, these deliverables will be made available to all the clinics participating in the study as well as informing the consensus meeting.
Analysis process: Data on how the impact on health status of patients is currently evaluated in relation to the use of clinical digital communication will be extracted from the case study material and summarised for each clinic. The data extracted from routine clinic records for the planned clinic evaluations, will be analysed using descriptive statistics, cross-tabulations, and statistical tests of association. To analyse the difference in 'Did Not Attend' (DNA) rates before and after implementation of the use of digital clinical communication we will report the proportion of DNA patients and calculate the difference in these proportions with the appropriate

95% confidence interval based on a delta-method standard error for the difference in proportions. We will also report the P-value from the test of the difference in binomial proportions (88). We will also report similar analyses for rates of emergency hospitalisation, and rates of Accident and Emergency Department attendance. Each clinic based analysis will be fed back to the clinic.

For all clinics included in the case study, whether or not they have used digital clinical communication, we will compare 'Did Not Attend', emergency hospitalisation and Accident and Emergency Department attendance from a time point prior to the introduction of digital clinical communication (or a similar time point for non-users) with current rates. We will compare rates between clinics to understand overall trends and any exceptions. For example, use of digital clinical communication may be associated with increased Accident and Emergency Department attendances for one long term condition and not another. We will also compare study clinics with published data for the same condition and its management in the UK. We will search the web for publicly available data sources to use as comparator. Public bodies are legally obliged to publish requests for information and their responses under the freedom of information act. At least 15 NHS trusts have published data online for years 2009-10 and 2010-11 about DNA rates in specific clinics or specialties e.g. (89-91). In addition, some NHS trusts publish the DNA rates for their services overall within their annual reports e.g. (92, 93). We will also use the overall data for each study clinic's own NHS Trusts as a comparator where available. Statistical modelling of each outcome ('Did Not Attend', emergency hospitalisation, and Accident and Emergency attendance) will be performed using multilevel mixed effects logistic regression using clinic level random effects and treating the before and after 'Did Not Attend' data (and data at any additional time points) as repeated measures (94). This will allow estimation of an intra-class correlation coefficient for the proportion of variance explained by the within clinic variance. The use of digital communication will be included in the model as a binary covariate allowing estimation of an odds ratio for the specific outcome for the effect of digital communication.

Analysis package 3.5.3
Research questions: What value do patients place on digital clinical communication? What are the direct resource use implications for the NHS of implementing it? How does the direct resource use vary when used with different patient groups? What are the resource implications for scaling up in the NHS?
Deliverable: 3.5.3 A summary of the costs and benefits of digital clinical communication used by NHS providers with young people, for a range of clinical conditions and of the value placed by patients on this form of communication and what is particularly valued about it.
Analysis process: To understand the value patients place on digital clinical communication we use the willingness-to-accept approach and link the answers to data from patients (or patient/parent carers) on their experience with such communication, to better understand what aspects are highly valued. Data collected from the case study sites about cost, design features, staff work load and time will be combined with evidence from the literature to build up a picture of the costs associated with digital clinical communication, and the immediate benefits to patients and health care professionals. We will explore how these costs and benefits vary according to the design of the system and the disease area where it is used. We will also explore the extent to which costs are fixed or vary with size, in order to explore the impact of scaling up particular interventions to be available across the NHS.

Analysis package 3.5.4
Research questions: What concerns do patients and clinicians have about confidentiality in relation to digital clinical communication? How does it affect the patient/clinician relationship and the clinician's duty of care? What regulatory framework is needed to reassure patients and clinicians regarding its use?
Deliverable 3.5.4 An analysis of the ethical implications and risks associated with digital clinical communication.
Analysis process: Given the research gaps identified in relation to privacy and data protection and the effect of digital clinical communication on the patient-clinician relationship, we will include an empirical ethical analysis of interview and observational data focussing on patients and clinicians views on the nature of confidentiality and privacy, clinical duty of care, and trust between patient and health care professional in the context of their experience of digital clinical communication. We will follow the method described by Ives and Draper for 'normative policy oriented empirical ethics' (95). This approach recognises the need for ethical policy (in this case policy on the use of digital clinical communication) to be informed by both a theoretical analysis of the ethical concerns and the moral intuitions of the relevant stakeholders. Analysis involves an iterative process of reflective equilibrium between the empirical data (intuitions of patients and clinicians on confidentiality and trust in the context of digital clinical communication) and theoretical analysis (ethical and legal discourse on confidentiality and duty of care).

Analysis package 3.5.5
Research questions: What are the significant risks to patient safety associated with the use of digital clinical communication in the context of supporting young people with chronic disease?
Deliverable: A summary describing the most significant risks to patient safety arising from the intended use and reasonably foreseeable misuse of clinical digital communication, and credible failure scenarios.
Analysis process: The introduction of technology may change the way in which a service is delivered and used. It is important to identify proactively and to assess any potential threats to patient safety that may arise as a result of this. Such a risk assessment needs to consider both intended use scenarios as well as scenarios where the technology may be used in ways that may not have been intended (reasonably foreseeable misuse). In addition, credible failure scenarios (i.e. situations where use of the technology fails) need to be identified and their impact on patient safety assessed. The risk analysis will be informed by: (a) consideration of actual events through the study of incident reports from the participating organisations as far as these are available to the research team, and (b) perceptions of staff and patients elicited through the semi-structured interviews using a variation of the critical incident technique (described above).

Analysis package 3.5.6
Research question: In future, how can its effectiveness be measured across health conditions?
Deliverables: 3.5.6.1. Synthesis of evidence from Patient and Public Involvement activity and case study of the dimensions the impact of digital clinical communication for inclusion in a generic outcome measure. 3.5.6.2 Either, summary of the relevant existing generic outcome measures identified in literature review 2.1 or, if no relevant generic measures are identified, draft of a potential outcome measure.
Analysis process: We will undertake thematic analysis of qualitative data from the case studies specifically for aspects of impact. We will continue analysis of data until no new themes are being found. Themes will be summarised and compared with those covered by existing generic measures identified from literature review 2.1 or will be developed into a draft outcome measure for future development and testing beyond the scope of this study.

Work Package 4: Synthesis of results and consensus meeting

Research questions What are the risks to patients and to NHS specialist care providers of its use? What policy and procedural changes are needed for gaining benefit and limiting harm? In which clinical areas is benefit most likely, and how is benefit most likely to be achieved? What future evaluation is needed and how should it be undertaken?
Deliverables: 4.1 Description of the consensus reached on each of the research questions. 4.2 Description of the consensus process.
Consensus process We will prepare the deliverables identified in work packages 1-3 for presentation at the consensus meeting. Further we will prepare a working paper synthesising the results of the work packages. During the process of synthesis we may return to the empirical data to shed light on an issue arising during synthesis. The synthesis will aim to provide evidence to answer the research questions for this work package. We will also write a series of scenarios to illustrate the key themes of the synthesis for presentation at the consensus meeting.

We have considered the various designs for running the consensus meeting (96). Ensuring attendees have experience or insight relevant to the topic and bringing a range of views to the meeting is probably the most important aspect of design (97). We will invite national stakeholders (approx. 8) representing various aspects of health care provision for young people, recruit young people (approx. 8) and representatives of specialist service providers (approx. 8). We will advertise for young people to attend among all those who engaged with Patient and Public Involvement Activities, as these young people will already have developed some insights into the issues. We will advertise for representatives of specialist service providers by contacting all providers who expressed an interest in the research in work package 3 (even if they did not become a study site). National stakeholders are likely to include representatives of the Association for Young People's Health, General Medical Council, the Nursing and Midwifery Council, the National Information Governance Board, National Institute for Health and Care Excellence, Royal College of General Practitioners, the Health and Social Care Information Centre and a representative from the commercial sector.

The format will be a modified form of the NIH Consensus Development Conference (97). The form of consensus may be agreement about the multiple options available and the caveats that apply to different contexts. The meeting will run as follows: a series of short presentations on the different aspects of the study; discussion of the scenarios in small groups followed by plenary feedback and discussion; in different small groups consideration of each of the research question for this work package; feedback to the whole group; continued discussion until consensus is reached. The meeting will be chaired by a Patient/Public representative from the project Management Group – potentially a young person (with appropriate coaching and support).

Dissemination and projected outputs

The outcome of the consensus meeting will form the basis the following outputs for dissemination to NHS providers:
1. The dissemination report, with executive summary, will include research results, suggest future innovations, assess the risks and procedures for minimising the risks of innovation, assess the risks of not innovating, assess actual cost of provision including start up, continuation and up-scaling, and make recommendations
2. Draft new national information governance policy
3. Manual on implementation for local managers.

Those involved with the consensus meeting will be asked for advice about dissemination. We will disseminate the outputs to individuals and organisations that are in some way concerned with the development of policy and guidance for the NHS in relation to digital clinical communication and in relation to services for young people with long term conditions. The executive summary, with a web-link to all the outputs, will be emailed to relevant officers in all NHS Trusts and Boards in the UK and to each Commissioning Group in the UK. It will be sent to relevant national organisations including those engaging with the consensus meeting; organisations representing patients such as The Patients Association, Diabetes UK, MIND and Rethink Mental Illness; health professional organisations such as Health and Care Professions Council, Royal College of Nurses; policy makers including the Department of Health; and organisations representing health service managers such as the Institute of Healthcare Management.

We will seek to meet with representatives of organisations responsible for relevant policy and guidance.

The project will also recommend future evaluation research and the form of a generic measure of impact.

With assistance from Patient/Public representatives and representatives of case studies, we will present our findings at four UK conferences and a European conference where the audience is mostly professionals responsible for policy and health care provision.

The study will be written up for publication in peer reviewed journals and we will seek press coverage for the project findings. We will take care to ensure clinics/staff cannot be identified from our publically available reports and papers.

Plan of investigation and timetable

Research activity/Quarter years of the two years	-1	1	2	3	4	5	6	7	8
Ethics, governance									
Management Group meetings		X	X	X	X		X	X	
Steering Committee Meetings			X		X		X		
Patient and Public Involvement activity									
Literature review (work package 2)									
Case study (work package 3) recruitment and sampling									
Case study (work package 3) data collection and analysis									
Synthesis and consensus meeting (work package 4)									
Writing up and dissemination									
Recruitment of clinics as case studies									
Number of clinics with expressed interest in being a case study	12	18	10						
Number of clinics recruited as a case	4	5	5	3	2	1			
Number of clinics with data collection taking place		3	5	5	4	2	1		

Work package	WP1		WP2		WP3	WP4	Dissemination
Month of completion of deliverables	4	16	4	22	22	23	24
Deliverables	1.1, 1.2	1.3, 1.4	2.1-2.3	2.4	3.5.1; 3.5.2.1-3; 3.5.3; 3.5.4 3.5.5; 3.5.6.1-2	4.1 4.2	Project report

Project management

The project will be led by co-PIs Griffiths and Sturt. They have a track record of collaborative research and publication. Griffiths and Sturt will manage the researchers employed to undertake project field work and analysis. Sutcliffe will manage the researcher and information scientist employed to undertake literature review. Madan will manage the researcher focusing on health economics in close collaboration with Griffiths and Sturt. Griffiths, Sturt, Madan and Sutcliffe will meet every week in the first three months of the project (Sturt by telephone) to ensure rapid initiation of activity. Subsequently they will meet by telephone at least every two weeks along with researchers and administrators to ensure appropriate allocation and timetabling of tasks. Targets will be set and reviewed each meeting. All co-applicants will attend the Project Management Group meetings. If necessary video conferencing will be arranged if a co-applicant is unable to travel to the meeting. At each meeting the Group will receive a report on each aspect of the project. The Group will agree a programme of meetings when specific research team members will meet for specific tasks such as refining the interview schedules, initial analysis focused on safety or ethics, identifying topics for rapid reviews. The Project Management Group will also agree recruitment targets, data collection and analysis targets and a writing plan for the deliverables, presentations, project report and academic papers, and review progress. Co-applicants assigned leadership of work packages or analysis packages will be responsible for ensuring the data they need is collected and analysed, and deliverables produced.

Ethical issues

The key ethical issue in this study is confidentiality in both recruitment and data collection. Patients will be invited to participate by clinic staff and the research team will not have access to patient records. NHS staff will extract clinic data and provide it in an anonymised form. Participants will be reassured that the information they provide will be confidential. If concern arises about unethical or unsafe clinical practice the researcher will consult a principal investigator (PI) who will decide if it is necessary to initiate action through normal professional channels. During data collection we are asking clinic staff to reveal activities that may breach information governance policies. This is a difficult issue as these clinicians are likely to be rich sources of data. We will draw up a protocol for action for serious breaches of confidentiality. However, we do not expect to take action for activity that we find is common practice. We will ensure it is not possible to identify clinics or staff from our publically available research reports. Data collection will be across 20 different sites so preserving anonymity should be possible. Patients/parents/carers may disclose difficulties in their relationship with a clinician or exhibit psychological distress or high risk behaviour. We will provide information about sources of support. If a serious risk of harm to the patient or others is identified the researcher will discuss with a PI who will then assess and take appropriate action. If information is disclosed participants will be informed that this is happening.

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