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Mapping the Patient Complaints Journey

Enhancing the patient complaints journey: harnessing the power of language to transform the experience of complaining.

Mapping the Patient Complaints Journey

PROTOCOL VERSION NUMBER AND DATE

- V1.3 (10/12/2020)

RESEARCH REFERENCE NUMBERS

IRAS Number: 266628

SPONSOR'S Number: 20/0011

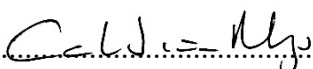**FUNDER'S Number:**   NIHR127367

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:..

Date:
29/07/2020

Name: (please print): Dr Catrin S Rhys
....

LIST of CONTENTS

KEY STUDY CONTACTS

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Study Steering Committee	Chair: John Compton cjohn.compton@hotmail.co.uk Merran Toerien – University of York Julie McCarroll – Research & Governance, PHA Nick Curry – Research Governance, Ulster University Victoria Scanlan – PPI participant

STUDY SUMMARY

Study Title	Enhancing the patient complaints journey: harnessing the power of language to transform the experience of complaining.
Internal ref. no. (or short title)	Mapping the Patient Complaints Journey
Study Design	We will use a novel, innovative approach that combines: (i) a detailed longitudinal observational study of communication in encounters throughout the complaint journey; (ii) a parallel qualitative study using complainant diaries and interviews about the subjective experience of the complaints journey; and (iii) an audit of patient expectations of the prevailing cultural context in which complaint handling takes place. This approach constitutes a detailed, contextualised examination of the relationship between complainants' observable, complaint-handling experiences and their personal, evolving perspective on both the complaint issue(s) and the complaints process. It will thereby open the 'black box' of real-time

	complaints experiences, a significantly under-researched matter.
Study Participants	Complainants will be invited to participate when they make their initial approach (by letter, by phone, by email) and recruitment will involve consecutive convenience sampling; data will be gathered from all complainants who give their consent. The sample size of the initial encounters population will be governed by the time it takes to recruit 20 longitudinal case study participants from the initial encounter. Longitudinal Case Studies: Recruitment to the longitudinal study will end once a representative sample of 30 participants has been recruited. Complaint handlers: complaint handlers will be recruited from each of the two Trusts. Existing connections between the research team and the Trusts will facilitate access.
Planned Size of Sample (if applicable)	At least 30 participants for the full longitudinal sample
Planned Study Period	January 2020 – March 2023
Research Question/Aim(s)	How can the power of language be harnessed to transform complainants' experience of complaining in the NHS and reduce their recourse to litigation?

FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
NIHR HS&DR Programme	£556,802.41

ROLE OF STUDY SPONSOR AND FUNDER

Sponsor for this project is Ulster University. The Sponsor oversees research governance and indemnity as well as assuming overall responsibility for the initiation and management of the study. The funder of this project is the NIHR HS&DR Programme. The funder monitors and supports the timely delivery of the contracted study, including approving all changes to the study protocol. Neither sponsor nor funder has any role in the study design, conduct, data analysis and interpretation and manuscript writing.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Management and oversight of the project will be conducted through the following:

1) Project Management Group

2) Project Manager

3) Project Advisory Board

4) Study Steering Committee

In addition, financial management of the project will be overseen by the Faculty Research Contract Manager (Ulster University), while the overall conduct of the project will be subject to the university's research governance procedures, overseen by Nick Curry, Director of Research Governance, Ulster University.

Project Management Group

The Project Management Group (PMG) will include all members of the research team, including RAs, the Lead Trust, the PCC and a PPI member, invited through the PCC membership list and the Project Manager. The PMG will hold bi-monthly online project meetings. These will be chaired by the CI (Rhys) with support from the Project Manager. The meetings will be formally recorded and circulated to all project partners.

The main responsibilities of the PMG will be to:
- Monitor progress of work against milestones
- Review project outputs
- Monitor project risk management and contingency planning
- Agree on any requested project changes
- Agree and monitor communication and dissemination plan

Project Manager

The Project Manager (PM) will coordinate with the different strands and sites of the research project to ensure that the project is completed on time and within budget and that the project's objectives are met. The PM will coordinate written reports on aspects including (1) progress against milestones (2) current project summary and financial situation and (3) a log of all risks and steps to mitigate. The PM will hold full responsibility to ensure adequate records and other supporting documentation are on file to prove that the corresponding tasks and actions have been implemented appropriately and will ensure all the records are kept on file for the appropriate period after the final balance is paid. The PM will provide reports as required to the Faculty Research Contract Manager (Ulster University), who will oversee the financial management of the project and to the Study Steering Committee.

Project Advisory Board

Mapping the Patient Complaints Journey

The Project Advisory Board (PAB) is designed to provide enhanced stakeholder participation in the project. Membership will include complaints staff (handlers and managers), complaints researchers, and three PPI representatives (who may or may not have been past complainants). PAB members will contribute directly to project decision making through collaborative workshops at strategic points in the project timeline. Open communication with the PAB will be maintained via a project email distribution list which will also facilitate reporting and feedback following collaborative workshops. Outcomes from PAB meetings will be reported to the PMG.

Study Steering Committee

The Study Steering Committee (SSC) will provide independent supervision of the project to ensure that the project adheres to the rigorous standards of the Research Governance Framework for Health and Social Care. The SSC for this project is constituted following the NIHR guidance on the role, constitution, composition, meeting requirements and primary reporting line.

Role:

The SSC will:
- Monitor the management of project progress towards its interim and overall objectives
- Ensure appropriate ethical approvals are obtained in line with the project plan
- Ensure that the rights, safety and well-being of the participants prevail at all stages of the research, through the monitoring of ethics and data management protocols
- Review and endorse the annual report prepared by the Chief Investigator (CI) on the progress of the project, prior to this being submitted to the NIHR
- Agree proposals for substantial amendments, should such become necessary, and provide advice to the sponsor and funder regarding approvals of such amendments
- Provide advice to the investigators on all aspects of the project.

Membership

The SSC will comprise:
- An independent Chair
- An independent researcher with expertise in the application of conversation analytic research in healthcare contexts
- PPI representation to contribute a patient and/or wider public perspective
- A representative from Research Governance, Ulster University to ensure that the overall conduct of the project adheres to the university's research governance procedures.
- A representative from HSCNI

Patient & Public Involvement

The PPI in the study involves both direct PPI representation by individual members of the public recruited via the PCC and indirect PPI representation via representatives of patient advocacy

Version 1.40 29th November 2022 – Research Protocol

organisations. Direct individual PPI is integrated throughout the ongoing decision making of the project, including research design, data analysis and interpretation and the co-design of the training intervention through the paid recruitment of individual service users to the project Advisory Board and the co-design workshop. Indirect PPI in the study is provided primarily by the Patient Client Council who are involved with every aspect of the project and bring detailed complaints intelligence *from the complainant's perspective* based on their extensive experience of supporting clients. In addition, the PCC provide a well-established route for disseminating information about the individual PPI roles in this project and inviting participation as they actively promote and support PPI through their website, newsletter and membership list and through regular involvement events and workshops throughout Northern Ireland. PIER NI also provides an additional and effective route to recruiting PPI participants. We will also engage with patient advocacy organisations in England, Scotland and Wales, such as PALS, PASS, POhWER and seAp, and invite their participation in the Advisory Board. The management and oversight of this project also includes both direct PPI and indirect PPI through the PCC on both the Steering Group and the Project Management Group.
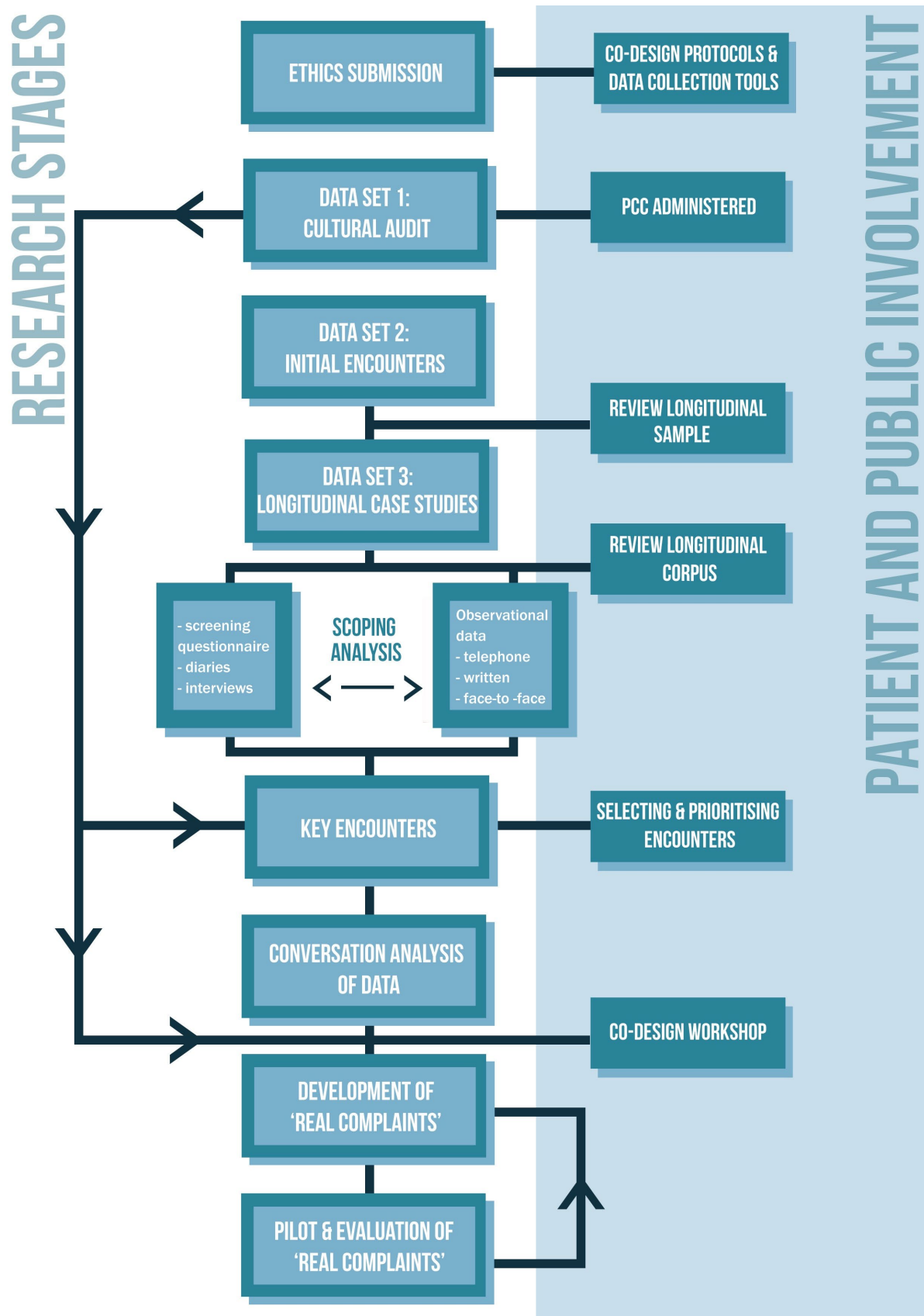
PROTOCOL CONTRIBUTORS

Protocol contributors include all members of the research team listed above. In addition, PPI participants with past experience of the NHS complaints process were invited to review and refine the data collection approach in the project. The PPI contributors re-enforced the importance of: emphasising the impartiality of the project team in relation to the substance of any complaint; articulating the value of the project outcomes to participants; maintaining regular contact with longitudinal participants (including visits to the participant's home). They also significantly informed the range of formats to be provided for completing the diary of the complaint journey. In particular, participants were in favour of an online digital format that might be completed on a phone or a tablet. Participants also argued for simplified Participant Information Sheets with additional information on the project website.

KEY WORDS: Complaints, communication, healthcare, conversation analysis, ethnography, NHS

STUDY FLOW CHART

Mapping the Patient Complaints Journey

RESEARCH STAGES

PATIENT AND PUBLIC INVOLVEMENT

ETHICS SUBMISSION ——— CO-DESIGN PROTOCOLS & DATA COLLECTION TOOLS

DATA SET 1: CULTURAL AUDIT ——— PCC ADMINISTERED

DATA SET 2: INITIAL ENCOUNTERS

REVIEW LONGITUDINAL SAMPLE

DATA SET 3: LONGITUDINAL CASE STUDIES

REVIEW LONGITUDINAL CORPUS

- screening questionnaire
- diaries
- interviews

SCOPING ANALYSIS
< ——— >

Observational data
- telephone
- written
- face-to -face

KEY ENCOUNTERS ——— SELECTING & PRIORITISING ENCOUNTERS

CONVERSATION ANALYSIS OF DATA

CO-DESIGN WORKSHOP

DEVELOPMENT OF 'REAL COMPLAINTS'

PILOT & EVALUATION OF 'REAL COMPLAINTS'

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Mapping the Patient Complaints Journey

STUDY PROTOCOL

1   BACKGROUND

The UK has the highest health litigation costs in Europe and these are increasing significantly: According to the recent National Audit Office report, in 2016/17, NHS Resolution spent almost £1.8bn on administering and settling claims against the NHS (secondary care). £1.7bn was spent on clinical claims, an increase of 15% on 2015/16, following an increase of 27% in the year before that. In 2016/17 there were 10,600 new new clinical negligence claims registered with NHS Resolution, under its Clinical Negligence Scheme for Trusts, in 2016-17 (compared with 5,300 in 2006-07).

NHS Digital reports the number of complaints about NHS care, but this will not include all complaints about healthcare since some will go directly to professional regulators, or to social care systems, and there is possible duplication of channels used by complainants. NHS Digital (2017) reported that there were 208,415 written complaints annually to the NHS, and increase of 4.9% from the previous year. HealthWatch's research suggests that less than half of those who experience poor care go on to complain, with an estimated 250,000 unreported incidents, and the number of social care complaints is not reported nationally.

Patient experience of complaints systems was highlighted in Healthwatch's research based on a YouGov Complaints Survey of 1676 adults. Some 23% did not know who to complain to, and among those who complained, 47% found it difficult to find out how to do so, 61% did not feel their complaint was taken seriously, less than half received an apology, 26% were deterred from complaining as they anticipated negative repercussions on their care. Two thirds said they would have complained if they had received advocacy and support to do so, but only 10% received such support. More than fourth fifths of people said their main motivation to complain was a desire to improve care services.

There are a number of toolkits that guide NHS providers and commissioners on complaint management and learning from complaints which draw on the report by the Parliamentary Health Service Ombudsman (PHSO) "My Expectations for raising concerns and complaints". Guides have been produced by Healthwatch, also covering social care. The Department of Health has announced it is exploring proposals to improve the way complaints involving serious incidents are handled, particularly how providers and the wider care system may better capture necessary learning from these incidents. There were several investigations arising from the government's response to the Francis inquiry, including a review of the NHS complaints system. Complainants want and expect admission of responsibility, apology and reassurance that lessons will be learnt and enacted, and where appropriate, individuals will be sanctioned, and that investigations should be open to scrutiny and where necessary independent of the NHS. The PHSO report related to complaints where serious and avoidable harm was alleged, and Care Quality Commission reports evidence that the NHS has considerable scope to improve how complaints are managed and investigated within local NHS services. The PHSO report investigated 150 complaints investigations from their caseload of 288 cases in "acute" trusts in 2014 where avoidable harm or death was alleged, and surveyed 170 complaints managers. Some 40% of

investigations were inadequate, and trusts did not find failings where the PHSO subsequently found failings in 73% of cases. Further, in 41% of cases, complainants were given inadequate explanations for what went wrong and why.

The National Quality Board (NQB) issued guidance to NHS trusts on managing and learning from deaths, including the importance of listening to the experience and concerns of family members. The Department of Health has announced it is exploring proposals to improve the way complaints involving serious incidents are handled, particularly how providers and the wider care system may better capture necessary learning from these incidents.

The Clwyd Hart review of the NHS complaints system was critical of the capability and low levels of training for complaints management staff. It makes recommendations about their training and supervision and for an accredited training programme. In 2017 an on-line programme was launched for NHS staff in the UK (https://www.e-lfh.org.uk/programmes/complaintshandling/). In Scotland 2013, an e-learning and development programme for NHS Scotland staff dealing with patient feedback and complaints was developed by NHS Education Scotland (NES), the Scottish Public Services Ombudsman (SPSO) and Scottish Government Health and Social Care Directorates http://www.gov.scot/Publications/2013/11/5156/4.

Existing research indicates that complaints handling often falls short of patient expectations; much dissatisfaction resides in poor communication (Cowan and Anthony 2008). In 2009 The Health Professional Council (HPC) conducted a scoping review looking at existing research on complaints. Most studies of complainants found that people were dissatisfied with the procedure and there may be 'unintended consequences' such as health problems caused by the handling of complaints. A lack of common understanding of the complaints process can also be a source of dissatisfaction amongst complainants. The report recommended that there is clearly a need for research on complaints in relation to non-medical professionals including; exploring the overlap between local and national complaints procedures and the extent to which people are appropriately referred to them; the levels of awareness of complaints processes amongst different populations and different professions; finding successful methods of reaching underrepresented groups; and following-up individuals who make complaints and exploring whether or not expectations of complaints procedures have been met.

The strongest predictor for litigation in the NHS is not medical error or patient demographics but dissatisfaction with communication, either within the clinical encounter (Vukmir 2004) or subsequently in the complaints handling process (Durand et al 2015). A challenge in addressing litigation rates is therefore to develop more effective ways of communicating for healthcare complaints handling. An analysis of the talk between complaints handling staff and patients (and their families) has been neglected in previous attempts to reform the complaints process (Cowan and Anthony 2008) and is likely to improve our understanding of good and poor communicative practice.

Mapping the Patient Complaints Journey

Description of study

This study will examine the longitudinal experience of making a complaint to the NHS from the patient's perspective. The project builds on this team's previous work on NHS complaints, including a pilot study of a small set of recorded complaints calls to a Scottish NHS Health Board, which examined patterns of response by call handlers and the resulting effects on the conversation. The findings clearly demonstrate the potential for research on communication to lead to improvements in patients' experience of NHS complaints handling.

Existing research elsewhere indicates that complaints handling often falls short of patient expectations; much dissatisfaction resides in poor communication (Cowan and Anthony 2008). Failure of the system to meet a service user's needs can lead to litigation. However, we know little about the 'complaints journey' from the service user's perspective (Adams et al. 2018), nor do we know enough about the actions of the NHS staff who manage patient complaints (Mirzoev & Kane 2018) except that these actions can profoundly affect outcomes of the complaint.

Using a bespoke combination of observational and qualitative methods, we will fill these knowledge gaps, and use our findings to build an evidence-based communication training resource for complaint handlers. The importance of good communication in healthcare contexts is widely recognised, but there is a *problematic gap between policy and practice*. For example, while full disclosure of errors is known to discourage litigation (Pelt & Faldmo 2008), the introduction of a 'disclose and apologise' policy in Harvard medical institutions failed to improve litigation rates (Giraldo et al. 2017). Mazor et al. (2004) argue that this was because of a lack of research and understanding of HOW disclosure can be done. The gap between policy and practice in relation to complaints handling similarly points to the need for detailed empirical research on the *actual practices* of responding to complaints. Direct observation is vital to understanding communication practices: it is well documented that neither participant recall, nor simulated interaction can accurately and fully represent the complexity of human communication. By prioritising the consumer-citizen voice in the complaint process and focusing on how people in real life communicate in complaint contexts, we will fill important gaps in existing knowledge.

This study will thus focus on the interactions between complainants and Trust staff throughout the whole complaints journey. Friele et al. (2008) show that complainants make nuanced distinctions in their expectations of the interpersonal conduct of complaints handlers and clinical staff (e.g. in their demonstration of understanding or of sympathy). Each of these expectations is essential for complainant satisfaction but prioritised differently at different stages of the process. This variability in the evolving expectations and shifting levels of satisfaction reinforces the need identified in this proposal for a *longitudinal case study design* capturing interactions throughout the complaint journey.

3

Mapping the Patient Complaints Journey

The data will comprise a cultural audit of NHS patient expectations and impressions[1]; recordings and transcriptions of meetings, telephone calls, letters and emails; and ongoing reflections of complainants gathered from diaries and semi-structured interviews. Analysis will detail patients' understanding and assessment of their complaint trajectory. Conversation Analysis (CA) will be employed to study, in fine-grained detail, how complainants and Trust staff communicate. Discourse Analysis (DA) will be used to analyse written texts. We will examine the effects of the communicative interventions and styles, the interactional challenges specific to NHS complaints handling, and how participants overcome (or not) these challenges.

Finally, we will develop a communication training resource, 'Real Complaints', based on our findings and in consultation with key stakeholders. Drawing on conversation analytic approaches to training that have been successfully adopted in other public services (e.g. Stokoe 2014) and developed within NIHR funded projects (NIHR Signals 2019; Parry 2008), the resource will incorporate extracts from the complaints interactions gathered during the project to support evidence-based learning points. The materials will be piloted, evaluated and refined for online publication. By recalibrating how complaints staff respond to complainants, we can transform the service users' experience, thereby addressing, in an evidence-based manner, key system failures that can lead to litigation.

2   RATIONALE

Existing NHS guidance recognises the importance of communication in complaint handling but deploys top-down, vague prescriptions, such as adopting a 'non-judgemental, transparent and appropriate manner' (NHS England 2017), or an 'appropriate and timely manner' (NHS e-learning for healthcare). Such recommendations do not provide enough guidance on HOW this can and should be accomplished. Current policies and guidelines are limited as they fail to recognise the significance of a *relational, interpersonal view* of the complaints process (Simmons & Brennan 2013, 2016). As Healthwatch England notes in '*Suffering in* Silence', improvements to-date have focused on *systems* for complaint handling rather than understanding and improving the *experience*. Additionally, patients, managers and call handlers working at the complaints process frontline have told us that the current emphasis on optimising system design, process and especially timeliness has taken precedence over generating understanding of how trust and positive relationships between healthcare staff and complainants can be built through communication.

Two specific principles have underpinned the complaints process in recent years: Power of Apology (Scotland) and Duty of Candour. It is often uncritically assumed that associated communicative events (respectively an apology and an explanatory account) will improve patient satisfaction (Pettker et al. 2014; Friele & Sluijs 2018). However, what an *effective* apology or explanation would look like and how it might be received in an actual interaction remains poorly evidenced. For example, the 'Power of Apology' initiative (Armstrong 2009) is now a central

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[1] This part of the project has gone through separate ethics procedures at the University of Stirling.

orthodoxy of NHS complaint handling in Scotland. Armstrong proposes that components of a successful and 'authentic' apology include: 'avoidance of vagueness, empathy and conditions'. However, technical linguistic research using Conversation Analysis (CA) on recordings of authentic interactions has shown that precisely when and how apologies are produced is fundamental to how people receive and respond to them (Robinson 2004; Heritage & Raymond 2016). Moreover, complaint handling involves a series of encounters rather than a one-off moment of apology, adding further complexity (Birks et al. 2014).

Simmons and Brennan in their evidence to the 2014 PASC inquiry ('Complaints: do they make a difference?') note that the public expect the NHS to be responsive to them in their times of need. Complainants recognise and are critical of poor communication, such as 'grudging apologies' (Armstrong 2009; NHS Resolution 2017; Rhys & Benwell 2017). Complaint staff also report that the *quality of the complaint experience* is fundamentally important to satisfactory resolution (personal communication). A central problem here is the lack of data on service users' *quality of experience* during the 'complaints journey' and the 'absence of focused empirical assessments of the behaviour of staff who manage patient complaints' (Mirzoev & Kane 2018). Our study will deliver these.

Complaining is a sensitive, delicate and complex social activity which is significantly shaped by social/institutional context (Heinemann & Traverso 2009). Handling complaints is therefore challenging for all institutions (Edmonds & Weatherall 2017) but particularly for the NHS where the topic of the complaint is likely to be emotionally fraught (Benwell & McCreaddie 2017) and where clinical staff subject to the complaint may react defensively (Adams et al. 2018). Complaints handlers must therefore simultaneously manage the institutional information requirements of the investigation process, complainants' emotional and interpersonal expectations and needs (Benwell & Rhys 2017; Weatherall, 2015), and finally clinical staffs' perceptions about complainants' motivations (Adams et al. 2018). Our pilot study showed that the ways that complaints handlers negotiated these competing demands can have a profound effect on complaints' outcomes (Benwell & Rhys 2017, 2018; Rhys & Benwell 2017, 2018). Promoting empathy and 'affiliation' (Benwell & Rhys 2017) and minimising insensitivities (Simmons & Brennan 2017) are crucial to (i) sustaining patient engagement and (ii) avoiding 'frustration' points that lead to alienation (and possible legal action). However, institutional, procedural, and interpersonal factors can thwart such patient-centred intentions (Bismark et al. 2011). Our approach acknowledges and accounts for all the components of the complaints experience but prioritises the interpersonal – getting directly to the heart of the subjective experience of complaining, examining the real-life *progress of encounters* between complainants and the NHS *throughout the complaints journey*. This level of detail is the *new frontier for NHS complaints research*; it is essential to achieving evidence-based improvements.

3   THEORETICAL FRAMEWORK

At the heart of this investigation are principles that underpin Conversation Analytic research, namely that we can only understand social experiences through directly examining the empirical details of social encounters. This means that in any encounter, the participants' communications display their

understanding about social activities, norms and so on. Their communications are evident not just to one another, but also to the analyst. For this reason, the core of this project involves detailed micro analysis of the language used in direct encounters between complainants and the NHS. However, this analysis will be supplemented by careful attention firstly to the organisations' policies, practices, assumptions etc regarding complaints and complaint handlers' work, and secondly to individual complainants' reports of their expectations and retrospective appraisals of their complaints experience. We will thereby generate important insights into the relationships between expectations, observed experience and retrospective appraisal, and provide a holistic, explanatory and comprehensively evidenced picture of the complaints journey experience.

Our innovative methodological design combines the following key components: a cultural audit; longitudinal, micro-level CA and DA analysis of complaints encounters throughout the complaints journey; a parallel analysis of complainants' appraisals of those encounters; and delivery of impact through the translation of the findings into accessible training resources for NHS staff.

Cultural Audit
Cultural analysis helps identify how patients perceive that health service organisations structure their communicative and functional practices. Using a validated measurement tool (Simmons 2016, 2018), the cultural audit identifies important gaps in complainants' expectations and experiences. The focus is on relational aspects of service cultures, to determine whether the patterns of social relations that matter most to complainants are supported in the health service cultures they encounter. It will assess the relative influence of cultural perspectives on four key aspects of respondents' relational expectations and experiences within the NHS: 'courtesy and respect'; 'how knowledge is valued'; 'how fairness and equity issues are resolved'; and 'how rules are set and policed'. These criteria are based on detailed, extensive empirical work and testing by Simmons (2016, 2018). The perceptions of patients in the identification of institutional culture contribute to an elicitation of "the critical voices of patients" that Adams et al. (2018) recommend as a vital step in understanding the socio-political context of the patient – healthcare provider relationship.

Longitudinal, micro-level CA and DA analysis of complaints encounters
CA is a form of observational research which studies in fine-grained detail how people methodically display their understanding of each other's turns at talk and how they negotiate those understandings with one another (Sacks 1984). CA is motivated by a concern to faithfully record how people create and understand social actions and social life as revealed through social interaction. Applied CA research in healthcare has demonstrated powerfully that minor differences in the way that healthcare providers communicate can significantly impact outcomes, for example revealing that certain ways of opening consultations can increase parents' uptake of vaccinations for their babies (Opel et al. 2013) or that how doctors format their treatment recommendations directly impacts prescription rates for antibiotics (Stivers 2005). CA can, thus, reveal the consequences of seemingly insignificant differences in language choices by a complaints handler, as well as providing understandings of how participants orient to the interpersonal challenges of complaining and the normative expectations of the institutional setting. This focus on interpersonal communication has been neglected in previous attempts to revise

the complaints process, despite its clear potential to improve rates of litigation. Crucially, these associations between communicative practices and outcomes require detailed observational research, as they are not amenable to introspective intuition or post hoc reflection. Similarly, DA is a linguistic approach to the analysis of written texts, which focuses on the meanings, intentions, ideologies and consequences of particular language choices by the writer, and views discourse as a form of social action or practice (Gee 2014). Written communication is a more challenging medium through which to express empathy and rapport (compared to face-to-face encounters), particularly where the kind of language required in written and institutional communication constrains expression. By focusing on choices in grammar, word choice and pragmatic meaning (what is implied or presupposed), a more robust, systematic and objective account of good and poor communication can be provided.

4 RESEARCH QUESTION/AIM(S)

The purpose of this study is to develop a qualitative understanding of the experience of making a complaint from the perspective of the patient.

Our primary research question is: *'How can the power of language be harnessed to transform people's experience of complaining in the NHS and reduce their recourse to litigation?'*

4.1 Objectives

1) To examine complainants' lived experience of interacting with the 'system' through detailed micro-analysis of direct communications, both spoken and written, with NHS representatives.
2) To audit patients' perceptions of cultural bias in NHS contexts, and show how this may create patterns of social relations that can help or hinder effective complaint resolution.
3) To record self-reported expectations and experiences of the complaints journey and its timeline, focusing on evolving perceptions of the complaints experience and the complained-about issue, and the impact of the process on complainant wellbeing and satisfaction.
4) To identify and cross reference moments of change and key drivers of change in complainants' responses and intentions (including intentions to litigate) throughout their complaints journey.
5) To develop an evidence-based 'Real Complaints' communication training resource to provide effective, evidence-based intervention that addresses the specific interactional and interpersonal challenges of NHS complaints handling.
6) To disseminate good practice recommendations to service users, NHS staff, local and national policy makers, and ombudsmen that will improve NHS complaint handling processes and experiences.

4.2 Outcome
The project aims to develop our understanding of the qualitative and longitudinal experience of making a complaint to the NHS from the patient perspective.

Mapping the Patient Complaints Journey

The project will develop targeted training resources to improve complaints handling and reduce litigation.

The project outcomes will be published as a series of articles in academic journals, reported via the project website and disseminated through professional and academic associations, patient organisations, academic conferences as well as popular media to ensure that the results of the research are visible and able to inform policy and practice.

5   STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Description of data collection methods

Data collection will involve audio and video recording and the gathering of written communications. For telephone encounters, participants will be provided with recording devices to record their calls. Call handlers will be asked to record all calls. Face-to-face encounters will be video recorded. Video recorders will be supplied to the Trust researchers and to the PCC for this purpose. Where it can be supported by the Trust, encounters with service staff that are part of the complaint journey will also be recorded.

First, cultural-contextual analysis will identify gaps between expectations and experience of the organisational culture of each Trust. The survey will employ a validated measurement tool developed by Simmons (2016; 2018), administered via the PCC membership list (over 1200 members) and website.

Initial approaches to the Trusts or PCC may take the form of email, letter or telephone calls. Recordings and written texts of complainants' initial approaches to make a complaint will provide direct observational data for the analysis of the social experience of setting out on the complaints journey. Where a complaint is made by telephone, complaints handling staff will be asked to audio-record telephone interactions with patients who intimate their wish to make a verbal complaint. Where the Trust or PCC responds by telephone to an initial email or letter approach, Trust or PCC staff will be asked to record these calls as well. Collection of initial calls will end once a relevant sample for the longitudinal study is achieved. All relevant written communication (letters, emails) from complainants setting out their complaint will be gathered where consent for their use has been secured. The recording of subsequent encounters (telephone calls, face-to-face or online meetings and written communications) provides the observational data for the micro analysis of the lived experience of the complaint journey.

The central element of the project involves a longitudinal case study design involving participants across two HSC Trusts and the Patient Client Council. Telephone information meetings will be held with complainants who agree to participate in the longitudinal study. The team will liaise with them via telephone or video chat (depending on social distancing restrictions and preference of participants). Our pilot study shows that regular contact with participants is necessary to support their

Version 1.3 10th December 2020 – Research Protocol

involvement in the longitudinal study and minimise gaps in the data. Following the Trust's closure of the complaint, the team will again meet with participants to arrange collection of diaries and conduct post-complaint closure interviews. Recruitment to the longitudinal study will end once 30 participants have been recruited. Call handlers will be provided with recording devices to record their calls and be asked to record all calls. Face-to-face encounters will be video recorded. Video recorders will be supplied to the Trust researchers and the PCC for this purpose.

The second form of data collection here involves semi-structured diaries completed by participating complainants. To minimize the burden of diarising their experience, the diary will firstly be easy to use, consisting of non-leading, non-judgmental, open questions. Interview schedules have been developed based on conceptual parameters of the project and the empirical gaps in the complaints literature. Second, diarists will be given a choice of diary format: paper or e-diaries (text, voice, video; sent via a secure platform such as Box). Third, diarists will receive instruction and ongoing support in completing their diary of choice. Video/audio recorders will be supplied to the participants electing to keep a video/audio diary. (Following analysis, all diaries will be returned to respondents to keep if desired by the participants, including those held on voice recorders supplied by the project).

Following closure of the complaint by the Trust, the team will liaise with participants to collect the diaries and to conduct post complaint closure interviews. This will involve a recorded semi-structured interview (which may be via phone, video call or in-person depending on social distancing restrictions and wishes of participants) with each longitudinal participant to provide the participants' retrospective evaluation of their complaints experience. The team may also collect data relating to complaints that are already ongoing at the beginning of data collection. For any data of this type the team will also conduct two interviews with complainant participants. If a participant is recruited mid-journey, we will interview them at the beginning of data collection to understand their complaints journey so far. As with the previous forms of recorded data, the recording will be transcribed by the researchers or a third party academic transcription service. We will also conduct semi-structured interviews with three members of complaints handling staff in each Trust (3-6 in total) to gain their perspectives on the nature and priorities of people's complaint journeys.

Data analysis methods

Cultural Audit (**Leads:** Simmons)
Cultural analysis helps identify how patients perceive that health service organisations structure their *communicative* and *functional* practices. Using a validated measurement tool (Simmons 2016, 2018), the cultural audit identifies important gaps in complainants' expectations and experiences. The focus is on relational aspects of service cultures, to determine whether the patterns of social relations that matter most to complainants are supported in the health service cultures they encounter. It will assess the relative influence of cultural perspectives on four key aspects of respondents' relational expectations and experiences within the NHS: 'courtesy and respect'; 'how knowledge is valued'; 'how fairness and equity issues are resolved'; and 'how rules are set and policed'. These criteria are based on detailed, extensive empirical work and testing by Simmons (2016, 2018). The perceptions of patients in the identification of institutional culture contribute to an elicitation of "the critical voices of patients" that

Mapping the Patient Complaints Journey

Adams et al. (2018) recommend as a vital step in understanding the socio-political context of the patient – healthcare provider relationship. Responses will be analysed using descriptive and paired-sample statistics in SPSS 25.

Micro-level CA and DA analysis of complaints encounters (**Leads:** Rhys, Benwell, Erofeeva)
CA is a form of *observational* research which studies in fine-grained detail how people methodically display their understanding of each other's turns at talk and how they negotiate those understandings with one another (Sacks 1984). CA is motivated by a concern to faithfully record how people create and understand social actions and social life as revealed through social interaction. Applied CA research in healthcare has demonstrated powerfully that minor differences in the way that healthcare providers communicate can significantly impact outcomes, for example revealing that certain ways of opening consultations can increase parents' uptake of vaccinations for their babies (Opel et al. 2013) or that how doctors format their treatment recommendations directly impacts prescription rates for antibiotics (Stivers 2005). CA can, thus, reveal the consequences of seemingly insignificant differences in language choices by a complaints handler, as well as providing understandings of how participants orient to the interpersonal challenges of complaining and the normative expectations of the institutional setting. Similarly, DA is a linguistic approach to the analysis of written texts, which focuses on the meanings, intentions, ideologies and consequences of particular language choices by the writer, and views discourse as a form of social action or practice (Gee 2014). By focusing on choices in grammar, word choice and pragmatic meaning (what is implied or presupposed), a more robust, systematic and objective account of good and poor communication can be provided.

Data Analysis: Recordings will be anonymised using Audacity or Audition.. Calls in the longitudinal corpus will be categorised using a simplified version of the Healthcare Complaints Analysis Tool (Gillespie and Reader 2016). The initial encounters data set will also provide the first encounters for each of the longitudinal case studies. Once those participants have been identified, their initial encounters will be transcribed using broad CA transcription methods and incorporated into the data set for conversation analysis. Rhys, Benwell and Erofeeva will conduct extensive micro-analysis of selected key encounters using the detailed and sequential methods of Conversation Analysis.

Longitudinal case studies

The central element of the project involves a longitudinal case study design involving participants across two HSC Trusts and the Patient Client Council. Each case study will include both direct observation of encounters and participants' appraisals of their experiences in order to identify moments of change and understand the key drivers of change in complainants' responses and intentions. Analysis will take two forms: scoping analysis across the two types of data (observational and appraisal) and detailed micro-analytic examination of selected key encounters using CA (KE-O). As with the observational data, the interview and diary entries will be examined to identify *key encounters* from the perspective of the participants' subjective evaluation of their experience (KE-S). This process will involve thematic and narrative analysis of the data to understand the patient's subjective experience of their complaint journey and identify moments in each journey that were *experienced* as particularly consequential.

Version 1.3 10th December 2020 – Research Protocol

Analysis of complainants' appraisal of their complaints encounters (**Lead:** Simmons)

The complaint journey can involve a complex and extensive set of experiences (Meth 2003). Diaries solicited by researchers provide a popular data collection method in detailed ethnographic research, including health services research (Bartlett 2012; Snowden 2015; Milligan et al. 2005). This method allows a *contemporaneous record* of people's interpretations, experiences, events and motivations to understand the complaint in the context of their lives (Bytheway 2012). Diaries also provide *longitudinal insights* throughout the complaints journey, in chronological order, allowing flexibility and variation in the narratives presented, in an unobtrusive manner (Snowden 2015). This allows insights into not only what actions a respondent took, but also what they did not take or intend to take (Milligan et al. 2005). Importantly for this study, diary methods are particularly useful for triangulating observational research (Robson 2011; Schroder 2003; Alaszweski 2006). This analysis will be complemented by post-complaint closure interviews in which complainants will be invited to reflect back on the overall complaint journey.

6   STUDY SETTING

The project will be conducted across multiple sites in Northern Ireland – specifically in two Health and Social Care Trusts (HSCNI) and in the Patient Client Council (PCC). The PCC was established by the Health and Social Care Reform Act (2009) to provide an independent voice for patients, carers and communities on health and social care issues. A statutory function of the PCC is to provide support to individuals making a complaint and Trusts are required to provide potential complainants with information about the support available from the PCC. It is therefore essential that this project include complainants who choose to make a complaint via the PCC. Working with these multiple sites will allow the research 1) to take into account the impact of variability in the implementation of complaints handling policy associated with differences in organisational size, structure, and geographical location; 2) to involve a larger number of complaints handlers – important in capturing a wide range of communicative styles; 3) to evidence the impact of complaining with the support of the PCC's independent advocacy service. To manage the complexity of working with multiple sites, data collection will be staggered across them.

7   SAMPLE AND RECRUITMENT

The CA approach does not require a representative sample, rather a broad enough sample to capture an adequate range of encounters and responses. Criteria for judging the sample will take into account the unpredictable nature of the population, the proportion likely to extend beyond the 20-working day deadline, and the proportion likely to extend beyond the initial complaint closure by the Trust. In addition, sampling will balance the need for breadth with the practical demands of detailed CA and DA analysis.

7.1   Inclusion criteria
Being a current complainant or complaint handler in any one of the two NI Trusts or the PCC.

Mapping the Patient Complaints Journey

7.2   Exclusion criteria

Exclusion criteria relate primarily to evidence of lack of capacity to give informed consent or of losing the capacity to consent during the course of the research (resulting in immediate cessation of participation and deletion of existing data).

7.3   Sampling

There are significant differences in the volume of complaints received by different Trusts that will impact on sampling (e.g. in 2016/17, the volume of complaints ranged from 1,747 complaints in the largest Trust down to 512 in the smallest Trust). In addition, the project's design, focusing specifically on live complaints and on the entire complaints journey, has implications for sampling procedures because the population is limited to complainants whose complaints journey falls within the fieldwork period and who are willing to complete the longitudinal data collection.

7.4   Size of sample

Recruitment to the longitudinal study will end once 30 participants have been recruited.

7.5   Sampling technique and Recruitment

Data Set 1) Cultural Audit

An online survey will be administered via the PCC membership list (over 1200 members) and website. One function of the PCC is to invite the patient voice on issues relating to Health and Social Care so this will be an efficient and appropriate route to recruitment. The sample will comprise those members who have been active as patients or carers in the last three years to ensure currency and relevance.

Data Set 2) Initial encounters

Complainants will be invited to participate when they make their initial approach (by letter, by phone, by email) and recruitment will involve consecutive convenience sampling; data will be gathered from all complainants who give their consent. (Exclusion criteria relate primarily to evidence of initial lack of or lack of continued capacity to give informed consent.) Collection of initial calls will end once a relevant sample for the longitudinal study is achieved (at least 30).

Data Set 3) Longitudinal case studies

All complainants will be asked for their informed consent to participate in the longitudinal research following initial logging of their complaint with the complaint handling team. The journeys of all complainants who give their consent to participate in the study period will be followed as case studies.

7.6   Consent

Mapping the Patient Complaints Journey

We will obtain prospective and retrospective consent at both the initial encounter and at the invitation to participate in the longitudinal study. Additionally, we will provide a clearly communicated right to withdraw from the study at any stage. Data will be gathered from all complainants who give their consent. (Exclusion criteria relate primarily to evidence of initial lack of or lack of continued capacity to give informed consent.)

The consent forms will explicitly address all *forms* of data (audio, video and transcript) and all *uses* of the data (research, presentation, training) to ensure that informed consent is comprehensively addressed. The Trust researchers will complete informed consent and training with staff taking complaints calls. For initial approach telephone calls, consent will be sought at the start of the telephone call by the call handler. Once consent is verbally secured, the recording will begin.

1) The call handler will invite the caller to participate in research and provide verbal consent where the caller opts-in.
2) Recording will start following the securing of verbal consent, and consent will be requested once more to be captured on the recording.
3) Callers may opt out verbally at any stage during the call.
4) For participating calls, the CH should provide an opportunity for the caller to withdraw, prior to the call closing.
5) For each participant, the researchers should email a participant pack, as follows:
   a. Participant information sheet (providing written opportunity to withdraw) completed with complainant's name, Trust name, date of call and latest date for return.
   b. A stamped envelope addressed to the researcher at Ulster University.
   Participants will be allowed a period of two weeks to opt out in writing/email or by telephone to the Trust.

Where an initial approach is made in writing, the complainant will be contacted by email or post with information about the project, an invitation to participate and a consent form to complete if they are willing.

Potential longitudinal participants will be invited to participate in the longitudinal research following the initial logging of their complaint with the complaint handling team. They will be contacted by post/email with information about the project, an invitation to participate and a consent form to complete if they are willing.

Additionally, information meetings will be held with complainants who agree to participate in the longitudinal study. This will be done either via phone or video call and will address the participant information and informed consent.

8   ETHICAL AND REGULATORY CONSIDERATIONS

Mapping the Patient Complaints Journey

8.1 Assessment and management of risk

The primary ethical issues that the project must address concern informed consent for recording and use of data, privacy and intrusion for both patients and clinical staff, burden of participation, and particularly the sensitivity of working with live complaints and complained-about staff.

Consent protocols will include prospective and retrospective consent at both the initial encounter and at the invitation to participate in the longitudinal study as well as a clearly communicated right to withdraw from the study at any stage. The consent forms explicitly address all forms of data (audio, video and transcript) and all uses of the data (research, presentation, training) to ensure that informed consent is comprehensively addressed.

The Participant Information Sheets will clearly describe the extensive anonymisation processes that will be employed for all forms of data. The RAs will also demonstrate for longitudinal participants how the audio and video data will be anonymised to build confidence in the effectiveness of the anonymisation processes and the assurances of confidentiality.

The RAs will work closely with research participants to minimise the burden of participation. The diary tool has been co-designed with PPI advisors to minimise burden..

Complaints communication is potentially challenging, stressful and upsetting for all concerned. It is vital that the research process doesn't add to the stress and distress. Confidence in the rigour of the anonymisation and confidentiality assurances will be essential. It will also be important to minimise the intrusiveness of the data collection procedures. This will be achieved through self-recording and through the maintenance of a single point of contact in the research team for all participants. The PCC and the Trusts have distress protocols in place to address the potential vulnerability of both complainants, complained-to staff and complained-about staff which involves referral to support services for both staff and patients.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Prior to the start of the study, NHS ethical review will be sought via ORECNI. Any substantial amendments that require review will not be implemented until that review is in place. The Chief Investigator is responsible for keeping all correspondence with the REC, producing annual reports, notifying the REC at the end of the study and producing final reports.

Regulatory Review & Compliance

The Chief Investigator will ensure that appropriate approvals from participating HSC Trusts and the Patient Client Council are in place. For any amendment to the study, the Chief Investigator, in agreement with the sponsor, will submit information to ORECNI in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at HSC sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

Version 1.3 10th December 2020 – Research Protocol

Mapping the Patient Complaints Journey

The Chief Investigator will submit a valid notice of amendment to the ORECNI for consideration should a substantial amendment to the REC application or the supporting documents be required. The sponsor will determine whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

A history of amendments will be detailed within the protocol and previous versions of the protocol will be retained for reference.

8.3   Peer review

The NIHR application process involved the following stages of review. At each stage we provided detailed feedback that either justified our proposals or agreed to modify them in the light of recommendations.

STAGE ONE – NIHR internal review

STAGE TWO – External Independent Reviews Open Comments (x4)

STAGE THREE – Funding Committee Review

STAGE FOUR – Filter Committee (internal – Ulster)

STAGE FIVE – ORECNI

8.4   Patient & Public Involvement

All levels of project management will include PPI members: the Project Management Group, the Steering Committee and the Advisory Board. The Patient Client Council (PCC) has a statutory function to invite the patient voice on issues relating to Health and Social Care so provides a crucial route to PPI recruitment. . We will also engage with patient advocacy organisations in England, Scotland and Wales, such as PALS, PASS, POhWER and seAp. The Project Management Group will report on the analysis, interpretation and direction of the research at all stages and PPI members will be invited to take an active, participatory role in decision making. PPI members of the Advisory Board will be given a clear description of their responsibilities, terms of reference and time commitments, as well what they can expect from the project team in terms of mentoring, guidance and expenses. PPI members will be advised of their freedom to leave the project at any point. Project activities in which PPI will be fully involved include:

- Co-design of participant information sheets and post-encounter data collection tools (a major component of the ethics application). PPI here is crucial to ensuring that information sheets are clear and accessible, that the interview agenda is sensitive and relevant to complainants, and that the diarising tools are flexible, appropriate and not too burdensome.
- Feedback on initial interpretations of data and identification of 'key encounters' in the complaints journey at collaborative workshops
- Co-design of "Real Complaints" training outcomes

Mapping the Patient Complaints Journey

- Collaboration on the development of Patient Guidelines with the PCC to ensure acceptability and usability
- Attendance at the 'Real Complaints' Launch at the conclusion of the project

8.5 Protocol compliance

The Study Steering Committee and the funder's monitoring team will have oversight of protocol compliance. Accidental protocol deviations will be documented on the relevant forms and reported to the Chief Investigator and Sponsor for immediate action to review and address.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.6 Data protection and patient confidentiality

Anonymity

The research team will adhere to the principles of the General Data Protection Regulation (GDPR) 2018 with particular reference to Principle 3 – Security of personal data; and the Human Rights Act 1998.

Conversation analysts research many areas of sensitive workplace interactions such as doctor/patient consultations, and it is standard practice to work ethically by anonymising recordings and transcripts. The anonymity of all participants will be observed via a variety of methods.

1. Any data that could be linked to an individual through the potential ability of a known person to reconstruct a narrative, will be anonymised.
2. Audio/video-recorded data will have names, dates, place names or any other identifying references (such as Trust details) removed using Audio software (Audacity or Audition) to create noises or silences in place of personal identifiers
3. All verbatim transcripts will be stripped of identifiers, and pseudonyms (for example – with names, addresses), or replacements (for example – with dates) will be applied.
4. Video recordings will be anonymized using video data anonymization software (this can involve the rendering of video into animation or the blurring of faces).
5. The project team will also redact identifying details in the written communications (emails, letters).
6. Coding will be applied and data logs securely maintained so that raw data and anonymised data can be matched by the researcher, in the event of a participant requesting to withdraw from the study; or any other legal or ethical reason. Coded data will be protected such that no person could access it and subsequently identify any participant. This information will be recorded on a password protected Excel file.

Mapping the Patient Complaints Journey

Storage

1. Raw versions of recordings will be stored in securely on Ulster University's Sharepoint. A specific Sharepoint site has been set up for this purpose with access limited only to the Research team.
2. The research team will ensure that raw files are never stored locally on personal computers when uploading and accessing raw files on Sharepoint at home on personal computers.
3. Anonymised recordings and transcripts will be securely made from the raw data and only ever using university IT facilities.
4. The anonymised recordings as well as redacted written complaints will be kept indefinitely. It will be impossible to identify participants from these recordings. The University's COP for Professional Integrity in the Conduct of Research requires that research data must be kept for a minimum period of 10 years after the end of any particular study. We would like to keep our anonymised data indefinitely in line with CA tradition.

Data Usage and Access

Ulster University's COP for Professional Integrity in the Conduct of Research requires that research data must be kept for a minimum period of 10 years after the end of any particular study. We would like to keep our <u>anonymised</u> data indefinitely in line with CA tradition.

  i. Anonymised data will be retained indefinitely as per CA convention.
 ii. Raw soundfiles will be played through headphones only.
iii. Only the appropriate **extracts of anonymised sound-files** (ie. usually not the entire call and never unedited material) will be broadcast to an audience (ie. for academic purposes/ research data sessions/ training, conferences and the like). This will only happen after data has been doubly anonymised.
 iv. Transcripts of raw data (unanonymised) will **not** be created in order to lessen risks.
  v. All transcripts will be fully anonymised and may be used for future academic/training purposes in connection with this study, as stipulated.

The data custodian for this project is the Chief Investigator, Dr Catrin S Rhys.

8.7   Indemnity

The sponsor (Ulster University) is responsible for potential legal liability arising from the design and management of the research. Indemnity insurance is in place to cover this liability.

8.8   Access to the final study dataset

As per above, extracts from anonymised transcripts may be used for academic purposes ie. in publications, conferences and presentations; and for training workshops. It is standard practice and tradition to share <u>anonymised</u> data extracts amongst other conversation analysts.
This practice is done in the interests of learning, and also permits other researchers to view the data in order to make their own analyses, or to build upon an analysis.

Secondary uses of anonymised data: As the data we intend to collect will be so interactionally rich, we would like to retain the anonymised data in a repository for potential use in future approved studies by the research team. Any such studies would seek ethical approval prior to using the data. We will be open with participants and will stipulate on consent forms, the possibility of secondary research with the data.

9 DISSEMINATION POLICY

Our dissemination strategy builds on recent evidence for translating knowledge into practice, including systematic reviews, good practice guidance and wider research evidence.

Publications

The research team will develop a number of publications for submission to healthcare services journals (e.g. Healthcare Services and Delivery Research, Journal of Healthcare Management, Health Services Research), Qualitative Healthcare journals (e.g. Social Science and Medicine) and communication and language journals (e.g. Research on Language and Social Interaction) as well as conference presentations (e.g. International Conference on Communication in Healthcare (EACH); Conversation Analysis and Clinical Encounters (CACE); NHS Complaints Managers' Forum). These will be a combination of theoretically oriented, methodologically oriented and impact-oriented publications and will showcase the application of CA in healthcare contexts.

Research summaries for professional journals

We will develop reports aimed at healthcare services managers, and patient and public groups for publication in online journals and newsletters (e.g. Health Services Journal; Patient Experience Journal; PPI Journal).

Good practice guidance and transferable recommendations to improve the experience of NHS complaints encounters.

Summary guidelines arising from our analysis, such as 'Guidance for written complaints communication' will be published on the project website. A series of relevant policy briefings will also be produced for specific audiences, complemented with blogs and social media posts to give high visibility to policy benefits and develop shared platforms for learning and decision-making.

'Real Complaints' training resources

The practical application of the research findings will involve the co-design of the 'Real Complaints' training resources. The resources will be piloted and evaluated and then the materials, train the trainer pack, and additional resources will be refined and made available on the project website. (NB the data recordings and written complaints files will be password protected on the website.) We also propose to work with Health Education England, NHS Education Scotland and HSC Clinical Education Centre, and with the International Association for Communication in Healthcare (EACH) to ensure that these resources are promoted and made available through the training areas on their respective websites.

Patient Guidelines

The findings will be used to create guidelines for patients that will contribute to improving their experience of the complaints process. Firstly, given the documented importance of complainants' expectations prior to complaining, the research findings will be adapted into short narrative guidelines that help complainants understand what to expect from the complaints process. In addition, the findings will be used to develop resources to support patients in preparing for communicating their complaint issue(s) and their hopes and expectations at different stages of the complaints process. These will be developed in collaboration with the PCC to ensure acceptability and usability.

By collaborating closely with the PCC, the Trusts and NIPSO, the project is firmly contextualised in the community it serves. More widely, there are five key target audiences for this research:

A. Patients and the public (e.g. PCC, PALS, PASS, POhWER, seAp, VoiceAbility)

B. NHS complaint handling and frontline staff (e.g. NHS Complaints Managers Forum, NCPAS)

C. NHS provider organisations (e.g. Trusts, HAs)

D. Relevant policy makers and external organisations (e.g. DH, HSCNI, Scottish Government Health and Wellbeing Directorate, NHSE and NHSI (Patient Experience), Health Improvement Scotland, Public Health Agency, Healthcare Safety Investigation Branch, NHS Resolution, Action against Medical Accidents, Ombudsmen (PHSO, SPSO, NIPSO), Health Watch, Scottish Health Council)

E. Academic research community

Clear and concise messages will be tailored for these audiences, taking into account how they absorb research evidence, their timelines, needs, perspectives, and so on - with particular attention to the balance of benefits and costs for them (including the potential costs of inaction). We will draw on the resources of organisations such as INVOLVE and the National Coordinating Centre for Public Engagement, which promote the dissemination of research to non-academic audiences. From research evidence we know that research is most effectively disseminated using a combination of channels and tools, ideally with face-to-face interaction. In this way, our dissemination activities will be targeted accordingly:

• Written publications including Full, Executive Summary and Plain English summary reports of the research (All audiences), local NHS newsletters (esp. A, B, C), policy briefings (esp. C, D), and peer-reviewed journals (esp. D, E).

• Interactive workshops to share research outcomes and discuss implementation of good practice guidelines (A, B, C, D).

Mapping the Patient Complaints Journey

- Piloting and evaluation of the Real Complaints resource, and raising of the profile of the resource nationally through training events delivered across the UK (A, B, C, D).

- Use of electronic media such as websites and social media such as Twitter and Instagram, including webinar and video content (Youtube/TED) as well as general and specialist traditional media opportunities (television, radio, newspapers) (All).

- Development of existing and new links with key organisations to contribute to and capitalise on their insights, opportunities and networks (All).

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Version 1.3 10th December 2020 – Research Protocol

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11.   APPENDICIES

11.1   Appendix 1- Required documentation

Participant Information Sheet

- Complainant Initial and Longitudinal

- Complainant Data Handling

- Complaint Handler Initial and Longitudinal

- Complaint Handler Data Handling

- Clinicians Interviews and Data Handling

Consent forms

- Complainant Initial Complaints

- Complainant Longitudinal Complaints

- Complaint Handler Initial Complaints

- Complaint Handler Longitudinal Complaints

- Clinicians

11.2   Schedule of Events

11.3   Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.2	29/07/2020	Rhys, CS et al.	Adjustments to data collection, access and storage to take into account COVID restrictions

List details of all protocol amendments here whenever a new version of the protocol is produced. Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.