Full Title of project: Improving patient, family and colleague witnesses' experiences of Fitness to Practise proceedings: A mixed methods study

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Ethical approval

This protocol precedes application to the The Open University Human Research Ethics Committee (WPs 1.1, 1.2. 1.3. 1.4) , to Manchester Metropolitan University (WPs1.5, WP2.2,2.3) and to the University of Glasgow (WP2.1).

Version No.	Author	Proposed change	Date
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Contents

Summary of research (abstract)

Aim:
We focus on cases of serious misconduct by health and social care professionals before a professional regulator involving harm to the person who experienced the misconduct. We aim to improve understanding of the expectations, experiences and recommend improved processes for witnesses involved in Fitness to Practise (FtP) proceedings.

Background
There are 2 million health and social care registrants in the UK and thousands of 'concerns' about their practice are referred to regulators, with <1% investigated further. If their behaviour is evidenced to fall below the professional standards, they may face a Fitness to Practise (FtP) hearing or tribunal. In 2019/20 2,783 FtP hearings took place across the 10 regulators under the Professional Standards Authority (PSA) to determine if there was misconduct, and whether sanctions should be taken to protect the public. There are three further social care regulators for Wales, Scotland and Northern Ireland concerned with the standards of practise of a wide range of social care professionals. All these regulators share a common legal purpose of ensuring registrants practise safely and act appropriately.

Witnesses to misconduct can be called to give evidence in a FtP investigation and hearing. A proportion of these will include patients, service users and colleagues who may have been significantly harmed by the registrant's behaviour. Such cases may include behaviours associated with sexual abuse, harassment and bullying, theft and fraud, and lasting clinical harm. We know from the research in the criminal justice system that there is potential for additional trauma caused by the experience of being a witness. To our knowledge, no academic research on witness experience in the context of professional regulation has been conducted in the UK or elsewhere. This is the first independently funded multi-regulator research on fitness to practise. We will collect and consider evidence about whether and how the conduct of FtP processes may adversely impact on witnesses and evaluate regulators' interventions designed to mitigate these secondary harms.

Objectives:
1. Examine the experiences of witnesses throughout the FtP journey from initial engagement, investigation, to the hearing and its outcome.
2. Conduct a systematic analysis of the content and user experience of the existing FtP information, resources and interventions for witnesses.
3. Identify where and how these could be improved to benefit witnesses and improve confidence in and efficiency of regulation.
4. Co-develop and co-produce 'good practice' guidance and resources for a range of stakeholders; the public, regulators, health and social care employers and regulated practitioners.

Methods:
We are investigating the experience of witnesses in cases managed by the majority of the UK's regulators. Sequential mixed methods will be used to understand the experience of witnesses in the FtP journey and in the co-design of guidance and resources. These methods include: 1). Surveys of witnesses (n=90); 2). Interviews with a) members of regulators' public engagement groups (n=6), b) witnesses who have used regulators' support services (n=6), c) health and social care employers regarding how they support colleagues who have been harmed by a registrant co-worker (n=9). 3). Document analysis to assess the readability and content of regulators' FtP witness support materials. 4) Case studies of completed cases involving harm (n=30) including a) content analysis of case materials and then for a subset of these cases b) further (n=24-36) interviews including

witnesses, regulator staff and adjudicators. These retrospective interviews will use memory reconstruction techniques and event mapping to identify key areas for improvement. To complement these retrospective case studies, 5) ethnographic study of 6 new FtP hearings will be gathered to extend insight into witnesses' expectations and experiences, as well as additional perspectives from regulator staff and lawyers, and researchers' direct observations of the hearing. 6) Film reflective narratives of up to 12 people's experiences of FtP hearings, including their needs for and use of witness support services, legal, complaints, health and care services. 7) Results will be analysed and synthesised in three iterative workshops.

Advisors:
Regulators, public and patient advocacy bodies, employers and professional bodies have all informed and support this proposed project. Our public and patient involvement collaborator will chair an advisory group of patient advocacy groups and people with lived experience of being involved as witnesses in FtP proceedings. A second advisory group with the PSA and all 13 of the UK's Health and social care regulators are advisers on the project. A third advisory group includes lawyers involved in cross examining witnesses in FtP, and employers and professional organisations who refer to and employ staff who could be involved in FtP proceedings. These advisers will be invited to contribute to the research and to its findings and the outputs. We will have an independent Study Steering Committee of research, regulatory and public experts.

Outputs:
As this is a new focus of academic research, we anticipate there will be considerable impact from the findings. In addition to academic outputs, we will co-produce resources including guidance for regulators. We will co-produce web resources such as podcasts, and films on digital platforms Healthtalk.org and Socialcaretalk.org, that incorporate audio and filmed witness stories available free to the public. We will create an 8 hour free to access OpenLearn course for professionals to promote understanding of professional regulation and the FTP processes, the experience of being a public member witness, and the support they may benefit from.

Regulator acronyms: General Chiropractic Council-GCC, General Dental Council-GDC, General Medical Council-GMC, General Pharmaceutical Council-GPhC, General Optical Council- GOC, General Osteopathic Council GOsC, General Medical Council-GMC, Health & Care Professions Council -HCPC, Northern Ireland Social Care Council- NISCC, Nursing & Midwifery Council- NMC, PSNI-Pharmaceutical Society Northern Ireland, Professional Standards Authority-PSA, Social Work England-SWE, Scottish Social Services Council-SSSC, Social Care Wales- SCW, UK Council for Psychotherapy-UKCP.
Others: Action for victims of Medical Accidents – AvMA, Association of Directors of Adult Social Services- ADASS, British Association of Social Workers-BASW, British Dental Association-BDA, British Medical Association-BMA, Department of Health and Social Care -DHSC, PHO-Parliamentary & Health Services Ombudsman, RCM-Royal College of Midwives, Royal College of Nursing-RCN

Universities: The Open University([OU], Manchester Metropolitan University [MMU], The University of Oxford [UOx]), the University of Glasgow [UG]

1. BACKGROUND AND RATIONALE:

1.1 Brief literature review

The problem being addressed:
Professional regulation protects the public and assures that professionals they rely upon are qualified, capable and competent. When professional conduct falls below standard, staff

may face misconduct investigation, and potentially, sanction via Fitness to Practise (FtP) processes (1). The focus is on the conduct of the registrant. It is understood that the process can be stressful for the registrant, including being associated with risk of suicide for those under investigation (2). Research has focused on what can be done to improve the experience of registrants (3), with little known about the effect of participation in a FtP process on those who have witnessed the alleged misconduct first hand; namely, patients, their families and colleagues.

A striking research omission is the experiences of those who may have been harmed or bereaved by the registrant. The focus of our research is to consider cases where the regulators' responsibilities to the patient, family or colleague witness are most tested, and whether and how the processes of FtP can create secondary harm, which can exacerbate the original harm experienced through the retrieval and reliving of these previous traumatic events required for FtP investigation and hearings.

FtP studies with regulators and our consultations with those who have been witnesses in FtP hearings, suggest the greatest risks from adverse experience arises where complainants have been directly, and lastingly, harmed by the registrant (4,5). This project focuses on such cases in which direct and lasting harm can arise, and which are also likely to test fully the efforts of regulators to best balance their interest in maximising engagement of these witnesses in the FtP process, while at the same time minimising further additional harms from such engagement.

The DHSC expects that regulators will work together more closely (6). This project will be the first independently funded regulator research on this topic working across several regulators and with the potential for uptake and impact by all 13 of the UK's health and social care regulators. It will provide fresh insight into FtP through consideration of different stakeholders' perspectives, and through such insights offer new and important ways to improve public protection and to develop new more targeted support. Given the commitment of participating regulators, it is an opportunity to improve public protection and evidenced-based FtP process improvement across all regulators.

Professional Regulation, the public: and those who have been harmed by a registrant

Health and social care is the biggest employer in the UK, but it is complex comprising 33 professions that are regulated by 10 regulators under PSA, and 3 further regulators for Wales, Scotland, Northern Ireland for Social work. (7). There are thousands of "concerns" about their practice referred each year to regulators, with less than 1% registrants for each regulator being investigated further. The PSA's data from 2017/18 reveals 4095 registrants were involved in a FtP hearing to determine if there was misconduct, and whether sanctions should be taken to protect the public (8).

The PSA defines harm as 'physical injury or psychological distress experienced by people through interaction with health or social care practitioners' (9, 10). The PSA acknowledges differing definitions and categorisations of allegations of misconduct from regulators, stemming in part from their differing standards of professional conduct (11).

Our project focusses on cases where the potential witness believes they have suffered harm as an outcome of the behaviour of the registrant and there are relevant allegations of misconduct (since some harm can occur in the course of care without reaching the threshold of misconduct or may not be attributable to the registrant under investigation, for example, due to systemic issues beyond the registrant's control)[1].

The regulatory FtP process has distinct stages, including initial complaint, initial investigation, and decision-making as to whether the case is sufficiently serious to proceed

[1] While acts or omissions that amount to misconduct and impair a registrant's fitness to practice may be alleged this is not proven until it is admitted or found proven. Both instances will apply to different parts of this study.

to a hearing for adjudication. Our project aims to investigate and generate a better understanding of the impact of FtP investigations and hearings processes and its distinct stages on witnesses in order to identify how to better support those adversely affected by a registrant's conduct. Once a person refers misconduct to the regulator, and if there is material evidence, they become a witness and give evidence. If their evidence is disputed, a FtP panel seeks to ascertain if the witness is truthful, subjecting their evidence to scrutiny through cross-examination; this can be a daunting procedure (12).

Regulators all use a range of measures designed to support witnesses, including information about the FtP process and hearings; virtual tours of FtP hearing rooms; some have a single caseworker point of contact, shielding witnesses under cross-examination from the registrant's sight. Experience from criminal justice systems, however, suggests legally available adjustments often fail to be made because needs are not identified (13,14). Critically, there has been no evaluation of the effectiveness of these interventions for FtP witnesses; this gap is addressed in this project, examining i) the expectations, experience and insights of witnesses of FtP processes, and ii) evaluating the adequacy of regulators' witnesses support intervention provisions, with particular focus on cases where the witness claims to have experienced lasting harm from a registrant's misconduct.

Patient and public expectations of regulation:

Patient safety regulatory healthcare oversight in England is provided by over 126 bodies, as well as NHS commissioners (15). There can be multiple bodies involved alongside professional regulators where patient safety is a concern. New research will map NHS complaint pathways (16) and will compliment this research. The resultant complexity of these different and concurrent investigations can require a witness to recall their experiences multiple times over protracted time periods. Our research specifically explores the exacerbating effects of these multiple investigations, to investigate what regulators can do to mitigate these further effects.

For legal and professional practice reasons, regulators differ in how they define misconduct and the sanctions they apply. The GDC sought to refine its criteria for 'seriousness' in determining breaches of standards constituting "impaired fitness to practise". Highlighting the differing legislative contexts, their review concluded; "Establishing clear definitions from the literature of what constitutes misconduct, let alone what distinguishes serious misconduct, is challenging (17, p.28)."

Dutch Healthcare Inspectorate research on complaints by individuals to health care regulators reveals that service user/patient and family experiences are given lower credence in an implicit hierarchy of evidence, below that of clinical records (18). Yet evidence shows patients' views of their experience of professionals contain more than just clinical concerns (19-22) but include matters of breaching professional boundaries which patients may experience as harmful, which are not evidenced in a clinical record. So, for some people there is a disconnect between their expectations and experiences of engaging with regulatory processes.

Research on patient and family concerns about professionals when things go wrong:

Research on adverse events shows staff often have little understanding of the experiences of those who have been directly harmed, and of their exacerbation by the investigatory process itself (23).

Research exploring NHS complaints (24) and litigation (25) has revealed that patients who complain, or make a legal claim, cite a wide range of factors in their decision to take this action, including: the desire for an apology, to avoid similar incidents happening to others, to hold key individuals accountable, and/or for financial compensation. Much less is known about why people refer concerns to a regulator (26), non-academic research commissioned by a regulator found reports a range of expectations, including punishment which lies

outside regulators' jurisdiction (27). A study of 25 people who had been part of a FtP process before 2011 found participants were confused about the different channels for complaints and their distinct purposes Further they reported the process to be prolonged and taxing, with a mismatch between their initial expectations of the process and the final experience (28,29).

Research on the experience of FtP cross examination of witnesses:

A long research tradition exists on the role and experiences of witnesses in criminal trials. This includes the experience of different types of witnesses – including experts and lay witnesses – as well as the extent to which witness participation is facilitated or restricted due to structural or other reasons, and the potential for traumatisation and secondary victimisation (30). We see that there are analogies here to be drawn, for example in relation to the literature on vulnerable witnesses (31). But there are differences that we will need to interrogate. For example, there are key structural differences in relation to both the procedural rules that govern Fitness to Practise (FtP) and criminal proceedings. Further, these proceedings have different purposes: while criminal proceedings are punitive, FtP proceedings are (primarily) aimed at protecting the public (32).

The adversarial approach to cross examination in FtP hearings can be particularly distressing in cases of serious harm. Exploration by the HCPC of the determinations (outcomes) of sexual abuse cases against social workers describes the intrusive testing of victims' truthfulness as a witness, the lack of apology or remorse shown by registrants, the regulator's failure to protect them from harm that ran counter to the wishes of victims and undermined their motivation to participate. It questioned the low rates of special measures applied to support these victims, and unfavourably compared the level of support with that provided in the criminal justice system (33). Our research will address this gap by examining first-hand accounts of witnesses, including as they anticipate and experience a FtP hearing. Our research advisers (GP, EB) will enable us to consider these different literatures in our study and in our outputs.

The professional duty of candour includes, where relevant, a professional making an apology and expressing regret. A recent study found little is known about patients' responses to this in the context of FtP hearings (33). Yet studies of PTSD following trauma highlight the importance of these processes in promoting a "coming to terms" and the forgiveness of the perpetrator in achieving post traumatic growth (35). We are not aware of studies that have specifically examined the impact of apology, or the registering of regret during regulatory proceedings for victim witnesses. Our proposed research on case studies of witness experience of FtP hearings will address this important omission.

Staff concerns about colleagues' misconduct:

Some behaviours towards colleagues that may amount to misconduct are likely to be intentional. For example, staff bullying in the NHS is found to be a frequent and persistent problem affecting at least 15% of staff, with particularly high levels towards junior doctors (36). The consequences of bullying for colleagues and bystanders can include serious and lasting physical and psychological harm. Study of sexual misconduct occurrences leading to FtP adjudication revealed they occurred in NHS contexts that also had wider bullying and harassment climates (5) and could be prevented by employers.

Our research will examine the perspectives of colleague witnesses, who have been harmed by co-workers, of the FtP processes. From such insights we aim to produce employer-focused outputs which complement policies of candour, anti-bullying and speaking up.

1.2 Why this research is needed now:

The research addresses concerns raised by people (see below) who have had adverse experiences of being a witness that lessons should be learnt and effective actions (by regulators, employers and professional bodies) taken to prevent recurrence of adverse effects of engagement with regulation for others. While there are implicit assumptions about the cathartic effect of public inquiries, NHS investigations and FtP processes (37), there is little recognition that such experiences may actually add to the distress. Bereavement research shows how the suffering following a traumatic death can be aggravated through revisiting the memories of events and the death over a prolonged period of time, either through rumination or discussion prompted by others (38). There has been little consideration of the distinct, but also aggravating, impacts of FtP processes for those grieving.

Regulators' duties to the public

Professional regulation aims to protect the public and to promote public confidence in the professions and professionalism of registrants. FtP processes are dependent on information or complaints being brought to the attention of the regulator, and, where necessary, on witnesses being willing to provide relevant evidence throughout the process, including at public hearings. Attending to these currently omitted perspectives will enhance public confidence in regulation.

This research will examine regulators' processes and interventions from these distinct neglected stakeholders' perspectives, evaluating how they contribute to improved public understanding of the purpose and processes of FtP involved, and through these insights develop better and more efficient FtP proceedings. Further our research will identify where to improve FtP proceedings and enable the better tailoring of information to the public, professionals and employers about the purpose and processes of FtP proceedings, and through the outputs of research enhance engagement with proceedings, and so meet an expressed need of regulators for improvement.

Research interest of regulators and capacity to generate new knowledge

We have worked with the PSA, and the regulators to shape this proposal. They are committed to participating in our research and to being involved in the regulators' Advisory Group. Further, we have involved patient organisations, as well as professional bodies and lawyers, NHS employers throughout our proposal development, who will form our two further advisory groups.

Our preliminary study of the impact of pandemic restrictions on FtP hearings with bereaved family members, regulators' FtP directors and registrants' staff defence lawyers, (39) confirms: (a) the topic's significance to regulators, employers, professional standards bodies; (b) the importance of conducting the research whether FtP hearings are conducted in person, or (as currently) by videoconference as result of pandemic restrictions. Critically this current research has revealed that the "support offer" to witnesses does not currently allow better witness engagement, especially for those with low digital literacy or limited language skills. "We help them set up the videoconference call but we can't be there with them" (Hearings support officer, SWE). There is urgent interest in evaluating new approaches for supporting witnesses in remote hearings.

This project involves data collection with a range of regulators with over a million registrants (7). Also, we have invited a wider group of regulators to join the co-production of outputs and dissemination. This will include the other regulators under the PSA with registrants, with a total of 1,670,071 registrants, and the UK nations' three other social care bodies not under the PSA, covering 376,151 registrants in social work and social care, and 26 voluntary registers of professionals with around 86,000 registrants (under the PSA) where FtP process

are managed. This first independent multi-regulator focused research into professional regulation has huge potential for impact.

2. AIMS, OBJECTIVES AND RESEARCH QUESTIONS:

Aims: Our mixed-methods study focuses on cases of serious misconduct that involve harm to others in order to increase awareness and improve understanding of the expectations and experiences of witnesses involved in FtP proceedings, identify improvements to the processes to minimise the secondary harm that can arise witnesses and improve public trust in regulation and the professions.

Objectives:

1. Examine the experiences of patient/ family/ and colleague witnesses in the different stages of FtP processes, including; initial contact; and engagement, other complaint/investigations related to their contact with the registrant and services involved; the hearing stage; cross-examination processes; the outcome/ sanction and their responses to admissions and expressions of apology, or regret by the registrant.
2. Conduct a systematic analysis of the content and user experience of existing FtP information, resources and interventions for witnesses.
3. Identify where and how these processes and interventions could be improved to benefit complainants and witnesses and improve the efficiency of regulation.
4. Co-develop and co-produce 'good practice' guidance and resources for a range of stakeholders, namely the public, regulators, health and social care employers, and regulated practitioners.

Research Questions:

1. What are the experiences, support and information needs of patient/ family/colleague witnesses involved in different stages of FtP processes of the professional regulators' FtP investigations and hearings in the UK? (Objective1)
2. What factors influence these witnesses' view of the outcome of pre-hearing disposal decisions and hearings, including their view of the registrant's admissions, the weight given to their testimony, expressions of apology or regret by the registrant? (Objective 1)
3. How accessible are the witness support offer (information, staff and independent witness support/victim support and adjustments to FtP processes by regulators), how they experienced, and how might these be improved? (Objective 2,3)
4. What are the experiences of health and social care employers of the support needs of witnesses, including the decision to refer, and throughout FtP investigations and hearings? (Objective 3)
5. What is the experience of lawyers for the registrant and for the regulator of the support needs of witnesses, and the approach to fair witness testimony, and cross-examination in hearings? (Objective 3)
6. How could regulators and employers improve the engagement and experience of witnesses in their FtP processes? (Objective 3,4)

3. METHODS

Harm

In recognition of the different definitions of harm across regulators and the NHS, the initial meeting of our Regulator Advisory Group (below) will agree a project definition of harm cases. This will be the basis used by each regulator to identify, based on their categorisation systems, cases in which a witness is alleged to have suffered harm. Harm is especially likely in cases involving sexual abuse and harassment, professional boundaries concerns, financial exploitation, violence, sustained injury and the unexpected death of a family

member. Retrospective analysis of completed cases consider the allegations, the determination (outcome of a hearing) together with witness testimony to ascertain if the witness suffered harm. We will refer to the National Reporting and Learning System's definitions of harm (40) and subsequent guides (41,42,), which is relevant to determining clinical injury harm, although this is limited in application due to its application to recent events where long-term effects are not known.

Overall sampling, recruitment and setting

We are mindful of consideration of the sensitivities, confidentiality and data security constraints, the practicality of accessing witness (their willingness and availability), regulator capacity to provide redacted documents and data on the numbers of harm cases. To secure the samples for meaningful survey analysis and interviews we have allowed for over sampling to achieve sufficient numbers in the project's timescales, with possibilities of further additional participants and cases from different regulators allowing for their relevant caseloads. Recruitment for all WPs involving witnesses will be initiated through the regulators' staff. Invitations will be sent from regulators using carefully worded research designed letters that outline the design of the study and the opportunity to help inform ways to improve FtP processes (see recruitment/ethics below), using opt in methods of consent, with no detriment to themselves or the cases with which they were involved. Regulator staff will be approached via the regulator as the employer.

Critical distance and engagement of regulators:

Partnership working is essential with the regulators to gain access to participants and to case information held for regulatory purposes rather than for research. We work with 3 distinct Advisory Groups (Lay Advisers, Regulators, and Employers/Professionals/Lawyers) to support our data collection and the accessibility of our outputs to enhance the take-up of the findings. Through this process there is a clear separation of control and accountability in the project.

Pandemic restrictions:

Pandemic restrictions have resulted in the pausing of full hearing initially, using remote technologies for public and witness attendance (43). The legal requirement to include the public enables our research to continue using this public access provision for both in person and remote FtP hearings. These differing formats for hearings are factored into our study with questions about remote participation already trialed in a small pilot study (39). There is research in the criminal justice system that allows us to the anticipate the adverse impact of remote hearings for those with cognitive impairment, mental health and/or intellectual disabilities (44). In our design observations of hearings, interviews and focus groups can be conducted remotely or in person.

WP1: Analysis of FtP information, resources & interventions.

WP1.1 (RQ1) [OU] A cross-sectional survey (n=90) will be conducted of public and colleague witnesses who claim to have been harmed by the registrant. Sampling will include distinct FtP stages, including rejected at triage/screening; at conclusion of investigation including decisions not to proceed/consensual disposal/proceed to a hearing; and after FtP hearings. Data from these surveys will be subject to descriptive and multivariate analyses by personal characteristics, regulator and harm case type. Although prior regulators' survey response rates are around 30%, we have the advantage of research that is independent of the regulator and uses a small voucher incentive (£20). A sample size of 180 is likely to have a meaningful response rate (>50%). Descriptive statistics on those approached by the regulator will be used to analyse non-respondents to allow us to assess potential sampling skews. These results will inform WP1.5.

WP1.2 (RQ3) [OU] Documentary analysis of regulators' public and witness materials in the public domain produced by 10 regulators under the PSA. The content of the documents

will be captured in NVivo 12 or similar software and coded for comparison using content analysis (45)The analytical coding framework will be developed in conjunction with regulators, to include information content, readability level (46), and accessibility features (47) such as information presentation to include font and pictorial additions. By conducting this work in conjunction with the regulators, this analysis will take account of the constraints of the regulators' respective regulatory frameworks.

WP1.3 (RQ3) [OU] **Interviews and/or Focus groups** will be conducted to explore the usefulness of the information offered to the public and witnesses, including those who have and have not been involved in a FtP hearing. Recruitment will be via the patient participation groups of some regulators and our PPI and Lay Advisory Group including public bodies (n=4-6 interviews).

WP1.4 (**RQ4) [OU] Interviews with NHS and social care employers** on their expectations of referral to FtP of their staff, involvement of their staff and patients/service users as witnesses (particularly where they are in a "vulnerable group"), witness preparation and how they mitigate witness stress or traumatisation (n=9 interviews).

WP1.5 (RQ 3) [MMU] Interviews with vulnerable witnesses who have used regulators' support offer

Qualitative interviews will be conducted with a small number (4-6) of vulnerable witnesses (for example, people with learning disabilities/mental ill health or bereaved family members) who have used support provided by regulators. This will include in-house witness support officers, independent victim support services and the use of lawyers appointed to cross-examine witnesses where the registrant is unrepresented. This data will supplement the survey data generated in WP1.1. Potential participants will be identified by the regulators.

Analysis of data generated in WP1.3, WP1.4, WP1.5 will use a modified grounded theory approach (48).

OUTPUT: Taxonomy of materials, support and interventions, three interim reports for regulators, professionals and the public; to be updated with analyses from WP2 in WP3.

WP2 Evaluation of experience of participants throughout FtP proceedings

Case studies will be identified by each regulator based on agreed criteria concerning the case and type of harm (e.g. sexual abuse/harassment/breaching professional boundaries, financial exploitation, violence, injury, serious and lasting clinical harm, death) including: (a) those with a decision not to proceed due to insufficient evidence or where facts are admitted, and (b) those with FtP hearings.

WP2.1. (RQs1,2,5,6) [UG] Retrospective comparative FtP process analysis:

Examination will focus on different types of harm case (theft/fraud and sexual harassment and abuse, in line with our focus on witnessing harm and a case involving serious clinical harm). These cases may vary between regulators, but will be selected by the regulator as a key example to analyse and draw insights about how to support those who witness or experience harm from such activities. We will compare up to 30 completed cases, with at least three per regulator. Case study methods will include case file documentary analysis (determination, withness statement, hearing transcript of witness evidence) for all 30. We will supplement 8-12 of these cases' documentary analysis with multi-stakeholder interviews. These will comprise a maximum of three distinct case perspectives and develop a timeline of activities that illuminate eventss and ways to betterintervene and/or support to reduce or alleviate some of the unnecessary trauma and anxiety of these events. The use of opt-in interview protocols, as for all participants, will result in only a sub-set of further cases. We aim to ensure coverage of regulators and types of case in this further sample.

We will use memory reconstruction techniques (49) to produce participant-led generation of event maps (50) that will indicate key events and trigger points within FtP processes to

indicate where improved support and different experiences could have occurred. Our event mapping process will incorporate self-administered solutions (51) and solution-focused techniques (52) that enable those opting-in to these interviews to manage their distress and focus their attention into what could have been done differently to reduce trauma and to add further support in these FtP proceedings. We will work with regulators to carefully select and invite participation in our supplementary case study interviews.

A three-stage coding process will be used to analyse the 30 cases' data (witness statements, hearing transcripts and sub-set of interviews). i) Cases will be qualitatively coded for ecological factors including location of the incident(s); misconduct/sanction; registrant (profession, gender, work setting); investigation complexity. These data will be used to develop a preliminary event map (50) which will be compared with those generated in case interviews. ii) Coding of interviews and case materialswill identify process stages (triggers, positive and negative experiences). The coding will be developed using the pre-identified dimensions and the researchers will rely only on the evidence presented and 'found proved' in the document. Coding will be reviewed, checked and verified on an ongoing basis at the end of each case and then again after each regulator group, and across each FtP categories. iii) Following the initial deductive 'first-order' coding, data will be thematically grouped around inductive 'second-order themes' (53) based on the commonest discernible patterns (for example, individual, social and organisational factors). Themes will be illustrated using exemplar quotes. Aggregated event maps will be developed to capture different themes through the FtP processes and avoid breaching participant anonymity.

WP2.2 (RQs1,2,5,6) [UOx, MMU] Prospective design: Ethnography of FtP processes:

Prospective design using ethnography of FtP hearings (one to two per regulator, allowing for case availability): This study will trace the unfolding processes of FtP hearings as experienced by participants to produce an ethnographic account of this phenomenon. This will generate insight into aspects of the process involving the witness that cannot be captured through surveys, interviews or analysis of case data alone. Regulators will be asked to identify 1-3 suitable cases to create a purposive sample of cases to provide a diverse sample of perspectives and experiences across regulators, type of case/harm, and witness (patient/service-user, family, colleague). Participant-observation will involve observation of the hearings by the ethnographer as a member of the public. Once the case has concluded, the regulator will send a letter and participant information sheet to the witness to invite them to participate in the study by contacting the research team. Once the witness has consented one ethnographer will interview the witness. Witnesses may be interviewed on up to 3 occasions over a 3 month period to understand how their interpretation of the hearing unfolds over time and their use of any sources of advice or support. They will be invited to share any documents relevant to the hearings as well as to provide a narrative account of the hearing. Witness will also be asked to consent to the regulator sharing their witness statement and transcripts of cross-examination with the research team. Interviews will also be conducted with a further 5 people involved in each hearing (up to a total of 6 people per case n=36 total) (for example, the regulator's presenting lawyer, the registrant's lawyer, case investigator, witness support officer, hearings staff and hearing panel members). These participants will be contacted directly by the research team, or where necessary, via the regulator.

WP2.2 will produce a wide range of data including contemporaneous fieldnotes, audio-recordings of interviews and sets of case documents e.g. witness testimony, case determination. Data analysis will be conducted in three steps: 1) Iterative analysis (thematically, using modified grounded theory) to further focus and refine interview questions and identify additional participants to interview 2) Data synthesis by producing individual case narratives to form the basis for discussion with the wider research team 3) The systematic production (in collaboration with 2.1 and 2.3) of richly contextualised descriptions of the communicative genres, events and practices that are observed (54) to understand how meanings are constructed, the influence of moral and ethical dimensions, how

communication and interaction unfold and the institutional roles and routines that shape FtP hearings.

WP2.1 and WP2.2 will produce multi-perspective insights into the experience of a witness who has been harmed, those who influence the conduct of the FtP process and interventions to support witnesses. It will also afford understanding of the personal impact on the witness of the conduct of the registrant (e.g. expression of apology or regret), the FtP outcome, the impact of interventions to support witnesses, and the extent engagement in FtP processes has helped bring resolution or has aggravated the harms already experienced.

WP2.3 (RQs1,2,3,6) [MMU] Personal narratives of FtP hearings, processes and support interventions:
Building on and triangulating insights obtained in WP 2.1, in-depth narrative interviews (55) will be conducted with 9-12 people who have experienced FtP hearings completed in the last 3 years across the regulators (allowing for case availability and excluding those in WP2.1). Potential participants will be identified by the regulators and sent an invitation letter with the researcher's contact details. The interviews will explore participants' experiences, and subsequent needs for and use of witness support services and legal, health and care services (with input from the results of WP 1.5). Interviews will be filmed with participants' consent for use in web outputs (WP3.2).

Interviews and observations (WP2.2. & 2.3) will be analysed thematically during the fieldwork process using a modified grounded theory approach (44). Analytic interpretations will be developed to focus on the ongoing fieldwork. This will generate a thick description of the experiences and understanding of *what* is important to participants and *how* they respond to key events. We anticipate developing theory to make sense of this which will be informed by existing theoretical frameworks and literature.

OUTPUTS: 3 updated reports for regulators, professionals and the public. Input to WP3.

WP3 Synthesis of results
Findings from WP1 and WP2 will be synthesised by the whole research team in three iterative workshops. These workshops will map the experiences of our diverse sample in the distinct stages of the FtP processes to consider engaging with the regulator, preparing for, participating in, and reflecting on the outcome of a FtP hearing. This procedure will involve macro and micro reflections of the overall process, and in-depth insights into the distinct strands of the FtP process stages including expectations, experiences and the aftermath. Comparisons within and between different cases and different regulators will produce generalised and specific findings that inform WP3.2 by identifying where, when and what type of support is important to witnesses and families in cases of serious harm. In addition, our findings will identify what types of experiences undermine the confidence of witnesses in regulators.

WP 4 (RQ 3,6) Development of good practice guidance and resources for witnesses in FtP hearings, co-production of resources and dissemination. The whole research team will co-produce guidance and recommendations, public resources (video and social media) of witness experience and good practice: working with the regulators, patients, legal services firms, victim support and patient/service user's rights groups, including our Advisory Groups.

Co-design methods (56) will be used in 4 workshops (either face to face or virtually) with a range of people affected by adverse incidents with differing socio-economic class, ethnicity, gender, age, disability. The workshops will involve participants working with the research team and members of the advisory groups using 'beyond text tools' (57) to create guidance for (i) the public and third sector organisations (HeathWatch, Patients Association, AvMA, INQUEST),(ii) regulators, and (iii) staff witnesses, employers, and professional bodies including BMA,BDA,BASW,RCN and RCM and FtP defence lawyers).

A final workshop will build on the outputs from these earlier workshops to enable ideas to be tested, expanded, refined or removed across this WP. We will involve further regulators (e.g. GMC, social care regulators for Wales, Scotland and N. Ireland) to ensure the materials produced have the widest benefit.

Co-design workshop participants will be drawn from the Advisory Groups (AGs) and their networks, focused on findings and outputs for (AG1) the public (AG2) regulators (AG3) professionals/employers/defence and standards bodies. Workshops will present the findings from WP1 and WP2 in the form of accessible films (including WP2.3 film data) and short talks, and then in small groups consider particular questions. Each group will work on their question using a range of techniques including drawing, graphic design and producing vignettes. If held virtually, we will use webinar software to enable participants to break-up into these smaller groups.

The outputs and audiences are described below. How we will produce these tangible and actionable outputs differs for each product, but all will involve co-design with the intended audiences. We will develop a detailed dissemination plan with our AGs. Our approach to knowledge transfer (58) involves (i) ongoing dialogue throughout the project and including with wider audiences through our communication plan, (ii) knowledge generation related to the results and what they mean for regulators and other stakeholders, and (iii) dissemination for practical use of the outputs by the different audiences.

Our approach to dissemination and impact builds on the wide engagement we have already created and will be further developed throughout the project. From the outset, we will inform and engage patients and service users, the regulators, NHS and the wider population about the project through a communications plan and ongoing use of social media use by all 4 Universities and a social media consultant, Dr George Julian. We will use a bespoke OU project website to host public-facing materials throughout and beyond the project. https://wels.open.ac.uk/research/witness-harm-holding-account

We will monitor access and seek feedback on these products to ensure they are having impact and are updated beyond the project. For example, we will use user feedback and web analytics on all websites. Our collaborator, the DIPEx Charity which hosts the Healthtalk and Socialcaretalk platforms regularly monitor use and reach of the websites. The OU OpenLearn system produces reports on usage and user evaluation. We will also track the changes introduced by regulators in processes using our results to measure impact.

4. ADVISORY GROUPS AND STUDY STEERING COMMITTEE

There will be 3 Advisory Groups (AGs), which will meet with members of the research team in months 1,13, 20 and 27, and contribute to interpretation of analyses and outputs.

AG1. Public and Patient members, advice and advocacy bodies.
AG2. Regulators
AG3. Professional associations, lawyers and employers

A Study Steering Committee (SSC) with an external chair, subject experts and public members will be appointed by NIHR. The SSC will meet in Months 2,18,28.

5. OUTPUTS

We will produce a comprehensive set of actionable recommendations for regulators, NHS and social care provider employers, employees, professionals' educators/standards bodies and public bodies via our Advisory Groups. Films, an eight hour Open Learn free course, and podcasts will be produced for the public, and materials for professional training. A webinar or seminar will be held for family members, regulators, PSA, health and care

professionals, demonstrating the project's outputs and to generate discussion along with a series of academic papers and conference outputs.

6. PROJECT MANAGEMENT

The full research team, including all co-applicants will meet quarterly across the project via conference call. The core research team leaders at each university will meet monthly with more meetings scheduled, or cross-university team meetings organised as appropriate for specific agenda items. Full research team meetings will be coordinated by the project manager (PM). The PM will be responsible for organising the Advisory Groups, Study Steering Committee (SSC), coproduction events, ethics and research governance, internal and external communication, monitoring the project outputs and deliverables, and reporting to NIHR. The Advisory Groups will meet formally in months 1, 13, 20 and 27. They will be fully involved in production of outputs, advising on recruitment and dissemination.

7. ETHICS/REGULATORY APPROVAL

A favourable ethical opinion for the separate work packages will be sought from the appropriate Universities' Research Ethics Committees before the planned start date.

We are very mindful that our research design involves participants retelling experiences that may generate more distress to them. In our experience, taking part in research in which experienced researchers who are trained in approaching fieldwork with sensitivity and care can be an empowering process for participants. We will develop a participation protocol at the start of the project drawing on the team's experience of working in sensitive areas as well as existing resources available online, including those produced by Victim Support. This will cover strategies for mitigating potential harm to participants and guidelines for action to be taken if a participant experiences harm as an outcome of taking part in the project. A sub-group of the research team will be formed to oversee and monitor the involvement of participants across the WPs. This group will feed back to the wider research team meetings in order to bring any concerns or potential issues to the attention of the team. Accessible information, clarity in communication, flexibility and sensitivity will be key.

Informed consent and voluntariness are particular considerations for participants the regulator describes as a vulnerable witness. All participants will have capacity to consent as assessed by the regulator; and if there is any doubt, SH (qualified social worker) will arrange to assess a potential participant according to the Mental Capacity Act (2005). Informed consent will be obtained using an adapted accessible version of the information sheet and consent form, explained in person with each participant by the researcher and, where appropriate, with someone they know well. As for all participants, care will be taken to make sure that each participant understands the nature of the research, the risks and benefits and the possible outcomes and, in particular, that participation is voluntary and that consent may be withdrawn by participants at any time up until the data has been anonymously analysed, without adverse consequences.

Public participants will be paid a small token of thanks for their time and any expenses incurred. All such participants will be approached by the regulator who will pass on an invitation to the research team including a link to the project website. If they express interest, they will be invited to contact the research team. Participant information will be given to potential participants to enable them to contact the research team if they are interested in the project.

The most important principle here is that potential participants feel they have complete control over whether to participate in the research project ('opting-in') and with re-consent discussed at any subsequent contact. The invitation to opt-in would outline the purpose of the research, the use of independent and credible researchers, and establishment from the onset of their anonymity in participating. While some individuals may have no desire to be

involved, offering the opportunity to provide their unique and important insights in order to improve the process for others is a consideration. The information sheet will describe the research as being independent of the regulator, that no information shared with researchers is shared with the regulator, and critically their anonymity in the processes and their ability to withdraw at any time without adverse effects.

Recruitment via Advisory Groups and employer/professional body networks in WP1.4 will be via direct invitation from the research team and the usual consent processes.

Access to case materials (e.g. such as witness statements, hearing transcripts) and observation of FtP hearings will be facilitated by and under requirements for de-identification, anonymization and redaction of the regulators. Interview schedules will be included in the ethical committee applications with associated covering letters, information sheets, consent forms and de-brief (including complaint forms).

General Data Protection Regulation (GDPR) legislation will be followed. Consent forms will be stored separately from the data. Transcribed data will be pseudononymised, and all identifiable features removed from the data set. All recordings, transcripts and databases will be password protected, stored on an end to end encrypted (prvate) sharepoint site within the OU and only available to the research team. Only data specific and relevant to the project will be collected thereby minimising the risk of identifiable data. Archived data will be anonymised (apart from the consent forms which will be stored separately from the data). Data Sharing agreememts will be agreed with each of the regulators and the five universities involved.

8. PUBLIC AND PATIENT INVOLVEMENT

Our lay co-applicant RW and members of the PPI Advisory Group (above) will be supported to engage with the project comprehensively and throughout in addition to the four formal meetings.

Inequalities
We are mindful that specific groups are more likely to be victims and to be referred to FtP, so the relevant data will be collected, and this will be a consideration in the selection of case studies. We will incorporate a diversity monitoring form within the study documents for ethical approval which will include the demographic details of participants, Advisory Groups and research team members.

9. DATA MANAGEMENT PLAN

9.1.Type of data

The data is a mixed methods study combining a survey, interviews/focus groups, observations and documentary analysis.

Survey data will be obtained with consent and managed in Qualtrics, downloaded and managed by The Open University [OU]. Documents to be analysed will be obtained from the 10 Health and Care regulators under the Professional Standards Authority, and the PSA subject to agreements which will be place regarding data sharing and confidentiality.

Interviews will be conducted (with consent), audio recorded and transcribed by all universities. A selection of interviews (obtained with consent) will be video recorded (with consent) and transcribed. [MMU]. We will ask participants to assign copyright to their interview to the Open University and use these copyrighted data (text, audio and video recordings of interviews and transcripts) to develop and publish a new resource on Healthtalk.org, Socialcare.org and Open Learn.

Ethnographic observation [UOx, MMU] handwritten fieldnotes made contemporaneously, will be kept by GH and the research associate.

Documentary analysis data [OU] (WP1.2) includes materials in the public domain of the regulators, as well as internal policies and procedures related to management and support of public who refer to FtP and as witnesses.

Transcripts of hearings (with redactions of personal data by the regulator) and determinations in the public domain will be used in WP2.1, WP2.2).

Other material includes relevant to all Universities are consent forms and copyright forms, and contact and demographic details of participants.

9.2 Format and scale of data

Survey data [OU] will be a mix of closed and open questions recorded in Qualtrics and downloaded into Excel. We plan to achieve 90 responses across regulators

Documentary data for WP1.2 [OU] will be obtained from regulators and downloaded from their websites, and stored as PDF or word downloads, and held in password protected files. We anticipate about 40 documents.

Transcripts of hearings and public determination data from the regulators or their websites. We anticipate about 30 case files (WP2.1) [UG], 3 pieces of case information per case, total 18 in WP2.2., and the determination (in the public domain) for the 12 cases in WP2.3.

Interview data will be recorded on an encrypted digital voice recorder and stored as WMA file format by the respective university. Transcriptions will be stored in Microsoft Word, analyses will be stored in Word and NVivo files. We plan around 21 audio recorded interviews in WP1, in WP2.1 up to 30 interviews, WP2.2 up to 84 interviews.

Video data [MMU] will be recorded on a digital camera and stored as MPEG or AVHD file formats or online digital recordings will be captured through an approved platform such as MS Teams with a back-up copy captured with Open Broadcasting Software (OBS). There will be up to 12 films in WP2.3. An audio version will be collected, transcribed and stored as for interviews above.

Observational field notes in WP2.2 will be made contemporaneously by hand and written up into a digital format.

De-identified transcriptions will be stored by all researchers in Microsoft Word, analyses will be stored in Word and NVivo files. Participant contact details will be stored in Microsoft Excel and on paper forms.

Participant contact details will be stored by all universities in Microsoft Excel and on paper forms in locked cabinets in the universities until digitized.

9.3 Data Generation

Confidentiality, data protection and data sharing clauses will be agreed by all universities with each of the regulators.

Survey data will be held in Qualtrics until downloaded to Excel and transferred to a secure university network drive or encrypted hard drive. Paper versions of the questionnaire will be returned to the research office of WELS in The Open University and stored in secure filing cabinet digitized as soon as possible. Documents will be scanned and held in a secure university network drive or encrypted hard drive. [OU]

Documents will be as PDF or word downloads and held in password protected files.

Video/audio/image files will be captured on a digital camera and/or audio recorder and downloaded, through a university owned laptop computer, on to secure University (networks of the respective universities and encrypted external hard drives as soon as practicable and deleted from portable devices. MMU will transfer filmed material to the OU using OneDrive, or other subsequently approved secure means.

Online digital recordings of interviews, focus groups and meetings will be captured by all universities through an approved platform such as MS Teams, with a back-up copy captured with Open Broadcasting Software (OBS) onto an encrypted University owned laptop, and immediately transferred to a secure university network drive or encrypted hard drive.

If other IG compliant remote technologies which make participation more accessible to participants are subsequently approved by all universities then these may be used in future.

Paper contact forms, consent forms, copyright forms, reply slips will be digitised and stored on OneDriveby each university, then transferred to The Open University before the end of the study. All video and audio data files will be deleted off the camera and voice recorder once two copies have been made.

9.4 Data Quality:

Survey data will be downloaded into Excel with no individual identifiers, and quality checked for completeness and duplicates. [OU]

Documentary data from regulators (WP1.2) [OU] will have no individual identifiers. Case data from WP2.1, [UG] and WP2.2 , WP2.3 [MMU, UOx] will have individual identifiers removed before storage and will be quality checked for completeness and duplicates.

The WP leader from each university will be responsible for assigning a unique identifier to digital audio files before being sent via the approved secure file transfer system for transcription by approved transcribers with confidentiality and data protection contracts in place and required IT security. Transcripts will be returned the same way, checked, and de-identification completed by a member of the research team.

Digital film recordings will be downloaded from the camera, uploaded to a secure university platform and checked for sound and visual quality.

9.5 Managing and storing data

The Open University is the data controller. The project manager will check the data is being stored correctly.

Paper documentation will be held in a secure location in a locked cabinet, in the respective university and digitized as soon as possible and uploaded to Sharepoint.

Handwritten field notes generated as part of the ethnography study in WP2.2 will be destroyed once they have been written up in electronic form and stored on secure university platforms. [Oxford and MMU]

Electronic documentation: Survey downloads [OU], transcripts of interviews, field notes, demographic details,[all universities] will be stored in password protected word documents onSharepoint.

Video and audio data will be stored on a secure university platform by each university onSharepoint. These actions will be done as soon as possible after each interview to minimise risk of data loss. Data will then be deleted from recording devices. Access is restricted to the Master copy to preserve data viability. Audio recordings will be transcribed by the respective university's approved transcriber company, with data sharing contracts containing confidentiality clauses in place, and necessary IT security requirements. Data will be sent password protected by secure file transfer.

Password and decryption keys will be managed centrally using a password manager for any shared documents, with each university keeping a password manager for any documents that will not be shared. The identifier key will be kept in a separate password protected study sub-folder only accessible by the study team. It is necessary to preserve personal data and the identifier key so that we can remove people's interview data from the archive and their clips from the resources if they ever decide that they would like to withdraw.

De-identified data will be shared with co-investigators on the wider programme of work together with researchers, who report to them, using password protection as above and sent via secure file transfer or the OU Sharepoint site. Appropriate data protection and data sharing clauses will form part of the collaboration agreement between vested institutions. This is to facilitate the analysis and creation of resources for dissemination.

Research (not personal) data will, with consent, be published under licence on Healthtalk, and Social.care.org websites run by the DIPEx charity. Some data may be in the form of de-identified text extracts. Other data will be audio or film extracts, using first names or pseudonyms, as preferred by the study participants. Textual data will be preserved for 10 years using the OU's research repository (ordo.open.ac.uk). Textual, audio and film at MMU will be stored on the MMU Depository e-space for up to 10 years. Data will be preserved on ORA. Data by the University of Oxford and will be retained for as long as it has continuing value and for a minimum of three years after publication of research. University of Glasgow textual data will be retained for 'as long as it has continuing value', but for a minimum of three years after publication of research'. This data will be stored in an encrypted and password protected area on University of Glasgow secure one drive storage system.

Where we engage the wider team in analysis we will share de-identified transcripts and video excerpts (with appropriate data-sharing agreements in place). From this analysis we will develop resources to stimulate design discussions with stakeholders in the co design and dissemination events; this will include a 'catalyst' film or montage of video extracts.

9.6 Metadata standards and data documentation

Consent/copyright forms, participant demographic data and participant contact details will be stored in Excel, password protected and saved on Sharepoint by each university.

9.7 Data security and confidentiality of potentially disclosive information

This study will be compliant with data protection policies of each university, which are informed by the Data Protection Act 1998 and the EU General Data Protection Regulation (effective from 25th May 2018). Personal data will be collected as part of the surveys and interviews (names, e mail and phone contact information, healthcare information). It is confidential and will not be shared with unauthorised third parties. All data will be de-identified and peudonomised for analysis, and anonymized for archiving We will not have permission to use any of the audio and film material until it is copyrighted.

Data security will be handled with extreme care using the following procedures:

(i) Video interviews and audio files will be deleted off the camera and digital recorder at the earliest opportunity once two copies have been downloaded onto the researcher's password protected and encrypted drive and a Master password protected and encrypted drive kept in a locked cabinet at the university.
(ii) All paperwork relating to the study (consent form, copyright form, participant contact details) will digitized as possible and paperwork destroyed.
(iii) If a person withdraws from the study all copies of the paperwork, video, audio and transcript files will be deleted.
(iv) Audio files will be encrypted and password protected and sent to transcribers via a secure file transfer system.
(v) As all information disclosed by participants will be confidential and anonymized, relating only to closed cases, researchers on the team who are registered professionals are not required to report any disclosure about a registrant or their testimony to a regulator.

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