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# Study protocol: Optimising the outputs of National Clinical Audits to support organisations to improve the quality of care and clinical outcomes

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# 1 Summary

**BACKGROUND.** Audit and feedback (A&F) aims to improve patient care by reviewing health care performance against explicit standards. It is widely used to monitor and improve NHS care, including in national clinical audit programmes. Ideally, where a discrepancy is detected, changes are implemented at an individual, team, and/or service level. A&F generally has small to moderate and variable effects on patient care, although potentially substantial population impacts. Yet cumulative meta-analysis of A&F trials indicates that effect sizes stabilised over 10 years ago, suggesting a lack of learning on how to improve effectiveness. We need to improve the effects of A&F. Moreover, how healthcare organisations respond to national audits is highly variable, further limiting the impact of A&F. Building on collaborations with partner national audit programmes, we will develop and evaluate methods to enhance A&F and explore how to routinely embed such work within UK national audits.

**AIM.** To improve patient care by optimising the content, format and delivery of feedback from national clinical audits.

**OBJECTIVE 1.** To develop and evaluate, within a web-based randomised screening experiment, the effects of modifications to feedback on intended enactment, user comprehension, experience, preferences and engagement. This offers an efficient way of identifying leading candidate modifications for further 'real world' evaluation.

A consensus panel will prioritise theory and evidence-informed modifications to feedback interventions, drawing upon a state-of-the-science summary of recommendations. 500 individuals drawn from organisations targeted by four national audits will take part in a randomised screening experiment with a fractional factorial design, whereby they receive and respond to different combinations of feedback modifications through a web portal; proxy outcomes include intended enactment, comprehension, user experience, and preferences and engagement.

**OBJECTIVE 2.** To evaluate how different modifications of feedback from national audit programmes are delivered, perceived and acted upon in healthcare organisations. This will include feedback modifications identified in Objective 1 and more organisationally-focused modifications less amenable to web-based experimentation. Testing feedback modifications in 'real world' settings will allow us to understand inter alia how the wider institutional context influences A&F.

A case study will examine how four purposively sampled, linked pairs of healthcare provider and commissioner organisations (two for each of two national audit topics) respond to feedback modifications. We will use both institutional and systems perspectives, the latter guided by a logic model. We will use documentary evidence, observations and interviews with board members, clinicians and managers to examine how feedback is delivered, perceived and acted upon. The analysis will exploit diversity sampling, comparing and contrasting findings across localities and audits. Framework and thematic analyses will focus on understanding how and why the intended effects are achieved, or why they are not. We will assess how feedback is aligned or misaligned with other activities and policies across different levels in each locality, for each audit.

**OBJECTIVE 3.** To explore the opportunities, costs and benefits of UK national audit programme participation in a long-term international collaborative to improve audits through a programme of trials.

We will interview 30 purposively sampled national audit staff, A&F researchers, clinicians and managers targeted by feedback to explore understanding, experience and expectations of integrating research within national audit programmes.

**OUTPUTS.** We will (i) identify a set of modifications for national audits which can enhance their impacts and underpin future rigorous evaluations of cost-effectiveness; (ii) develop a training manual, templates and online resources to help organisations optimise the delivery and use of feedback; and (iii) establish the optimal conditions for embedding collaborative trials within national audits.

**EXPERTISE.** Our team combines international expertise in audit and feedback research with experience of designing and delivering national audits.

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## 2 Background and rationale

Clinical and health services research continually produces new evidence that can benefit patients. However, this evidence does not reliably find its way into everyday practice in the NHS [1]. There are frequent failures to introduce effective new interventions and clinical practices quickly enough, consistently use those already proven to be effective, or stop using those found to be ineffective or even harmful. The resulting inappropriate variations in health care and outcomes are well documented and pervasive across different settings and specialties [2-9]. The gap between evidence and practice is a strategically important problem for policy-makers, healthcare systems and research funders because it limits the health, social and economic impacts of research [10].

National clinical audit programmes compare recommended against actual practice for a range of priority topics (e.g. diabetes, cancer care) and therefore play key roles in both measuring the extent of inappropriate variations and using feedback to promote improvement. A&F is widely used at national and local levels across the NHS and other healthcare systems internationally as a quality improvement method. The most recent Cochrane Review of 140 randomised trials found that A&F had modest effects on patient processes of care, leading to a median 4.3% absolute improvement (interquartile range 0.5% to 16%) in compliance with recommended practice [11]. One quarter of audit and feedback interventions had a relatively large, positive effect on quality of care, while another quarter had a negative or null effect. The review found that feedback may be more effective when the source is a supervisor or colleague, it is provided more than once, it is delivered in both verbal and written formats, and when it includes both explicit targets and an action plan. Given the relative paucity of head to head comparisons of different methods of providing feedback and of comparisons of A&F versus other interventions, it remains difficult to recommend the use of one feedback strategy over another on empirical grounds [12].

Strategies to promote the uptake of guideline-recommended practice need to take account of the costs and cost-effectiveness of implementation interventions [13]. Given that healthcare and research resources are finite, it is important to determine how we can enhance the effects and reliability of A&F to maximise population benefit. There is little evidence about the cost-effectiveness of implementation strategies, including A&F [14, 15]. Although national audit programmes may appear to be relatively costly, any modest effects can potentially be cost-effective if audit programmes build in efficiencies. For example, the increasing availability of routinely collected data on quality of care provides opportunities for large scale, efficient A&F programmes [16, 17]. Effective use of feedback offers potential advantages over other quality improvement approaches (such as educational outreach visits or inspections) in terms of reach and cost-effectiveness [13], particularly given the scope to enhance impact on patient care within existing resources and systems. There are further opportunities to improve the alignment of A&F with national and local quality improvement drives, such as aligning audits more closely with National Institute for Care Excellence (NICE) guidance and standards.

We have identified, through expert interviews, systematic reviews and our own experience with providing, evaluating and receiving practice feedback, 15 state-of-the-science, theory-informed recommendations for effective feedback interventions [18]. These recommendations relate to the nature of the desired action (e.g. improving the specificity of recommendations for action), the nature of the data available for feedback (e.g. providing more rapid or multiple feedback), feedback display (e.g. minimising unnecessary cognitive workload for recipients), and delivery of feedback (e.g. addressing credibility of information). These represent practical ways to bring about tangible improvements in feedback methods which can maximise the value of existing national audit programmes and healthcare infrastructures, and hence improve patient care and outcomes.

A&F sits on a conceptual 'fault line'. On one side are systems theories: the history of A&F thinking is, largely, a history of systems thinking. Systems theories of organisations, including feedback theories, have a long history in the social sciences [19]. Over time the problems with these theories have become apparent, particularly their difficulty in dealing with informal organisational practices and with conflict [20]. On the other side, new institutional theories (including sociological institutionalism) have shed light on many organisational phenomena over the last 30 years. Many HS&DR studies have been conducted in this broad tradition [21, 22]. Intuitively, the observed variations in A&F may be explained by differences in the institutional contexts where it has been introduced. Yet their weaknesses have also become apparent, not least in explaining how and why practices change over time [23].

A range of recent health service research studies have sought to combine the best of these traditions, while minimising the conceptual and methodological problems associated with them. There are, for

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example, cluster randomised trial designs which explicitly incorporate team-level interventions alongside interventions focusing on individual behaviour [24]. Observational studies of network governance have sought to quantify network relationships within case study designs [25]. The HS&DR programme encourages the use of logic models to articulate the sequences of events that link interventions and outcomes. Our design and methods will also draw on these developments.

### 3 Evidence explaining why this research is needed now

We (NI, JG) undertook a cumulative meta-analysis of A&F trials included in the Cochrane review [26]. The effect size and associated confidence intervals stabilised in 2003 after 51 comparisons from 30 trials. Cumulative meta-regressions suggested new trials are contributing little further information on the impact of common effect modifiers. We therefore argued that this field of research has become 'stagnant.' We need to shift our focus from asking whether A&F can improve professional practice towards how the effect of A&F interventions can be optimised. We identified a research agenda for A&F at an international meeting of experts in Ottawa in 2012 [27]. Our project builds on this and offers an opportunity to **revitalise research**, **reduce research waste** and **enhance the impact** of national audit programmes in three ways linked to our objectives:

1. Our 15 recommendations for improving feedback indicate a way forward but require further development and evaluation [18]. Rigorous evaluation methods, such as well-conducted cluster randomised trials, can establish the relative effectiveness of following such recommendations. However, varying only five elements of feedback (e.g. timing, frequency, comparators, display and information credibility) produces 288 combinations – not allowing for replication of studies or the addition of other interventions, such as educational meetings or outreach visits [28]. Given the multiplicity of factors that would need to be addressed, such an approach is not feasible; more efficient ways are needed to prioritise which to study. In **Objective 1**, we intend to undertake a fractional factorial screening experiment, building on current evidence and knowledge of behaviour change, and produce a statistical model to predict the effects of a large number of single and combined feedback modifications. This model can subsequently guide choices for further evaluation as well as offer practical feedback modifications which can be adapted to enhance impacts across a range of national audit programmes.
2. Our overall approach fits with the development, feasibility and (early) evaluation stages of Medical Research Council (MRC) guidance on complex interventions [29]. Having identified the most promising single and combined feedback modifications in a virtual experiment, we need to investigate how they work in 'real world' conditions. Our current programme, AFFINITIE (*enhanced A&F interventions to increase uptake of evidence-based transfusion practice*), is evaluating the separate and combined effects of enhanced content of feedback and enhanced practical 'follow-on' support following delivery of feedback. Both interventions target recommendations for action following feedback at organisational, team and individual levels. We have identified marked variation in local NHS trust responses to blood transfusion audits, including a lack of clarity about who feedback should target and who is responsible for action [30]; such deficits are likely to apply to other national audits. **Objective 2** will evaluate how our different modifications of feedback from national audit programmes are delivered, perceived and acted upon in healthcare organisations, guided by a logic model which takes account of multiple contextual factors moderating the feedback cycle.
3. Large scale improvement initiatives, such as national audit programmes, continually aim to enhance their impacts, often by making incremental changes over time (e.g. in use of comparators, feedback displays, etc). Given that such changes usually result in small to modest effects on patient care and outcomes, it is difficult to judge whether they are effective in the absence of rigorous experimental or quasi-experimental evaluations. There are potential significant returns on investment from national audit participation in a coordinated programme of research to improve effectiveness. We have proposed 'implementation laboratories' which embed research within existing large-scale initiatives such as national audit and feedback programmes [31]. Close partnerships between healthcare systems delivering implementation strategies at scale and research teams hold the potential for: a more systematic approach to identify and address priorities; sequential head-to-head trials comparing modifications to improvement strategies (e.g. of audit and feedback); promoting good methodological practice in both improvement methods and evaluation; enhancing the generalisability of research; and demonstrating the impact of improvement programmes. However, we recognise that establishing such implementation laboratories requires work (e.g. in negotiating shared understandings,

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expectations and ground rules) and need to learn from other research-practice partnerships if they are to become established. **Objective 3** will explore the opportunities, costs and benefits of UK national audit programme participation in a long-term international collaborative to improve audits through a programme of trials.

Finally, we understand the need for effective **dissemination** as well as research at this point in time. UK national audit programmes offer significant improvement opportunities. Current experience suggests that national audits are not realising their full potential, even in applying existing evidence to their conduct. We (RF, JF, SS, NG & FL) piloted an 'audit of audits' by applying evidence-based and good practice criteria to 23 recent national audit reports. We found clear areas for improvement (e.g. specification of target audience, linking findings to recommendations for action). We intend to use this proposed programme of work as a platform to engage national audit programmes, beyond those signed up as co-investigators or collaborators, in further work to review and improve feedback methods.

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## 4 Aim and objectives

*AIM:* To improve patient care by optimising the content, format and delivery of feedback from national clinical audits.

### *OBJECTIVES:*

1. To develop and evaluate, within a web-based randomised screening experiment, the effects of modifications to feedback on intended enactment, user comprehension, experience, preferences and engagement.
2. To evaluate how different modifications of feedback from national audit programmes are delivered, perceived and acted upon in healthcare organisations. This will include feedback modifications identified in Objective 1 and more organisationally-focused modifications not amenable to web-based experimentation.
3. To explore the opportunities, costs and benefits of UK national audit programme participation in a long-term international collaborative to improve audits through a programme of trials.

### *RESEARCH QUESTIONS:*

Out of a set of recent, state-of-the-science, theory-informed recommendations for improving feedback, which are the most important and feasible to evaluate further within national audit programmes? (Objective 1)

What is the effect of modifications to feedback on intended enactment, comprehension, engagement amongst clinicians and managers targeted by national audits, user experience and preferences under 'virtual laboratory' conditions? (Objective 1)

How do health care organisations act in response to modifications of feedback from national audit programmes under 'real world' conditions? (Objective 2)

What are the opportunities, costs and benefits of UK national audit programme participation in an international collaborative to improve audits through a programme of trials? (Objective 3)



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## 5 Research plan

### 5.1 OBJECTIVE 1. To develop and evaluate the effects of modifications to feedback on user comprehension, engagement, intended enactment, experience and preferences

*Design:* Our overall approach is consistent with the development, feasibility and (early) evaluation stages of MRC guidance on the development and evaluation of complex interventions [29]. This objective will comprise prioritising feedback modifications for further development and user-centred design, leading to a fractional factorial screening experiment [32-34].

*PRIORITY SETTING:* We plan to identify and develop feedback modifications which can readily be adopted by national audit programmes, preferably without the need for ongoing behavioural scientist input. Indeed, having seen a range of innovations shared at a Healthcare Quality Improvement Partnership (HQIP) meeting for national audits (London, March 2016) and based on discussions with our national audit partners, we know that several audit programmes are actively using or informally experimenting with a range of feedback modifications. However, few of these have been subjected to any rigorous evaluation.

We (JB, HC, NI & JG) have identified 15 recommendations for effective feedback through expert interviews, systematic reviews and experience with providing, evaluating, and receiving practice feedback [18]. These suggestions, summarised in the Box below, relate to the nature of the desired action (e.g. improving the specificity of recommendations for action), the nature of the data available for feedback (e.g. providing more rapid or multiple feedback), feedback display (minimising unnecessary cognitive workload for recipients), and delivery of feedback (e.g. addressing credibility of information). We recognise that effective feedback depends on having targeted specific individuals with responsibility for taking action to influence the behaviour of individuals, teams and organisations, and thereby improve patient care [30].

*Box. Fifteen recommendations for effective feedback [18].*

<b>Nature of the desired action</b> <ol style="list-style-type: none"> <li>1. Recommend actions that are consistent with established goals and priorities</li> <li>2. Recommend actions that can improve and are under the recipient's control</li> <li>3. Recommend specific actions</li> </ol>
<b>Nature of the data available for feedback</b> <ol style="list-style-type: none"> <li>4. Provide multiple instances of feedback</li> <li>5. Provide feedback as soon as possible and at a frequency informed by the number of new patient cases</li> <li>6. Provide individual (e.g. practitioner specific) rather than general data</li> <li>7. Choose comparators that reinforce desired behaviour change</li> </ol>
<b>Feedback display</b> <ol style="list-style-type: none"> <li>8. Closely link the visual display and summary message</li> <li>9. Provide feedback in more than one way</li> <li>10. Minimize extraneous cognitive load for feedback recipients</li> </ol>
<b>Delivering the feedback intervention</b> <ol style="list-style-type: none"> <li>11. Address barriers to feedback use</li> <li>12. Provide short, actionable messages followed by optional detail</li> <li>13. Address credibility of the information</li> <li>14. Prevent defensive reactions to feedback</li> <li>15. Construct feedback through social interaction</li> </ol>

A structured consensus process will guide our selection of modifications for further development and specify strategies for tailoring these to the needs of specific stakeholder groups [35]. Our method will enable initial elicitation of all views, social interaction and transparent decision-making.

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Consensus panellists will include members of a Reference Group, comprising six clinicians and managers involved in the design and delivery of feedback and/or targeted by national audits. We will also include three selected research team members with expertise in behavioural science or audit and feedback as well as two members of our PPI Panel to ensure that shared deliberations take account of service, public and research priorities. We will aim for 11 participants as consensus groups gain relatively little in reliability by exceeding this number [35].

The consensus development process will have three steps. First, we will present participants with online materials summarising and illustrating the 15 recommendations for effective feedback. We will summarise the strength of evidence for each recommendation [11] and their likely mechanism(s) of action. Participants will consider the following characteristics for each recommendation:

- Current evidence and need for further research (prioritising modifications for which there is greater uncertainty of effectiveness);
- Feasibility of adopting and embedding modifications within national clinical audit materials and processes;
- The extent to which feedback modifications can be combined with other data and quality improvement processes to the best effect.

Participants will independently rate characteristics for each recommendation on a 1-9 scale, where scores of '1' indicates the strongest disagreement and scores of '9' indicate strongest agreement.

Second, we will collate the scores for each and present the median and range and feed them back to all participants at a face-to-face meeting. We will discuss ratings, focusing on those with maximal discordance, defined as at least three participants scoring a recommendation 1–3 and at least three scoring it 7–9. Participants will then independently rate each item again.

Third, we will bring participants back again for a further face-to-face meeting. We will review the final ratings for each recommendation, prioritising those with higher aggregate scores for further evaluation. We will elicit and discuss suggestions for developing the most promising candidate recommendations. These will include potential modifications which incorporate 'the patient voice' within feedback; we will elicit suggestions on these from our PPI Panel beforehand. The consensus panel will also establish clear design goals as suggested by the following User-Centred Design approach.

*USER-CENTRED DESIGN:* This qualitative approach to design is intended to result in modifications that meet specific, pre-determined goals involving face-to-face testing with participants targeted by national audits [36], e.g. 90% of the time, a feedback recipient should be able to read and understand three key implications for their practice in 5 minutes or less. It is applied iteratively to assess the performance (i.e. not only content) of information, e.g. whether people can find and understand key points of information [37].

We will conduct 3-5 iterations with 3-5 feedback participants each whilst conducting audio-recorded 'think aloud' interviews as they work through various prototype feedback modifications [38]. Interviews will be conducted face-to-face in the most convenient site for the participants, such as their place of work or at one of our partner universities.

We will assess functionality (whether modification appears to work as intended), usability (whether participants can apply the feedback to plan or complete associated tasks), and user experience (e.g. participant satisfaction or frustration in working through feedback modifications). We will record how long it takes participants to work through materials and complete any associated tasks. We will adapt the user testing approach for modifications to delivery as opposed to content of feedback (e.g. changing the frequency of feedback) and interview participants regarding how these could be operationalised (e.g. more or less frequent feedback). We will revise each feedback modification as needed over each round of testing, anticipating around 3-5 rounds, until we have optimised the design for the online experiment.

User-testing will help us decide which recommendations are more or less suitable for online experimentation. We will carry forward and further evaluate feedback modifications less amenable to online experimentation (such as changes to the timing and frequency of feedback) within Objective 2.

#### *FRACTIONAL FACTORIAL SCREENING EXPERIMENT*

*Participants:* Clinicians and managers from provider and commissioner bodies targeted by national audit programmes. We will aim to recruit 500 participants from across the UK. We plan to work with

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the four national audit programmes which are co-applicants or collaborators on this proposal: the National Comparative Audit of Blood Transfusions; the Paediatric Intensive Care Audit Network (PICANet); the Myocardial Ischaemia National Audit Project (MINAP); and the Trauma Audit & Research Network (TARN). These four NCAs will ensure sufficient diversity in audit methods, topics and targeted audiences, thereby increasing confidence that our outputs will be relevant to the wider range of NCAs. Our assessment of 23 NCA reports in 2015 indicated significant variation amongst NCAs in the delivery of feedback (e.g. specification of target audience, linkage of findings to recommendations for action). However, we will hold further discussions with HQIP and other interested national audit programmes to identify any others which (i) wish to participate in this experiment, (ii) can construct feedback modifications based on recently collected audit data, and (iii) have identified networks of feedback recipients who could potentially take part in the experiment.

*Recruitment and consent.* We intend to identify and recruit participants via their respective national audits and specialist societies. Three of the audits (NCA Blood Transfusions, PICANet and TARN) already conduct surveys with participating audit sites or have specialist societies than can do so whilst MINAP possesses contact details for its sites. Audit reports are also distributed to relevant commissioning bodies, e.g. specialist commissioners in the case of PICANet.

We will send email invitations via existing national audit channels and email lists (so that that the national audits contact participants rather than ourselves). Reminder emails will be sent out one and two weeks following the first email. We will include participant information and offer online vouchers and Continuing Professional Development certification for those who participate.

The invitation email to participants will contain a link to the online survey. Once the potential participant accesses the portal the on line consent information must be checked before the participant is able to access the survey. We will explain that participants are free to withdraw without needing to provide any explanation at any time during the survey. We will explain that participants will not be able to withdraw their data once their survey responses have been submitted.

*Randomisation:* Individual-level, stratified block randomisation with randomly varying block sizes performed centrally by trials unit using an automated system. We will stratify by audit and recipient type (e.g. clinician, commissioning).

*Intervention delivery:* Participants will work through one combination of six online modifications, each a separate factor with two levels (presence/absence). We will choose a fraction of the full 2<sup>6</sup> factorial (=64 packages of modifications), ideally a quarter (=16 packages) but a half (=32 packages) if this would confound important effects when the modifications are known. The particular fraction of packages will be chosen to minimise complexity of the experiment and to avoid any packages that are felt to be infeasible or undesirable. Our design will be as close to orthogonal as possible to minimise the sample size required to detect the main effect of each modification. We will undertake feasibility testing with a sample of targeted participants and a prototype online survey to assess participant burden (perceived difficulty, time taken and completion) and reduce the number of modifications if necessary. Our experience of examining the receipt of feedback across different settings is that many recipients have or allocate only limited time to rapidly assess reports and decide whether or not to act. Similarly, for the online experiment, we anticipate that participants will aim to complete their responses within limited time (e.g. around 30 minutes); we will therefore effectively simulate the types of deeper, reflective and more superficial, reactive thinking processes that typically occur on receipt of feedback in service settings [39, 40].

Participants will be given access to a password-protected web portal. Participants will work through their assigned combination of modifications and complete an online questionnaire to assess outcomes. We will advise participants that they will be responding to hypothetical but realistic scenarios based upon recent or contemporary audit data.

As well as the above vouchers and CPD certificates incentives, participants will also be able to view some 'evidence-based tips' on how to improve their own audit and feedback practice at the end of the online survey.

*Outcomes:* Our primary outcome is intended enactment, i.e. plans to change behaviour. We will devise a range of graded potential responses which will range from general and non-committal (e.g. 'consider reviewing and changing our practice') through to specific commitments (e.g. 'present at next team meeting and ensure we have agreed procedures for doing X'). The primary outcome approximates to behavioural intention and, as such, we will develop and pilot the outcome first using procedures set out in our manual 'Constructing Questionnaires based on the Theory of Planned

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Behaviour' [41]. Measurement of intention involves a bespoke approach as questionnaire items have to refer to the specific behaviour under investigation.

Our systematic review of the literature on intention-behaviour relations demonstrated "a predictable relationship between the intentions of a health professional and their subsequent behaviour" [42]. We know that (i) there is almost no intention-behaviour gap when intention is low, (ii) there will be an intention-behaviour gap when perceived control over the behaviour is low, and (iii) there is an intention-behaviour gap when intention to do the 'right' thing is high (only 50% of those who intend will actually act) but we believe that our measurement strategies to reduce skewness will increase that percentage. We will consider: (i) ensuring that wording of responses to reflect high intentions (e.g. 'I will make it my top priority to do X'); reducing social desirability bias associated with low intentions (e.g. 'I will use my clinical judgment in deciding whether to do X.');

and raising the cut-off point on the response scale that identifies intenders. Secondary outcomes include comprehension (understanding of feedback data), user experience (ease of use) and preferences. Whilst these outcomes have a limited ability to predict subsequent behaviour [43], they are critical to understand in intervention development and early evaluation [29]. We also anticipate a degree of social desirability bias in responses. The randomised design will ensure that these are balanced across intervention and control conditions. However, we will aim to minimise any unintended 'loading' of potential responses, e.g. by devising general and non-committal responses which appear as socially acceptable as the specific commitments when measuring intended enactment.

We will also collect online data analytics to assess length of time spent working through each modification and the degree to which participants engage with selected modifications (e.g. working through all levels of feedback presented for a 'graded entry' modification).

*Data collection:* Online questionnaire completed after exposure to feedback modifications; web analytics. We will record data on the denominators for each audit and collect data on respondent characteristics (professional roles, seniority and geographical region) to inform judgments about generalisability.

The online survey will be hosted by City, University of London. We intend to use XXX software.

*Data management.* We will require participants to enter their names and email addresses to ensure that CPD certificates and online vouchers can be sent following survey completion. These data will be held separately from other survey response data. We do not plan to use these data for any other purpose in the research.

All data will be stored electronically on the secure 'S' drive of the University of Leeds to comply with Data Protection legislation and University of Leeds guidelines. Participants will be able to see what information is held about them by writing to the principal investigator (RF). The data will be stored 10 years after project completion. This will potentially allow other researchers or students to use our data. However, given the evolving context of healthcare and audit and feedback methods, we expect the data to be generally redundant after 10 years.

*Sample size:* As such, the experiment will be powered to detect main effects of small to moderate size (i.e. 0.3 SDs) for each modification, with the intention that the optimum package would result in a moderate or large effect (i.e. 0.5 SDs plus) compared to standard practice. Assuming no interaction between the effect of each modification and the audit or trust, a total of 500 participants would give 90% power to detect each important main effect using a 2-sided 5% significance test. No allowance is needed for loss to follow-up as data is collected at one time-point. This would provide about 80% power to detect main effects of 0.25 SDs and 70% to detect main effects of 0.22 SDs.

An eventual sample size of 500 respondents is achievable if we work with four national audits. Three of the national audits (NCA Blood Transfusions, MINAP and TARN) each cover 154 acute NHS Trusts in England alone, as well as other hospital sites in the devolved nations. We will aim to recruit at least one participant per site for each audit. PICAnet presently covers 34 specialist-commissioned sites and can provide multiple respondents per site.

*Analysis:* A linear regression will be fitted for each continuous outcome adjusting for design factors and including main effects and two-way interaction effects for modifications. Analysis will be carried out once on an intention to treat basis and point estimates and 95% confidence intervals will be reported. Sensitivity analyses will be reported including higher order interactions and simplifying the model to include only treatment effects that are statistically significant at up to a 10% level.

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*Outputs:* We will have a statistical model that can be used to predict the effects of a large number of single and combined modifications. This work will allow us to make evidence informed decisions about key recommended modifications tailored to different targeted people within organisations before bringing them into the field (e.g. What comparator is most likely to encourage stated enactment? Are individual-level or unit-level data more persuasive?) By virtue of having been evaluated across up to four audit programmes, we also anticipate that these feedback modifications can be adopted or adapted by a range of national audit programmes.

## 5.2 OBJECTIVE 2. To evaluate how health care organisations respond to modifications of feedback from national audit programmes

*Design:* Case study of four localities, each involving a paired commissioner and provider, receiving modified national audit feedback. Given that the study involves experimentation, our approach is also informed by guidance on process evaluations of complex interventions [44].

*Sampling:* Sampling will be both purposive and pragmatic. We will purposively sample four localities, a paired commissioner and provider in each one. They will be sampled to maximise diversity, on the basis of previously documented high and low performance in relation to audit criteria. We selected performance as a sampling criterion because feedback may be more effective when baseline performance is low [11]. We will also aim to maximise the diversity of audit programmes.

We will work with two national audit programmes with contrasting approaches to feedback. For example, the National Comparative Audit of Blood Transfusions designs and conducts audits for different clinical topics on a cyclical basis (e.g. Patient Blood Management in major surgery in 2015 and use of blood products in patients with haematological malignancies in 2016) whereas other audits, such as PICANet or TARN employ, continuous monitoring and feedback. In this way, we will seek to maximise the diversity of sites and audit programmes studied (see Table below).

The selection of the two national audits will also be pragmatic. It will be guided by feasibility and their characteristics, e.g. alignment of timing for feedback aligning with the timescales for this Objective. On the basis of our own previous experience we expect to align timelines for two national audits.

*Table. Sampling framework for Objective 2.*

	Sites	
Audits	<b>Higher performing</b> pair of provider and commissioner & feedback modifications from <b>national audit 1</b>	<b>Lower performing</b> pair of provider and commissioner & feedback modifications from <b>national audit 1</b>
	<b>Higher performing</b> pair of provider and commissioner & feedback modifications from <b>national audit 2</b>	<b>Lower performing</b> pair of provider and commissioner & feedback modifications from <b>national audit 2</b>

Our decision to adopt a 2X2 design is based on necessary trade-offs between technical and practical considerations. Thus technical considerations suggest that there should be more rather than fewer localities, with single-locality studies to be avoided if at all possible. But, each additional locality adds to the costs of a study, incurred in negotiating access, data collection and analysis. Similarly, for a given sum of money, minimising the number of localities maximises the depth of findings. Maximising the number of localities, on the other hand, favours breadth over depth. Our choice of four localities rests in part on our 2X2 design and in part on our view that earlier studies of three localities would have benefitted from a fourth (e.g. HS&DR 09/1002/02).

*Development of logic model:* We will build a logic model to represent the pathways by which feedback can bring about changes in professional and organisational behaviour and which takes account of key contextual factors. We will base the model upon one currently being developed by BB and which is based upon an on-going meta-synthesis of findings from qualitative studies of audit and feedback interventions (Figure, next page) [45]. This model builds on existing theories and frameworks relevant

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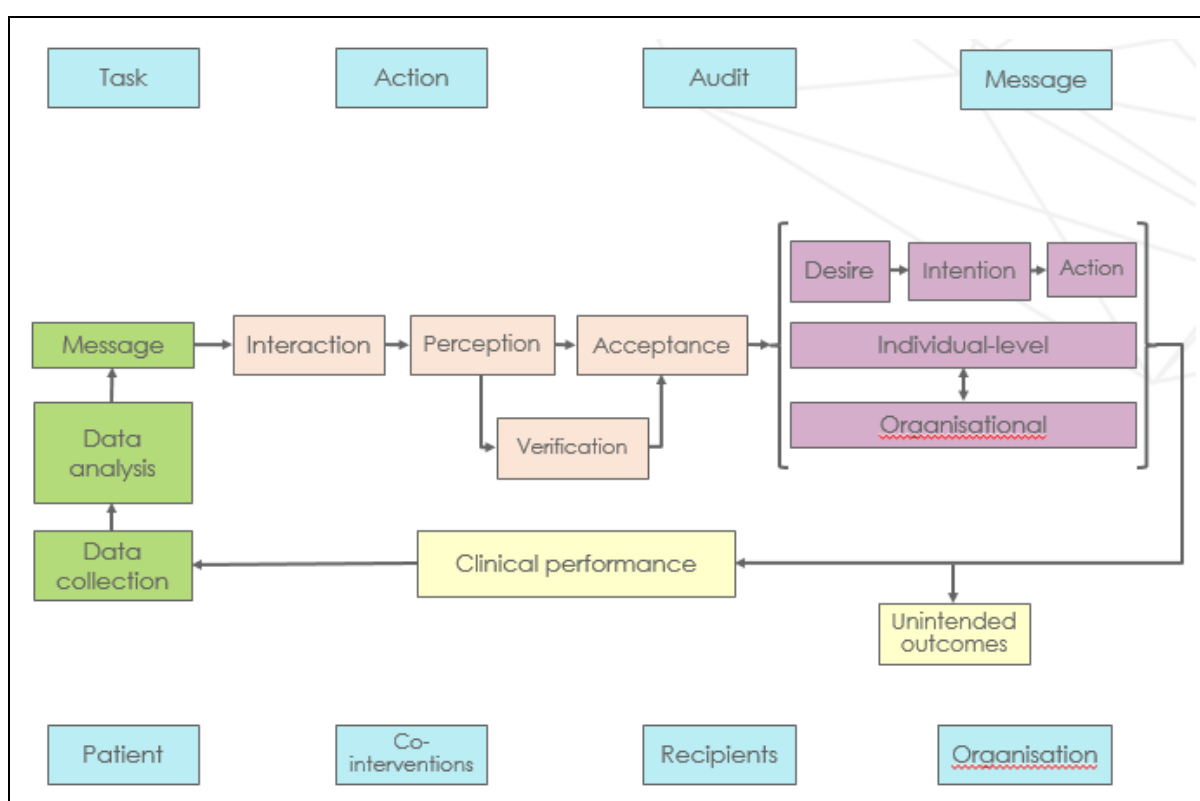
to A&F related to feedback recipients (e.g. [46, 47]), intervention description (e.g. [48, 49]), and organisational implementation (e.g. [50, 51]). It posits that effective A&F is a cyclical process consisting of: goal setting and audit, feedback message production, perception and acceptance of feedback message, recipient desire and intention to respond, action (at both individual and organisational levels), and ultimately care quality improvement. It suggests the success of this process is determined by a number of moderating variables (e.g. characteristics of the feedback message or organisation), and that mediating variables explain how these moderating variables exert their effects (e.g. compatibility of the feedback topic or relative advantage of the feedback message).

We will review and revise this model drawing upon:

- The collective inter-disciplinary perspectives and experiences of our study team – which include psychology, organisational change, audit design and delivery, and primary and secondary care.
- Empirical and theory-informed work designing feedback for current NIHR programme grants (RP-PG-1209-10040; RP-PG-1210-12010) [30, 46, 52]. The AFFINITIE interventions emphasize the importance of comprehensively addressing the feedback cycle whilst recognising that people have multiple, sometimes competing, goals, and that feedback can be aligned or misaligned with other resources, activities and policies across different levels in the healthcare system (i.e. individual, team, organisational, wider system) [53].
- Emerging outputs from Objective 1 predicting the effects of a range of single and combined feedback modifications.

The resulting updated model will guide data collection and analysis for this Objective (rather than make precise predictions about processes and outcomes), and will subsequently be refined following our empirical work.

*Figure. Draft logic model representing pathways by which feedback can bring about changes in professional and organisational behaviour [45].*



**Interventions:** Feedback modifications produced in Objective 1 and further organisational-level modifications less amenable to online experimentation. We will define the various components of planned feedback for each national audit, describing both general aspects of design and delivery and the specific feedback modifications being evaluated. We will draw upon our logic model to describe the wider known contextual features of each audit programme and understand where the specific feedback modifications under evaluation fit in.

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We appreciate that changes in embedded practices develop over long periods, but judge that an observational period of six months will allow us to observe changes in practices.

*Institutional perspective:* Sociological and institutional studies offer key insights here. Logic models, and other modelling approaches in the systems tradition, do not generally attempt to represent the ways in which local cultures (values and norms) influence causal or explanatory relationships. In this study we will address this point by studying the differences between work-as-imagined (reflected in our logic models) and work-as-done in practice in the four localities. A current HS&DR study by one of us (JK) is exploring this distinction in a related topic area, the use of (summary performance information in) dashboards [54].

*Data collection:* Data collection will be designed to follow the trail from the receipt of feedback data through to any actions taken to improve clinical care over a 6 month period. We will observe meetings and obtain relevant documents from the four organisations, e.g. observe clinical team meetings where audit data are discussed, obtain Trust board papers with agenda items on our national audits. In the four Trusts we will interview clinicians (training and consultant grades), directorate managers and board members (medical director and chief nursing officer), towards the end of the period (8 interviews per Trust, 32 in total). We will also interview lead commissioners towards the end of the period (1 per commissioner per audit, 4 in total).

*Analysis:* The analysis will exploit the diversity sampling, comparing and contrasting findings across localities and audits. We will use framework analysis for the meeting and documentary material to identify relevant themes, and then use these themes to inform a thematic analysis of the interview data. The analysis will focus on understanding how and why the intended effects are achieved, or why they are not. We will assess how feedback is aligned or misaligned with other activities and policies across different levels in each locality, for each audit [10].

*Outputs:* We will refine and annotate our logic model and define a set of 'best bet' modifications for national audits which can (i) be immediately adopted or adapted by national audit programmes to enhance their impacts and (ii) form the basis for more efficient, rigorous evaluations of cost-effectiveness. We will also produce a narrative account of the institutional perspective. Our Dissemination plan below further describes plans for an associated training manual and related support materials.

### 5.3 OBJECTIVE 3. To explore the opportunities, costs and benefits of UK national audit programme participation in a long-term international collaborative to improve audits through a programme of trials

*Design:* Semi-structured interview study.

*Participants:* We will purposively sample 30 staff: 10 from national audits, 10 healthcare professionals and 10 researchers with varying experience of participation in research evaluating A&F. Given that we wish to generate lessons relevant to an international audience, we will include interviewees from outside of the UK who have taken part in meetings to establish an international network for A&F research. The final number will be guided by evidence of data saturation [55].

*Recruitment:* We will approach potential interviewees via email, attaching an information sheet and consent form. We will ask those who wish to participate to sign the consent form and keep a copy for their own records before sending it back to us prior to interview. We will accept either an electronic or 'wet' signature as well as return of consent forms by email or post.

Before proceeding with any formal approaches to potential overseas interviewees, we will check with senior health services researchers in each country as to whether our procedures are likely to be relevant and acceptable. We anticipate mainly interviewing people from Canada, USA, Netherlands and Australia as the types of research and service improvement we are interested in predominantly go on in these countries (as well as the UK).

*Development of interview schedule:* We have provisionally identified a number of issues which influence the participation of national audit programmes in our current AFFINITE programme. These include negotiating an understanding of equipoise in experimenting with enhanced feedback interventions, aligning timelines and human resources, working out the level and type of support needed to build sustainable enhancements into national audit programmes, and ensuring secure data sharing arrangements are in place for researchers to analyse audit data. However, there are likely to

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be similar and further lessons generated from evaluations of major initiatives involving research-practice partnerships, such as NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) and the former Veteran's Administration Quality Enhancement Research Initiative (VA-QUERI) [56-59]. We will therefore identify issues from both AFFINITIE and published related research on research-practice partnerships to generate a list of (i) likely costs and benefits of audit and feedback implementation laboratories and (ii) relevant barriers to and enablers of their establishment and maintenance. We will discuss and refine this list with our Reference Group (from Objective 1) and develop a framework setting out conditions, actions and outputs hypothesized to enable successful audit and feedback implementation laboratories.

*Data collection:* All interviews will be audio-recorded and transcribed. We will send participants copies of their interview transcripts for checking and corrections. They will be encouraged to change any responses either in the interests of accuracy or if they wish to provide additional information. After approving or returning their transcripts, we will allow a period of up to two weeks during which they can withdraw. We require this cut-off period because data analysis may have started and may be continuous during the course of the interviews.

*Data analysis:* The above framework will underpin a semi-structured interview schedule. We will conduct interviews face-to-face or by telephone as required. All interviews will be audio-recorded prior to framework analysis.

*Outputs:* We will identify optimal conditions for sustainable collaboration between national audit programmes and researchers as well as the opportunities, costs and benefits of national audit programme participation in future collaborative research to improve the effects of feedback.



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## 6 Dissemination and projected outputs

**Plans for disseminating the findings of this research.** We will continue developing the collaboration between our research group and HQIP, the commissioner responsible for development and contract management of national clinical audits. Through this collaboration and conducting our proposed research, we will understand the strategic and operational considerations involved in supporting and guiding national audit programmes. This will therefore ensure that our outputs are relevant to our partners' needs and can be embedded within organisational policies and practice. We have worked with Danny Keenan (Medical Director) and Kirsten Windfuhr (Associate Director for Quality and Improvement) in developing this proposal.

Whilst still considering commissioning, we have an established partnership with the 10 clinical commissioning groups (CCGs) in West Yorkshire, building on one current NIHR Programme Grant for Applied Research and three recent Research for Patient Benefit projects. We will continue to work closely with our commissioning groups via their Research Manager and have discussed shared priorities relating to their Sustainability and Transformation Plans. Our 10 CCGs share priorities and challenges typical to others elsewhere. Our partnership with them offers a test-bed for shaping policy and clinical recommendations for wider dissemination nationally.

Our co-investigators include those involved in three national comparative audit programmes: Stanworth (NHS Blood & Transplant); Parslow (PICANet); and Gale (MINAP). Fiona Lecky and Maralyn Woodford (TARN) have also expressed a strong interest to collaborate. We work with HQIP and our national audit collaborators to build the Reference Group for our research and to ensure a two-way channel for communicating and discussing emerging research findings.

We are part of an international network which seeks to improve the evidence base for and use of audit and feedback, first proposed at a meeting funded by the Canadian Institutes of Health Research (CIHR) in Ottawa, 2012. Network members include researchers and knowledge users from Canada, UK, Australia, and the United States. We met again in April 2016 (Ottawa) and June 2017 (Leeds) to share emerging research findings, refine the research agenda and we established an international 'meta-laboratory' for audit and feedback research. This network provides a means to reduce 'research waste' [60] in this field and build a cumulative science of audit and feedback.

In addition to holding national and international stakeholder meetings, we will describe and report our findings through peer-reviewed journals, and national and international conferences.

**Expected Output of Research/Impact.** Our collective experience thus far of developing, conducting and evaluating feedback interventions across different audit programmes spanning primary and secondary care is that there are considerable variations in how feedback is delivered, shared and acted upon, even for one type of audit within one setting. We will therefore address the challenge to identify a range of core feedback modifications adaptable to different audit programmes and contingencies.

As suggested by initial feedback from the HS&DR Programme, after 18 months we will share interim findings from Objective 1 (evaluated modifications designed to enhance the impact of feedback) with our national audit partners and other national audit programmes via HQIP. Following Objective 2, we will then build upon previous guidance by HQIP and existing research by developing a 'user manual' and bank of resources to support national audit programmes. The manual will offer clear guidance on practical steps required to enhance the content, format and delivery of feedback. It will include sections or messages tailored to various types of user, i.e. national audit programme staff, providers and commissioners. We will explore the feasibility of including messages for patient groups with our PPI Panel.

Objectives 1&2 will also be able to identify feedback modifications which require further evaluation in later randomised trials.

Objectives 3 will inform a set of 'ground rules' and recommendations on how to optimise conditions for sustainable collaboration between national audit programmes and researchers.

We are keen to track the impact of our work. In pilot work (mentioned above), we applied a set of evidence-based and good practice criteria to the most recent national audit reports for 23 programmes listed on the HQIP website in 2015. Preliminary results indicate consistent strengths of audit reports (e.g. repeated feedback, presentation of data in mixed formats) and areas for improvement (e.g. specification of target audience, linkage of findings to recommendations for action). We will refine this as a method to undertake an annual 'audit of audits' and thereby track

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improvements over time which are potentially attributable to application of our proposed work here and the wider evidence base.

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## 7 Plan of investigation and timetable

### 7.1 Monthly project timetable, allowing for ethics and governance approvals

	Set up	M1-3	M4-6	M7-9	M10-12	M13-15	M16-18	M19-21	M22-24	M25-27	M28-30
Staff recruitment											
<b>Objective 1: development and evaluation of modifications</b>											
Ethical approval											
Priority setting by Reference Group											
Identification of audits and relevant participants for experiment											
User centred design of content for online screening experiment											
Recruitment and administration of online screening experiment											
Analysis											
Writing up and sharing of interim outputs with national audit partners											
<b>Objective 2: comparative case study</b>											
Ethical and governance approvals											
Identification and recruitment of sites											
Logic model development											
Further development and preparation of feedback modifications											
Implementation of modifications											
Data collection and analysis											
Writing up for publication											
<b>Objective 3: opportunities, costs and benefits</b>											
Ethical approval											
Development of interview schedule											
Recruitment of participants											
Interview conduct and analysis											
Writing up for publication											
<b>Preparation of guidance and materials for final dissemination</b>											
<b>Meetings</b>											
Programme Steering Group											
Patient and Public Involvement Panel											

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## 8 Project management

The Principal Investigator (RF) will be overall strategic lead. A senior research fellow will be responsible for day-to-day programme running and contribute to each Objective. Both and the wider programme will be supported by a secretary, who will also have a role in ensuring regular communications within the team and wider collaborators.

The Project Management Team will include members of the core scientific team (RF, JF, RAW, AF, SH & JK), the national audit partners (RP, SS & GC) and the training posts (NG, FL, SA & BB). The Project Management Team will meet every two months face-to-face or by teleconference (which we already do regularly and successfully in AFFINITIE). The Canadian-based co-applicants (NI, HC, JB, JG & JP) will join the Project Management Team meetings every six months, usually by teleconference but also come over for two face-to-face meetings. It is worth noting that members of the UK and Canadian research teams already visit one another regularly for related ongoing collaborations.

There will be parallel coordinating meetings for each Objective, chaired by RF or the senior research fellow. The teams responsible for the delivery of each Objective will comprise:

*Objective 1 (fractional factorial screening experiment):* JF, NG, FL & BB contributing to the development of feedback modifications and guiding the work of the behaviour scientist research fellow (based at City University); RAW, SH & AF contributing to the design and conduct of the online experiment; and RP, SS & CG advising on compatibility with national audit content and processes, and supporting recruitment for the online experiment. Programming of the online experiment will be conducted by a computer science academic and associated research fellow (also based at City University, London).

*Objective 2 (case study):* JK & JF providing methodological input and guiding adaptation of the logic model along with BB; the senior research fellow and research fellow (City University) collecting data from observed sites; all Objective 2 team members contributing to data analysis and interpretation.

*Objective 3 (interview study):* SA and the senior research fellow devising the interview sample, developing the interview schedule, and conducting interviews; and other Project Team members (especially RF) contributing to data analysis and interpretation.

This account describes key delegated responsibilities. We expect ongoing contributions to all aspects of the programme, especially from the Canadian co-applicants via electronic and telephone communications as needed for key tasks within each Objective. We will particularly seek their contributions around operationalising the 15 recommendations for effective feedback and developing the outcome measures for the online experiment (Objective 1), further development of the logic model (Objective 2), and ensuring international relevance of the interview study (Objective 3). We will time the two face-to-face meetings to facilitate in-depth discussions of these key issues.

We will convene a Project Steering Group which will meet five times over the course of the programme to ensure the quality of ongoing work, maintain our focus on healthcare and commissioning needs, monitor progress against Objectives, and guide planned dissemination. This Group will comprise a senior independent academic and representatives from commissioners, HQIP, a national audit programme and our PPI Panel.

## 9 Approval by ethics committees

We will not require NHS ethical approval for Objective 1 because we will be surveying and interviewing health professionals only and recruitment will occur outside of NHS bodies (e.g. via national audit networks and contacts for the Objective 1 online experiment). Consequently, we will apply to the Faculty of Medicine and Health Research Ethics Committee at the University of Leeds three months before the project start date.

We will require Health Research Authority (HRA) approval prior to Objectives 2 and 3; although we will mainly be observing and interviewing health professionals, we will be recruiting via NHS bodies and the feedback modifications may have implications for clinical care provided. We are unable to apply for HRA approval before the project starts and we have sufficient information about the feedback interventions and proposed study sites. We will therefore apply for HRA approval during months 6-12.

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## 10 Patient and public involvement

*Our PPI Panel and how they have influenced this proposal.* We discussed this proposal with an existing PPI panel, originally convened for an NIHR programme involving audit and feedback, Action to Support Practices Implementing Research Evidence (ASPIRE; RP-PG-1209-10040). We have been working with this panel for four years. It comprises nine people from diverse backgrounds and considerable collective experience in national audits, commissioning, trust governance, patient advocacy and community development. Kirsty Samuel, was the lay panel assessor in the national CEMACH Enquiry, *Diabetes in Pregnancy; are we providing the best care?* Graham Prestwich is a member of Leeds North CCG and Laurence Wood was a member of Leeds West CCG. Martin Rathfelder is an elected Governor of Central Manchester NHSFT. Farhat Yaqoob, Pauline Bland, Sue Hodgson and Gus Ibegbuna have experience in community development and/or patient advocacy.

The Panel strongly supports embedding research within routine healthcare and ensuring that audits address outcomes that matter to patients. For example, the Panel has played a role in advocating and encouraging general practice participation in quality improvement research as a routine. (Indeed, they expressed surprise that some organisations and professionals might wish to opt out of data sharing for such research.) Our earlier discussions with PPI Panel members for this proposed programme suggest a similar set of expectations around healthcare organisations and professionals routinely taking part in national audits (and research into improving national audits) to ensure accountability and improve the quality of care.

The Panel helped us refine the plain English summary of this proposal. It encouraged us to think about impacts of whole systems on organisational performance, constraints on professional practice, and ways of involving patients in audit. Within Objective 1, we will explore the feasibility of embedding the patient voice within feedback modifications.

All four national audit programmes collaborating with us have lay or public representatives on steering groups. We have invited representation of lay members of advisory boards or patient groups from collaborating audits. Roy Dudley-Southern is a retired NHS Strategic Planner and Specialised Commissioner who, amongst other voluntary roles, sits on the Trauma Audit and Research Network Board. He advised us that commissioner responses to national audits vary considerably and depend upon responses from individual commissioners with diverse portfolios. We intend to include commissioner responses to feedback in Objectives 1&2. He also highlighted a concern that audit criteria may fail to reflect outcomes which are important to patients and/or are evidence-based. Within our AFFINITIE programme, one of our feedback interventions aims to focus recipient attention on clinically important audit criteria; we will examine this again in Objective 1.

Our ASPIRE Panel wishes to continue working with us if this proposal is funded, accepting the value of continually refreshing Panel membership and expanding membership to include PPI or lay members from our partner national audit programmes.

*Aims of the PPI Panel and how they will be involved.* In **general terms**, our Panel will benefit the research by promoting:

- Accountability – ensuring that we work in the public interest and make proper use of resources;
- Appropriateness - ensuring that our work focuses on patient and population benefit;
- Advocacy – for making research a routine part of healthcare planning and delivery;
- Alerting networks to findings - participation in dissemination activities.

We have recently started a formal consensus process with our ASPIRE Panel to work through how PPI can enhance implementation research, where interventions often primarily target organisations and professionals rather than patients. Outputs of this panel will also influence our overall approach.

In **specific terms**, our Panel will contribute by:

- Highlighting public and patient support for research to professionals and organisations considering participation, potentially including the participation of national audit programmes in audit and feedback implementation laboratories
- Participating in the consensus to prioritise feedback modifications for further evaluation
- Exploring the feasibility of embedding the patient voice within feedback modifications
- Commenting and advising on the relevance of audit criteria to patients
- Identifying dissemination opportunities via PPI and commissioning channels. As our programme will aim to generate findings and lessons applicable beyond any one particular audit, we will work

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with our Panel throughout the programme to consider the types of generalizable messages we can generate.

- Exploring the feasibility of including messages for patient groups in our national audit ‘user manual.’
- Holding us accountable by reviewing and commenting on our progress. The Panel will meet five times over the course of the programme and contribute to the membership of the Steering Group.

## 11 Relevant expertise and roles

Our team spans expertise in implementation research, behavioural sciences, trial and statistical methodology, organisation of healthcare, and national audit design and delivery. We (NI&JG) published the Cochrane Review of audit and feedback and have applied for CIHR funding to undertake a substantial update. We have conducted pragmatic A&F trials as well as novel intervention modelling experiments of implementation strategies [61-63]. We (JG, NI, JB, HC, JP, RF, JF, NG, FL & JK) have collectively developed a substantial body of empirical and theoretical work on A&F as well as practical suggestions for improvement [11, 12, 18, 27, 30, 48, 64, 65]

We (RF, JF, SS, AF, RW, NG, FL, SH & JG) currently lead the NIHR-funded AFFINITIE programme. We developed and are evaluating two theoretically and empirically informed feedback modifications (enhanced content and enhanced practical ‘follow-on’ support following delivery of feedback) in two UK factorial cluster randomised trials, with accompanying process and economic evaluations [30].

This project brings together a large team, comprising:

*A core scientific team* will be responsible for driving the methodology and delivery of the programme. This comprises: Foy (implementation research; lead); Francis (behaviour change; theory-informed process evaluations); Walwyn (statistics; methodology); Farrin (trials; complex interventions); Hartley (trials management); and Keen (governance in health care).

*Our national audit partners* will be involved in the development of feedback modifications and facilitate involvement of national audits, including recruitment for Objectives 1&2: Stanworth (NHS Blood & Transplant); Parslow (PICANet); and Gale (MINAP).

*Our international collaborators* include leading researchers on professional behaviour change, audit and feedback, and evaluation: Grimshaw, Brehaut, Presseau, Ivers and Colquhoun. They will therefore specifically advise on the development and evaluation of our feedback interventions and help ensure that our work contributes to a cumulative science of audit and feedback. This project will also help build the foundations of a wider international collaboration and ‘meta-laboratory’ being led by our Canadian partners.

*Our training roles* recognise that there is a growing demand for implementation research but limited capacity. We also have a duty to support the development of promising, earlier career academic staff. Co-investigator status would fairly recognise their ongoing and future contributions to the programme. We suggest that they further offer excellent value for money. Two are already funded: Brown (Wellcome Trust Research Training Fellowship) and Alderson (NIHR Academic Clinical Lectureship). We seek modest funding to support inputs from Gould and Lorencatto (currently AFFINITIE Research Fellows). All four are presently leading or developing portfolios of research related to audit and feedback interventions.

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