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

Submission date
02/08/2017

Recruitment status
No longer recruiting

Registration date
17/08/2017

Overall study status
Completed

Last Edited
17/09/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Audit and feedback aims to improve patient care by comparing how healthcare is delivered against set standards. It is widely used by the NHS to work out how well they treat patients. NHS staff and organisations should remedy shortfalls found by audits. However, audits don't improve patient care as much as they should because organisations don’t always act on audit findings (i.e. feedback). The aim of this study is to identify better ways of giving feedback to improve the impact of audits on patient care. This will help to develop training and practical support for organisations to adopt these modifications when providing feedback.

Who can participate?
Clinicians and managers from provider and commissioner bodies targeted by national audit programmes

What does the study involve?
Participants are randomly allocated to look through different ways of presenting feedback. The feedback is hypothetical but based upon recent and real audit data. Reactions to feedback are then assessed by questions. This takes about 30 minutes. After submitting their responses, participants are able to see evidence-based tips on how to make feedback more effective which may be useful in their work.

What are the possible benefits and risks of participating?
No direct benefits to individual participants are expected although educational messages are embedded in the web content. No direct risks of participation are expected, other than time and inconvenience.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2017 to March 2020

Who is funding the study?
Health Services and Delivery Research Programme (UK)

Who is the main contact?
Prof. Robbie Foy

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TBC

Study information

Scientific Title
Optimising the outputs of National Clinical Audits to support organisations to improve the quality of care and clinical outcomes

Study objectives
This study is part of a programme with the overall aim of improving patient care by optimising the content, format and delivery of feedback from national clinical audits.

The specific research questions for this study are:
1. 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?
2. 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?

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Leeds, School of Medicine Ethics Committee (SoMREC), 03/08/2017, ref: MREC16-180

Study design
Fractional factorial screening experiment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
National Clinical Audits

Interventions
The intervention will be modifications to feedback which can be readily adopted by national audit programmes. A structured consensus process will guide selection of modifications for further development and specify strategies for tailoring these to the needs of specific stakeholder groups.

Participants will be randomised (stratified by audit and recipient type) to one combination of six online modifications, each a separate factor with two levels (presence/absence). A fraction of the full 26 factorial (=64 packages of modifications) will be chosen, 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. The design will be as close to orthogonal as possible to minimise the sample size required to detect the main effect of each modification.

Feasibility testing will be undertaken 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.

The trialists' 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, it is anticipated that participants will aim to complete their responses within limited time (e.g. around 30 minutes); the study 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.

Intervention Type
Behavioural

Primary outcome measure
Intended enactment, i.e. plans to change behaviour, on a range of graded potential responses from general and non-committal through to specific commitments. Data collected via online questionnaires completed after exposure to feedback modifications

Secondary outcome measures
1. Comprehension (understanding of feedback data)
2. User experience (ease of use)
3. Preferences
Data collected via an online questionnaire completed after exposure to feedback modifications

4. Length of time spent working through each modification
5. Participants' engagement with selected modifications (e.g. working through all levels of feedback presented for a ‘graded entry’ modification)
Collected using online data analytics during the intervention

Overall study start date
01/10/2017

Completion date
30/03/2020

Eligibility

Key inclusion criteria
Clinicians and managers from provider and commissioner bodies targeted by national audit programmes

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
500 participants from across the UK

Total final enrolment
638

Key exclusion criteria
Clinicians and managers not linked to a targeted national audit programme

Date of first enrolment
10/04/2019

Date of final enrolment
18/10/2019

Locations

Countries of recruitment
United Kingdom

Study participating centre
National Audit Programmes
United Kingdom
-

Sponsor information

Organisation
University of Leeds

Sponsor details
Medicine and Health Faculty Office
Worsley Building
Leeds
England
United Kingdom
LS2 9JT

Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists will continue developing the collaboration between their research group and the Healthcare Quality Improvement Partnership (HQIP), the commissioner responsible for development and contract management of national clinical audits. Through this collaboration and conducting the proposed research, they will understand the strategic and operational considerations involved in supporting and guiding national audit programmes.

The trialists are part of an international network which seeks to improve the evidence base for and use of audit and feedback and will continue to use this network to build a cumulative science of audit and feedback. Network members include researchers and knowledge users from Canada, UK, Australia, and the United States.

The trialists will also hold national and international stakeholder meetings, and describe and report their findings through peer-reviewed journals, and national and international conferences.

Intention to publish date
30/03/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results		01/07/2021	04/03/2022	No	No
Results article		26/05/2022	27/05/2022	Yes	No
Protocol file	version 1	11/08/2017	05/10/2022	No	No
Other publications	Detection and management of fraudulent participant responses	04/08/2023	04/08/2023	Yes	No
Results article		01/06/2022	17/09/2024	Yes	No