ISRCTN15490813 https://doi.org/10.1186/ISRCTN15490813

Two cluster randomised controlled trials to evaluate feedback in blood transfusion audits

Submission date
11/03/2015

Recruitment status
No longer recruiting

Registration date
11/03/2015

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Blood transfusion is a frequently used clinical treatment, but it's a costly and scarce resource. There are many cases where patients have been given blood transfusions when there has been no clinical need. Such transfusions are unnecessary and can put patients at risk of the wrong type of blood transfusion or infection. National audits of transfusion give information on compliance with standards and the number of unnecessary transfusions. "Audit and feedback" (A&F) seeks to improve patient care by reviewing health care performance against agreed standards. It allows changes to be made in areas where problems with patient care has been found. The aim of this study is to design and test an enhanced A&F intervention in order to promote uptake of evidence-based guidance and reduce the number of unnecessary blood transfusions.

Who can participate?
NHS trusts/health boards participating in the relevant national audit programme.

What does the study involve?
NHS trusts/health boards are randomly allocated to receive different ways of providing feedback following a clinical audit in two linked cluster trials. The data collected is then used as part of the NHS Blood and Transplant National Comparative Audit (NHSBT NCA) to evaluate the feedback. NHSBT NCA is a well-established quality improvement activity which compares current best practice with an agreed standard in blood transfusion practice.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
A number of NHS trusts in the UK

When is the study starting and how long is it expected to run for?
January 2014 to December 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Lauren Moreau

Contact information

Type(s)
Scientific

Contact name
Dr Lauren Moreau

Contact details
University of Leeds
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18531

Study information

Scientific Title
Two linked cluster randomised trials to evaluate feedback interventions embedded within a national audit of blood transfusion practice

Acronym
AFFINITIE

Study objectives
The development and evaluation of enhanced audit and feedback interventions to increase the uptake of evidence-based transfusion practice (AFFINITIE) is a NIHR Programme Grant for Applied Research which aims to develop and evaluate feedback interventions to promote the uptake of evidence-based transfusion guidance to reduce the unnecessary use of blood. In this research NHS trusts/health boards will be randomised to receive different ways of providing feedback following a clinical audit in two linked cluster trials. The data collected as part of the NHS Blood and Transplant National Comparative Audit (NHSBT NCA) will be used to evaluate the

feedback. NHSBT NCA is a well-established quality improvement activity which compares current best practice with an agreed standard in blood transfusion practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Leicester, 08/12/2014, ref: 14/EM/1295

Study design
Randomised; Interventional and Observational; Design type: Process of Care, Cross-sectional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Haematology; Subtopic: Blood (all Subtopics); Disease: Non-malignant haematology

Interventions
1. Enhanced Documents: Feedback with content written to deliver the relevant behaviour change techniques will be delivered as per usual practice by the NCA programme through written and graphic feedback presented in multiple feedback documents and presentations, once per audit topic. Feedback is provided electronically direct from the NCA to site, generally sent to the transfusion practitioner, audit staff, or junior doctor. Enactment at a site level varies and will be at a sites discretion.
2. Enhanced documents & f/o support: Feedback with content written to deliver the relevant behaviour change techniques will be delivered as per usual practice by the NCA programme through written and graphic feedback presented in multiple feedback documents and presentations, once per audit topic. Feedback is provided electronically direct from the NCA to site, generally sent to the transfusion practitioner, audit staff, or junior doctor.
3. Usual Documents: Feedback will be delivered as per normal practice by the NCA, once per audit topic. Feedback is provided electronically direct from the NCA to site, generally sent to the transfusion practitioner, audit staff, or junior doctor and is typically in the form of a written clinical audit report, a PowerPoint presentation and action plan templates. The content of the written report varies, depending on the audit. Enactment at a site level varies and will be as per standard practice.
4. Usual Feedback & f/o support: Feedback will be delivered as per normal practice by the NCA, once per audit topic. Feedback is provided electronically direct from the NCA to site, generally

sent to the transfusion practitioner, audit staff, or junior doctor and is typically in the form of a written clinical audit report, a PowerPoint presentation and action plan templates. The content of the written report varies, depending on the audit.

Intervention Type
Other

Primary outcome measure
The primary outcome for each audit topic, measured at the patient level and taken from the NCA follow-up audit, is whether a transfusion is categorised as unnecessary or not (binary).

A clinical algorithm is agreed by the NCA BT Audit Group (which is a multidisciplinary team including content experts) alongside reviews of guidelines and the literature prior to finalising each baseline audit tool. For each audit topic, a statistical algorithm will be developed by the CTRU statisticians and piloted and approved by the NCA BT Audit Group prior to the baseline audit. This will minimise the risk of detection bias. The final versions will be included in the Statistical Analysis Plan.

For the surgical audit, transfusion may occur pre-operatively, intra-operatively or post-operatively. There may also be multiple transfusion episodes after surgery but prior to discharge. As all patients will have had one or more transfusions over the entire operative period (14 days prior to surgery to 7 days following surgery), the primary outcome is whether any of these transfusions were unnecessary versus all transfusions being necessary (binary). The statistical algorithm given in the Statistical Analysis Plan will specify the statistical process needed to derive the primary outcome from the patient-level NCA audit. No clinical judgement will be required at a patient-level to categorise transfusions.

Secondary outcome measures
1. To generate data to serve as inputs for an investigation of the relative cost-effectiveness of the two feedback interventions compared to usual NCA feedback in each audit topic from a NHS perspective
2. To investigate whether the two feedback interventions reduce volume of blood products transfused (i) across specialities within NHS trusts and health boards and (ii) for patients treated in specialities targeted by transfusion topics, when compared to usual feedback, up to 12 months following the release of feedback by the NCA
3. To investigate whether two feedback interventions reduce the number of errors reported to SHOT, when compared to usual feedback, up to 12 months following release of feedback by the NCA
4. To explore whether there are differential predictors (or moderators) of the effects of the two feedback interventions when compared to usual feedback (i.e. subgroup effects)
5. To explore the mechanisms by which the two feedback interventions affect outcome (i.e. mediators of the treatment effect)
6. To explore whether the effect of the two enhanced feedback interventions when compared to usual feedback differs according to the transfusion topic

Overall study start date
01/04/2015

Completion date
18/09/2017

Eligibility

Key inclusion criteria
Trust/health board (cluster) inclusion criteria:
1. Participating in the relevant national audit programme
2. Receive NHS permissions
3. Male and female
4. Lower age limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 152; UK Sample Size: 152

Total final enrolment
152

Key exclusion criteria
Trust/health board (cluster) exclusion criteria:
1. Independent Hospitals (as clinicians involved in transfusion decisions at the NHS Trusts / Health Boards are also likely to practice at the independent Hospitals leading to potential contamination)
2. The four NHS Trusts that participated in the development of the intervention will still be invited to take part in the national audits but will not be randomised and will receive the enhanced feedback documents with post-feedback support. They will therefore not be included in the evaluation of the feedback of post feedback support. This is to prevent contamination whilst still allowing the site to be included in the NCA programme

Reasons for non-participation will be documented and reported in the final trial report. Note that, where at least one hospital site within a cluster is eligible, the cluster will be regarded as eligible. Where multiple hospital sites are eligible within a cluster, the NCA may treat them as separate but they will be regarded as a single cluster for the purposes of randomisation.

Date of first enrolment
01/04/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
Clinical Trials Research Unit (CTRU)
Woodhouse Lane
Leeds
United Kingdom
LS2 9JT

Sponsor information

Organisation
NHS Blood and Transplant (NHSBT)

Sponsor details
National R&D Office
500 North Bristol Park
Northway
Bristol
England
United Kingdom
BS34 7QH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination of the findings will be aimed at two main groups of stakeholders:
1. Specific feedback to health care professionals involved in transfusion practice, regionally, nationally and internationally.
2. General feedback to NHS staff involved in current audit and feedback (A&F) programmes, to ensure the lessons learnt from this programme of research can widely considered, for applicability in other health care settings The current regional structures of the Transfusion Liaison Teams for hospitals across England (slightly differently in devolved nations) support regional educational events in transfusion for all hospitals, at which discussion of national audits is one core function. These structures will provide an established means for dissemination of findings (alongside engagement in the research plans).

The findings will also be described and reported through peer-reviewed journals, in addition to national and international conferences (the trialists benefit from active engagement with Canadian collaborators).

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/12/2016		Yes	No
Protocol article	protocol	03/07/2017		Yes	No
Results article		01/02/2022	25/02/2022	Yes	No
Results article		01/03/2022	25/04/2023	Yes	No
HRA research summary			28/06/2023	No	No