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Scaling Up Quality Improvement for Surgical Teams

Submission date
15/02/2018

Recruitment status
No longer recruiting

Registration date
21/02/2018

Overall study status
Completed

Last Edited
14/03/2022

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
The Institute for Health Improvement (IHI) Breakthrough Series Collaborative model is a short-term learning system that brings together a large number of teams to seek improvement in a focused topic area and proven intervention. Collaboratives provide a suitable vehicle for delivery of a project at this scale, as they not only aim to maximise local engagement and leadership but are designed to build capacity, enable learning and prepare for sustainability. The key elements of participation in the Breakthrough Series Collaborative training and support for teams from Trusts are:
learning sessions, action periods, and summative congress. The aim of the trial is to assess the effectiveness and cost-effectiveness of the Breakthrough Series Collaborative (BSC) method for improving outcomes in patients undergoing elective total hip and knee replacement surgery.

Who can participate?
NHS Acute Trusts

What does the study involve?
Each participating NHS Trust is treated as a cluster, and are randomised 1:1 using minimisation by number of hip and knee replacement procedures performed and the traffic light indicators in the Learning From Mistakes league table. Trusts in both arms in the trial receive the intervention, i.e. training in the Breakthrough Series Collaborative. Trusts are randomised to receive either training on MSSA to control post-surgery infection (20 hospitals) or training on the anaemia optimisation programme (20 hospitals). None of the participating Trusts will have implemented either protocol prior to acceptance into the trial. Therefore, the control group for the anaemia optimisation quality improvement initiative are the other 20 hospitals who continue with their usual practice for anaemia and vice versa, the control group for MSSA are the other 20 hospitals who continue with their usual practice for MSSA screening. Trusts are given the opportunity to be trained in the quality improvement initiative they have not received after the evaluation period is over.

What are the possible benefits and risks of participating?
The potential benefit for participating Trusts is the prospect of improved care and costs. These are a reduction in anaemia related blood transfusions, critical care, length of hospital stay and

readmission rates leading to a potential saving of £160 per patient; and a reduction in surgical site MSSA related infections. Participating trusts are expected to save the NHS £6.3M per year, based on the experience at the Chief Investigator's own Trust. There are no perceived risks to Trusts or the teams from participating Trusts.

Where is the study run from?
This study is being run by Northumbria Healthcare NHS Foundation Trust (UK) and the sites will be added soon.

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

Who is funding the study?
1. NHS Improvement (UK)
2. Northumbria Acute Care Collaboration Vanguard (UK)
3. Vifor Pharma (Switzerland)
4. Schuelke

Who is the main contact?
Mrs Alison Booth (Scientific)
alison.booth@york.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Alison Booth

ORCID ID
http://orcid.org/0000-0001-7138-6295

Contact details
Department of Health Sciences
Lower Ground Floor, ARRC Building
Faculty of Science
University of York
Heslington
York
United Kingdom
YO10 5DD
+44 1904 321107
alison.booth@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1.6

Study information

Scientific Title
Scaling Up Quality Improvement for Surgical Teams: avoiding surgical site infection and anaemia at the time of surgery a randomised controlled trial

Acronym
QIST

Study objectives
Current study hypothesis as of 01/07/2019:
This cluster randomised controlled trial aims to assess whether Breakthrough Series Collaborative is able to deliver fast meaningful change with complex interventions across the UK NHS.

Previous study hypothesis:
This cluster randomised controlled trial aims to assess whether Institute for Health Improvement (IHI) Breakthrough Series Collaboratives are able to deliver fast meaningful change with complex interventions across the UK NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require research ethics approval as it does not involve patients or access to identifiable patient data. This has been confirmed with the Health Research Authority, their Confidential Advisory Group and the University of York Department of Health Sciences Research Governance Group. ref: SRGC/2018/256/D

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied
Healthcare service delivery

Interventions
Current interventions as of 01/07/2019:
The study intervention is a Breakthrough Series Collaborative model. A Collaborative is a short-term learning system that brings together a large number of teams to seek improvement in a focused topic area and proven intervention. Collaboratives provide a suitable vehicle for delivery of a project at this scale, as they not only aim to maximise local engagement and leadership but are designed to build capacity, enable learning and prepare for sustainability.

Each participating NHS Trust is treated as a cluster, and are randomised 1:1 using minimisation by number of hip and knee replacement procedures performed and the traffic light indicators in the Learning From Mistakes league table.

Trusts in both arms in the trial receive the intervention, i.e. training in the Collaborative. Trusts are randomised to receive either training on MSSA to control post-surgery infection (20 hospitals) or training on the anaemia optimisation programme (20 hospitals). None of the participating Trusts will have implemented either protocol prior to acceptance into the trial. Therefore, the control group for the anaemia optimisation quality improvement initiative are the other 20 hospitals who continue with their usual practice for anaemia and vice versa, the control group for MSSA are the other 20 hospitals who will continue with their usual practice for MSSA screening.

Hospitals are given the opportunity to be trained in the quality improvement initiative they have not received after the evaluation period is over.

The Trusts are involved in the training programme from May 2018 to October 2019, a total of 18 months. The evaluation period extends to April 2020.

Previous interventions:
The study intervention is the Institute for Health Improvement (IHI) Breakthrough Series Collaborative model. A Breakthrough Series Collaborative is a short-term learning system that brings together a large number of teams to seek improvement in a focused topic area and proven intervention. Collaboratives provide a suitable vehicle for delivery of a project at this scale, as they not only aim to maximise local engagement and leadership but are designed to build capacity, enable learning and prepare for sustainability.

Each participating NHS Trust is treated as a cluster, and are randomised 1:1 using minimisation by number of hip and knee replacement procedures performed and the traffic light indicators in the Learning From Mistakes league table.

Trusts in both arms in the trial receive the intervention, i.e. training in the Breakthrough Series Collaborative. Trusts are randomised to receive either training on MSSA to control post-surgery infection (20 hospitals) or training on the anaemia optimisation programme (20 hospitals). None of the participating Trusts will have implemented either protocol prior to acceptance into the trial. Therefore, the control group for the anaemia optimisation quality improvement initiative are the other 20 hospitals who continue with their usual practice for anaemia and vice versa, the control group for MSSA are the other 20 hospitals who will continue with their usual practice for MSSA screening.

Hospitals are given the opportunity to be trained in the quality improvement initiative they have not received after the evaluation period is over.
The Trusts are involved in the training programme from May 2018 to October 2019, a total of 18 months. The evaluation period extends to January 2020.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 01/07/2019:
1. Anaemia is measured using the Blood transfusion within 7 days following surgery
2. Deep infection is measured using the Public Health England and Centre for Disease Control and Prevention definition, both at 90 days post-surgery.

Previous primary outcome measures:
1. Anaemia is measured using the Blood transfusion within 7 days following surgery
2. Deep infection is measured using Centre for Disease Control and Prevention definition at 90 days post-surgery

Secondary outcome measures
Current secondary outcome measures as of 01/07/2019:
1. Patient-level outcomes are measured using:
1.1. Superficial infection up to 30 days post-surgery, and name of pathogen (if known)
1.2. Length of hospital stay in days (number of midnights spent in hospital)
1.3. Re-admission within 30 days of discharge
1.4. Critical care admission within 30 days of surgery (regardless of previous discharge)
1.5. Number of days spent in critical care within 30 days of surgery (number of midnights spent in the unit)
2. Process measured for QIST infection are:
2.1. Date patient screened for MSSA
2.2. Results
2.3. Date decolonising pack dispensed
2.4. Confirmation used by the patient: Yes/No/Not recorded
3. Process measures for QIST Anaemia are
3.1. Date patient screened for anaemia
3.2. Date pre-op treatment for anaemia given
3.3. Pre-operative blood results:
3.3.1. Hb <11.5
3.3.2. Ferritin >50
3.4. Was iron indicated: Yes/No/Not recorded
3.5. Was iron given to the patient: Yes/No/Not recorded

Aggregated baseline data will be extracted for the 12 months prior to the commencement of the trial. Individual patient data will be extracted monthly from one month after commencement of the trial to feed into the delivery of the intervention. Final data collection point will be one year and four months after start of data collection.

Previous secondary outcome measures:
1. Patient-level outcomes are measured using:
1.1. Superficial infection up to 90 days post-surgery, and name of pathogen (if known)

1.2. Length of hospital stay in days (number of midnights spent in hospital)
1.3. Re-admission within 30 days of discharge
1.4. Critical care admission within 30 days of surgery (regardless of previous discharge)
1.5. Number of days spent in critical care within 30 days of surgery (number of midnights spent in the unit)
2. Process measured for QIST infection are:
2.1. Date patient screened for MSSA
2.2. Results
2.3. Date decolonising pack dispensed
2.4. Confirmation used by the patient: Yes/No/Not recorded
3. Process measures for QIST Anaemia are measured:
3.1. Date patient screened for anaemia
3.2. Date pre-op treatment for anaemia given
3.3. Pre-operative blood results:
3.3.1. Hb <11.5
3.3.2. Ferritin >50
3.4. Was iron indicated: Yes/No/Not recorded
3.5. Was iron given to the patient: Yes/No/Not recorded

Aggregated baseline data will be extracted for the 12 months prior to the commencement of the trial. Individual patient data will be extracted monthly from one month after commencement of the trial to feed into the delivery of the intervention. Final data collection point will be three months after completion of the training.

Overall study start date
19/10/2017

Completion date
31/07/2020

Eligibility

Key inclusion criteria
1. NHS Acute Trust
2. Commitment from Trust Executive that consent to participate will be provided if Trust is recruited

Participant type(s)
Other

Age group
Other

Sex
Both

Target number of participants
40 Acute NHS Trusts

Total final enrolment

Key exclusion criteria
1. Quality improvement initiative for screening and pre-operative treatment of anaemia and/or screening for and decolonisation of MSSA already in routine practice for orthopaedic surgical patients.

Date of first enrolment
06/03/2018

Date of final enrolment
08/05/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Aintree University Hospitals NHS Foundation Trust
Liverpool
United Kingdom
L9 7AL

Study participating centre
Barking, Havering & Redbridge University Hospitals NHS Trust
Romford
United Kingdom
RM7 0AG

Study participating centre
Barts Health NHS Trust
London
United Kingdom
E1 2ES

Study participating centre
Basildon and Thurrock Hospitals NHS Foundation Trust
Basildon
United Kingdom
SS16 5NL

Study participating centre
Bradford Teaching Hospitals NHS Foundation Trust
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Huddersfield
United Kingdom
HX3 0PW

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Chelsea & Westminster Hospitals NHS Foundation Trust
London
United Kingdom
SW10 9NH

Study participating centre
Derby Teaching Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3NE

Study participating centre
Doncaster & Bassetlaw Hospitals NHS Trust
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Dorset County Hospital NHS Foundation Trust
Dorchester
United Kingdom
DT1 2JY

Study participating centre
East and North Hertfordshire NHS Trust
Stevenage
United Kingdom
SG1 4AB

Study participating centre
East Lancashire NHS Trust, Blackburn Hospital
Blackburn
United Kingdom
BB2 3HH

Study participating centre
East Sussex Healthcare NHS Trust
St. Leonards-on-Sea
United Kingdom
TN37 7PT

Study participating centre
Epsom & St Helier University Hospitals NHS Trust
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Gateshead Health NHS Foundation Trust
Gateshead
United Kingdom
NE9 6SX

Study participating centre
Harrogate and District NHS Foundation Trust
Harrogate

United Kingdom
HG2 7SX

Study participating centre
Ipswich Hospital NHS Trust
Ipswich
United Kingdom
IP4 5PD

Study participating centre
Isle of Wight NHS Trust
Newport
United Kingdom
PO30 5TG

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
LS9 7TF

Study participating centre
London North West Healthcare NHS Trust
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Manchester University NHS Foundation Trust
Manchester
United Kingdom
M13 9WL

Study participating centre
Mid Cheshire Hospitals NHS Foundation Trust
Crewe
United Kingdom
CW1 4QJ

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Milton Keynes University Hospital NHS Foundation Trust
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Princess Alexandra Hospital
Harlow
United Kingdom
CM20 1QX

Study participating centre
Queen Elizabeth Hospital, King’s Lynn NHS Foundation Trust
King's Lynn
United Kingdom
PE30 4ET

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust
Oswestry
United Kingdom
SY10 7AG

Study participating centre
Royal Free London NHS Foundation Trust
London
United Kingdom
NW3 2QG

Study participating centre

Royal Liverpool & Broadgreen University Hospitals NHS Trust
Liverpool
United Kingdom
L7 8XP

Study participating centre
Salisbury NHS Foundation Trust
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Stockport NHS Foundation Trust
Stockport
United Kingdom
SK2 7JE

Study participating centre
Surrey & Sussex Healthcare NHS Trust
Crawley
United Kingdom
RH11 7DH

Study participating centre
Tameside & Glossop Integrated Care NHS Foundation Trust
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre

United Lincolnshire Hospitals NHS Trust
Lincoln
United Kingdom
LN2 5QY

Study participating centre
University Hospital Southampton NHS Foundation Trust
Southampton
United Kingdom
SO16 6YD

Study participating centre
Walsall Healthcare NHS Trust
Walsall
United Kingdom
WS2 9PS

Study participating centre
West Suffolk NHS Foundation Trust
Bury Saint Edmunds
United Kingdom
IP33 2QZ

Study participating centre
Western Sussex Hospitals NHS Foundation Trust
Worthing
United Kingdom
BN11 2DH

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
Wigan
United Kingdom
WN1 2NN

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
Woodhorn Lane
Ashington
England
United Kingdom
NE63 9JJ

Sponsor type
Hospital/treatment centre

Website
http://www.northumbria.nhs.uk

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Not defined

Funder Name
NHS Improvement

Funder Name
Northumbria Acute Care Collaboration Vanguard

Funder Name
Vifor Pharma

Alternative Name(s)
Vifor Pharma Management Ltd., Vifor Pharma Management AG, Vifor Pharma Management SA, Vifor Pharma Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Schuelke

Results and Publications

Publication and dissemination plan
The findings will be published regardless of the results of the research. The findings will be disseminated to NHS Managers, healthcare professionals and patient groups through:
1. Publication in academic journals
2. Dissemination of a short plain English evidence briefing relevant to participating Trusts, and the groups
3. Presentations at high profile events such as the British Orthopaedic Association Annual Congress and NHS Improvement's Medical Director's Conference
4. Feedback to patients locally through relevant patient groups at individual Trusts and nationally through NHS England's Patient and Public Involvement Network
5. Dissemination of the findings to national policy makers such as NICE
6. Use of social media to highlight publications, events etc

Intention to publish date
21/07/2021

Individual participant data (IPD) sharing plan
Requests for trial data for the purposes of secondary analysis should be submitted to the CI Mike Reed at mike.reed@nhs.uk and will be considered on a case by case basis by the Trial Management Group. Only anonymised data will be provided and will only be available after publication of the main results.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/02/2020	02/03/2020	Yes	No
Results article		12/03/2022	14/03/2022	Yes	No