

Scaling Up Quality Improvement for Surgical Teams

Submission date 15/02/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 21/02/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/03/2022	Condition category Other	☐ 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)

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Contact information

Type(s)

Scientific

Contact name

Mrs Alison Booth

ORCID ID

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YO10 5DD
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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Cluster randomised controlled trial

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

Total final enrolment

41

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

United Kingdom

England

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

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

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?
Results article	protocol	12/03/2022	14/03/2022	Yes	No
Protocol article		28/02/2020	02/03/2020	Yes	No