Scaling Up Quality Improvement for Surgical Teams

Submission date 15/02/2018	Recruitment status No longer recruiting	[X] Prospectively registered[X] Protocol
Registration date 21/02/2018	Overall study status Completed	 [] Statistical analysis plan [X] 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 shortterm 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

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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 shortterm 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)
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- 3.1. Date patient screened for anaemia
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- 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

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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?		
<u>Protocol article</u>	protocol	28/02/2020	02/03/2020	Yes	Νο		
<u>Results article</u>		12/03/2022	14/03/2022	Yes	No		