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HEADS-UP: a structured team intervention to improve safety and quality on medical wards

Submission date
23/03/2015

Recruitment status
No longer recruiting

Registration date
24/03/2015

Overall study status
Completed

Last Edited
20/07/2017

Condition category
Other

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

Plain English summary of protocol

Background and study aims:
Most preventable hospital deaths are due to errors on general wards. Ward staff can report major safety problems they see each day, but turning that knowledge into safer care has been difficult. The aim of this study is to find out whether a daily safety briefing for medical ward staff helps to improve the quality and safety of care for their patients.

Who can participate?
Staff in seven different clinical areas in two hospitals

What does the study involve?
Each working day, ward teams taking part complete the HEADS-UP safety briefing. This is a short structured session each morning to find out what had happened the day before. For example, teams ask if there were any equipment problems or communication mistakes. They decide if they can do anything straight away to solve the problems they've discussed. If the problems can't be solved straight away, they are sent to more senior members of the team to decide how to put them right. HEADS-UP is designed to make sure that patients receive the best care already available, not to introduce new treatments, so patients on HEADS-UP wards may not notice any difference.

What are the possible risks and benefits of participating?
On a busy ward, it's easy to overlook important problems. Sometimes, the hospital may not even know there is a problem, even if it frustrates staff and is a risk to patients. HEADS-UP should help make sure that background problems are picked up, and corrected, before they lead to a patient being harmed. HEADS-UP teams should be more confident that they are providing safe care and working well as a team. Patients on HEADS-UP wards should receive more effective care and be discharged more quickly. We don't think there are major risks to a ward taking part in HEADS-UP. Senior doctors and managers want their teams to be more involved in delivering safe care. HEADS-UP shouldn't take doctors, nurses or therapists away from their ward jobs for more than a few minutes each day. Even if the hospital can't solve all of the problems that HEADS-UP points out, it's important that they know about them to plan for the future.

Where is the study run from?
The HEADS-UP study is run by the National Institute for Health Research Imperial Patient Safety Translational Research Centre (NIHR Imperial PSTRC), which is part of Imperial College London (UK)

When is the study starting and how long is it expected to run for?
December 2013 to May 2015

Who is funding the study?
The NIHR Imperial PSTRC and West Middlesex University Hospital (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A stepped wedge, cluster-controlled trial to evaluate a structured team intervention on medical wards (Hospital Event Analysis Describing Significant Unanticipated Problems)

Acronym
HEADS-UP (Hospital Event Analysis Describing Significant Unanticipated Problems)

Study objectives
1. Team use of the HEADS-UP briefing would empower junior clinicians to voice concerns, improving their teams' situational awareness (an important factor in mitigating risks) and their units' safety and teamwork climates
2. This would promote early team recognition of the deteriorating patient, and facilitate the process of escalation of care
3. Information generated by ward teams would both inform their own practice and prompt downstream service reorganisation
4. The combination of ward and support service improvement would improve clinical outcomes, with a dose-response relationship (i.e., the better the tool is used in practice, the greater the benefit seen)
5. An explicit focus on team-wide recognition of adverse events would improve engagement with existing incident reporting systems, thus leading to an increase in formally reported incidents within wards implementing HEADS-UP

Ethics approval required
Old ethics approval format

Ethics approval(s)
Permission for the study was sought from the relevant Research & Development authority at each participating institution. Both authorities approved the study as a quality improvement and service development initiative not requiring formal ethical evaluation (Imperial College Academic Health Science Centre Joint Research Compliance Office/West Middlesex University Hospital Research & Development Department)

Study design
Interventional multi-centre stepped-wedge cluster controlled additional mixed methods qualitative analysis

Primary study design
Interventional

Secondary study design
Non-randomised cluster controlled study

Study setting(s)
Hospital

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
Quality and safety of inpatient medical care

Interventions
A prompt-led team briefing (HEADS-UP) to help multidisciplinary medical ward teams discuss clinical and administrative challenges, including adverse events, of the preceding 24 hours. Regular feedback to participating teams, managers and senior clinicians, allied to an organisational response.

Intervention Type
Other

Primary outcome measure
Excess length of stay (a surplus stay of 24 hours or more, compared to peer institutions' Healthcare Resource Groups-predicted length of stay), measured in each cluster each month (according to the stepped wedge design) over the course of the 14-month study period

Secondary outcome measures
1. Excess length of stay or readmission within 30 days, measured in each cluster each month
2. In-hospital death or death/readmission within 30 days, measured in each cluster each month
3. Complications of care (hospital-acquired infections and pressure ulcers), measured in each cluster each month
4. Processes of escalation of care (use of the ICU outreach service, unplanned ICU admissions, and cardiac arrest calls), measured in each cluster each month
5. Staff engagement with incident reporting, measured in each cluster each month
6. Patient safety and teamwork subsections of the Safety Attitudes Questionnaire, at baseline and then 6 months later

Overall study start date
01/12/2013

Completion date
01/05/2015

Eligibility

Key inclusion criteria
1. Health professionals on participating medical wards available to take part in the HEADS-UP briefings
2. All patients admitted to those wards during the study period, unless they meet one of the exclusion criteria

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
7 clusters; approximately 15 staff in each cluster; 7840 patients

Key exclusion criteria
Patient exclusion criteria:
1. Time spent on the specified ward comprising less than 50% of the total inpatient stay
2. Discharge to a new skilled care facility or other hospital (i.e., not the patient's address at the time of admission; discharge to a new facility typically incurs substantial delays, outside of the ward team's control)
3. Multiple intra-hospital ward transfers. A single transfer from the initial admissions unit to a downstream medical ward is permitted. One further transfer to an escalation area to facilitate discharge (whereby the patient spends less than 24 hours in the escalation area immediately prior to their discharge home) is also permitted
4. Admission to the high dependency unit or ICU
5. Elective admission or direct admission from another hospital
6. Surgeon-directed care for more than 24 hours during the inpatient stay

Date of first enrolment
01/12/2013

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Middlesex University Hospital NHS Trust
Twickenham Road
Isleworth
United Kingdom
TW7 6AF

Study participating centre
St Mary's Hospital (Imperial College Healthcare NHS Trust)
Praed Street
London
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W2 1NY

Sponsor information

Organisation
NIHR Imperial Patient Safety Translational Research Centre

Sponsor details
5th Floor Medical School Building
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W2 1PG

Sponsor type
University/education

Website
http://www.cpssq.org

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
West Middlesex University Hospital NHS Trust

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/06/2015		Yes	No

Results article	results	05/04/2017	Yes	No
Results article	results	18/07/2017	Yes	No