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Using a "bundle" of treatments to prevent anemia in the intensive care unit.

Submission date
18/11/2012

Recruitment status
No longer recruiting

Registration date
30/11/2012

Overall study status
Completed

Last Edited
30/11/2012

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims:
Many patients in Intensive Care Units (ICU) develop a low blood count (anaemia). Researchers have
looked into various methods to prevent anaemia and to limit blood transfusions (due to the complications associated with this). We have also learnt that we can improve our performance if we bundle together a number of helpful treatments for a single problem. For example, we can do a better job of preventing pneumonia in the ICU when we do a bundle of all 5 things that we know decrease the risk of pneumonia. Therefore, in this study, we wanted to investigate if a combination of three things that prevent anaemia or blood transfusions would improve outcomes for our ICU patients if we bundled them together. The first thing was a device called a VAMP that allows us to waste less blood when we need to take blood samples from our patients. The second was to use smaller tubes to collect the blood so less blood was being sent to the lab. Finally, we reinforced the importance of limiting blood transfusions to only those patients who absolutely required them. By bundling these three things, we hoped to show that our ICU patients would do better in terms of the number of transfusions they require as well as based on how long they need to stay in the ICU.

Who can participate?
Patients who were admitted to our ICU during the time of the study.

What does the study involve?
We decided to form two groups by using two similar adult medical ICUs in our hospital. In one ICU, we would do the bundle of things mentioned above. In the other ICU, we would behave as we had in the past. Every patient who was admitted to the first ICU was enrolled in the study as long as they had a catheter in an artery or vein that would allow them to be a candidate for the VAMP device. Patients in the second ICU who also had catheters had their information recorded but they did not receive any special treatment. Other than for the bundle of therapies noted above, all patients in both ICUs were treated the same way.

What are the possible benefits and risks of participating?
The patients who received the bundle required fewer transfusions and had less anaemia. The VAMP device has been studied by the Food and Drug Administration of the US (USFDA) and has

been approved as safe to be used. There was a risk that by using smaller amounts of blood that the test would not have been able to be done and repeat blood tests would be required. There was also a risk that by limiting transfusions we could harm patients who required blood despite the lack of traditional indications for blood.

Where is the study run from?
Medical ICU pods at Henry Ford Health System in Detroit, Michigan, USA.

When is the study starting and how long is it expected to run for?
The study started in April 2009 and ran for a year until April 2010.

Who is funding the study?
Henry Ford Health System, USA

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
Impact of a coordinated blood conservation strategy in the medical intensive care unit: The Anemia Bundle

Study objectives
Anemia is a common problem in critically ill patients admitted to intensive care units (ICUs) with up to fifty percent of patients admitted to an intensive care unit (ICU) receiving multiple red blood cell (RBC) transfusions. The causes of anemia in the ICU can be broadly classified into two groups. The first main cause is related to the patients illness and underlying health status. Examples would include: sepsis, overt or occult blood loss, decreased production of endogenous erythropoietin, bone marrow dysfunction, and iron deficiency anemia. The second main cause is iatrogenic. Examples would include blood loss related to blood draws/sampling and procedure related blood loss.

Significant quantities of blood are withdrawn from critically ill patients in intensive care units for the purpose of laboratory analysis. However, much of this blood is wasted as a significant amount (24-30%) of the removed blood is discarded. Also, the quantity of blood sent to the laboratory for analysis is much more than what is required by the lab for analysis. Smoller and Kruskall reported that ICU patients had a mean phlebotomy volume of 762.2 ml during their hospitalization. Patients with arterial lines had even more blood drawn: 944.0 ml. When patients have arterial lines, they have a significantly higher number of blood draws with higher discard volumes resulting in higher incidence of anemia and need for blood transfusions.

Transfusion is associated with poorer outcomes with patients receiving blood transfusion showing a higher morbidity and mortality. A number of interventions have been studied to decrease the incidence of anemia and reduce blood transfusions in the Intensive Care Unit. These include the routine use of epogen, blood conserving devices, routine use of pediatric tubes, and restrictive strategies of transfusions.

In their study, Hebert et al. showed that a restrictive transfusion strategy was associated with lower 30-day mortality in those with lower severity of illness and a lower hospital mortality in the entire study population. Peruzzi et al. showed that the use of a blood conserving device was safe and effective and that the device significantly lowered discard volume with resultant less decline in hemoglobin in the intervention arm. Further study by Mukhopadhay et al. revealed that the use of a similar device was associated with reduced packed RBC transfusions. In addition, the routine use of pediatric tubes for
phlebotomy in the ICU has been shown to result in 33% decline in the volume of blood draws for diagnostic testing with resultant lower requirements for transfusion. Our study seeks to combine a restrictive transfusion policy, a blood conserving device and the use of pediatric tubes into a bundled intervention. Increasingly, "bundles" are being used in the intensive care unit to improve the reliability of delivering proven interventions to patients. Thus, we felt that making use of this quality improvement process would lead to more impressive changes that have been seen with these interventions individually.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Henry Ford Health System Institutional Review Board, 24 August 2007, ref: 4637

Study design

Single center quasi-experimental design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Patients with critical illness

Interventions
The patients admitted to the intervention group were exposed to three specific interventions. The first was the use of a blood conserving venous/arterial blood management protection Each patient with a central venous catheter and/or arterial line in the intervention group had a VAMP® device attached ensuring no discard volume with phlebotomy. While drawing samples, the device allows for blood to be drawn into a reservoir. At that point, blood can be drawn from a sample site. After the blood for testing is obtained, the blood in the reservoir can be returned to the patient. In addition, all blood was collected into pediatric tubes in the interventional pod. The final intervention was a restrictive transfusion strategy with documentation of indication for blood transfusion in all cases. The strategy ensured that in patients without a specific indication for a higher transfusion target, the target of 7g/dl was followed. Indications for a higher transfusion target for our study included septic shock, acute myocardial infarction, or active bleeding. The House staff and nurses in the intervention pod were educated during monthly orientation at the beginning of their rotation. Although extra emphasis was placed on these targets in the intervention group, these targets had been accepted in both pods as standard of care based on prior research.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The number of patients who received at least one blood transfusion

Secondary outcome measures
Number of units of blood transfused, ICU and hospital LOS, ICU and hospital mortality.

Overall study start date

01/04/2009

Completion date
01/04/2010

Eligibility

Key inclusion criteria
1. All patients who were admitted to each of these pods were evaluated for enrollment
2. Aged of 18 years or older
3. Placement of a central line and/ or an arterial line
4. Hospitalization in the ICU for more than 24hrs
5. Either genders were enrolled

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
398

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/04/2009

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
United States of America

Study participating centre
Henry Ford Health System
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Sponsor information

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Henry Ford Health System (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration