Evidence summary

to support

PICO question 17 on PBM implementation:

Effectiveness decision support systems for blood product ordering

April 2018 (version 1.0)
Centre for Evidence-Based Practice (CEBaP)
Belgian Red Cross
Content
Overview of included studies ................................................................. 3
Overview of studies awaiting classification ........................................... 4
Overview of ongoing studies ................................................................. 5
Overview of excluded studies ............................................................... 6
Overview evidence table GRADE software ........................................... 10
Detailed evidence summary ................................................................. 14
Overview of included studies

We used the evidence form the Cochrane review by Fisher et al. which will be published in 2018\(^1\): 1 RCT\(^2\) and 1 interrupted time series\(^4\) and 2 retrospective cohort studies\(^4,5\) re-analyzed as interrupted time series.


Overview of studies awaiting classification

Choi 2014

Chu 2015

Gross 2009

Kolton 2014

Sroujieh 2016

Tirado Angles 2013

Usmani 2014
Overview of ongoing studies

Overview of excluded studies

Arnold 2011 (reason for exclusion: Not a computerised decision aid)

Baer 2011 (reason for exclusion: Insufficient time points on interrupted time series)

Butler 2015 (reason for exclusion: Controlled but single centre)

Chang 2009 (reason for exclusion: Other inappropriate study design)

Chang 2011 (reason for exclusion: Other inappropriate study design)

Chang 2012 (reason for exclusion: Other inappropriate study design)

Connor 2017 (reason for exclusion: Not a computerised decision aid)

FernándezPerez 2007 (reason for exclusion: Simple before and after design)

Hibbs 2014 (reason for exclusion: Simple before and after design)
**Hicks 2017 (reason for exclusion: Not a computerised decision aid)**


**Jenkins 2017 (reason for exclusion: Simple before and after design)**


**Karkouti 2015 (reason for exclusion: Not a computerised decision aid)**


**Kenyon 2017 (reason for exclusion: Not a computerised decision aid)**


**Leon Justel 2015 (reason for exclusion: Not a computerised decision aid)**


**Li 2014 (reason for exclusion: Not a computerised decision aid)**


**Lin 2010 (reason for exclusion: Other inappropriate study design)**

Lin YC, Chang CS, Yeh CJ, Wu YC. The appropriateness and physician compliance of platelet usage by a computerized transfusion decision support system in a medical center. Transfusion 2010;50(12):2565-70.

**Littenberg 1995 (reason for exclusion: Not a computerised decision aid)**


**Loftus 2016 (reason for exclusion: Simple before and after design)**


**Masear 2017 (reason for exclusion: Not a computerised decision aid)**

McKinney 2015 (reason for exclusion: Not ITS study and unable to derive data from graph, unclear data points)

McWilliams 2014 (reason for exclusion: No control period without decision support)

Michetti 2016 (reason for exclusion: Simple before and after design)

Nakayama 2015 (reason for exclusion: Not a computerised decision aid)

Pentti 2003 (reason for exclusion: Simple before and after design)

Picton 2017 (reason for exclusion: Simple before and after design)

Rana 2006 (reason for exclusion: Simple before and after design)

Razavi 2014 (reason for exclusion: Simple before and after design)

Rinehart 2016 (reason for exclusion: Not a computerised decision aid)
Saag 2017 (reason for exclusion: Assessing effect of an education programme)

Scheurer 2010 (reason for exclusion: Other inappropriate study design)

Shah 2017 (reason for exclusion: Simple before and after design)

Shore Lesserson 1999 (reason for exclusion: Not a computerised decision aid)

Yazer 2013 (reason for exclusion: Other inappropriate study design)

Zuckerberg 2015 (reason for exclusion: Not ITS study and unable to derive data from graph, unclear data points)
Published and unpublished data
<table>
<thead>
<tr>
<th>Nº of studies</th>
<th>Study design</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
<th>Nº of patients</th>
<th>Effect</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>decision support systems</td>
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<td></td>
<td></td>
<td>no decision support systems</td>
<td></td>
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</tr>
<tr>
<td>1</td>
<td>randomised trials</td>
<td>serious a</td>
<td>not serious</td>
<td>serious b</td>
<td>not serious</td>
<td>none</td>
<td>546/1350 (40.4%)</td>
<td>503/1546 (32.5%)</td>
<td>RR 1.24 (1.13 to 1.37)</td>
<td>78 more per 1.000 (from 42 more to 120 more)</td>
</tr>
<tr>
<td>3</td>
<td>observational studies</td>
<td>serious c</td>
<td>not serious</td>
<td>serious d</td>
<td>not serious</td>
<td>none</td>
<td>A statistical significant reduction in overall red cell usage (red cell transfusions per 100 inpatient days) (P &lt; 0.0001) was found in addition to a statistically significant reduction in red cell usage over time (P = 0.01) (see boxplot 1)</td>
<td>🟢🟢🟢🟢 VERY LOW</td>
<td>CRITICAL</td>
<td></td>
</tr>
</tbody>
</table>

**Appropriate transfusions (follow up: 4 months)**

**Overall RBC usage (RBC transfusions per 100 inpatient days) (follow up: range 12 months to 42 months)**
<table>
<thead>
<tr>
<th>№ of studies</th>
<th>Study design</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
<th>Nº of patients</th>
<th>Effect</th>
<th>Relative (95% CI)</th>
<th>Absolute (95% CI)</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>observational studies</td>
<td>serious</td>
<td>not serious</td>
<td>serious</td>
<td>not serious</td>
<td>none</td>
<td>3x</td>
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<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

A statistically significant reduction in inappropriate red cell usage (red cell transfusions per 100 inpatient days) was found ($P < 0.001$), in addition to a statistically significant reduction in inappropriate red cell usage over time ($P < 0.001$) (see boxplot 2).

Box plot 1. Pre-post results – Interrupted time series (3 studies – x-axis). Overall RBC usage: number of RBC transfusion per 100 inpatient days (y-axis). Analysis (meta-regression) from upcoming/unpublished Cochrane review by Fisher et al. (confidential information).

Inappropriate RBC usage (RBC transfusions per 100 inpatient days) (follow up: range 12 months to 42 months)
<table>
<thead>
<tr>
<th>№ of studies</th>
<th>Study design</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
<th>Decision support systems</th>
<th>No decision support systems</th>
<th>Relative (95% CI)</th>
<th>Absolute (95% CI)</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

Box plot 2. Pre-post results – Interrupted time series (3 studies – x-axis). Inappropriate RBC usage: number of RBC transfusion per 100 inpatient days (y-axis). Analysis (meta-regression) from upcoming/unpublished Cochrane review by Fisher et al. (confidential information).

Mortality (follow up: 42 months)
<table>
<thead>
<tr>
<th>№ of studies</th>
<th>Study design</th>
<th>Risk of bias</th>
<th>Inconsistency</th>
<th>Indirectness</th>
<th>Imprecision</th>
<th>Other considerations</th>
<th>Nº of patients</th>
<th>Effect</th>
<th>CI: (95% CI)</th>
<th>Absolute (95% CI)</th>
<th>Certainty</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>observational studies</td>
<td>serious c</td>
<td>not serious</td>
<td>serious b</td>
<td>not serious</td>
<td>none</td>
<td>347/10528 (3.3%)</td>
<td>RR 0.60</td>
<td>(0.51 to 0.71)</td>
<td>22 fewer per 1.000 (from 16 fewer to 27 fewer)</td>
<td>VERY LOW</td>
<td>CRITICAL</td>
</tr>
</tbody>
</table>

30-day readmission (follow up: 42 months)

| 1            | observational studies   | serious c    | not serious   | serious b    | not serious | none                 | 894/10528 (8.5%) | RR 0.62 | (0.56 to 0.69) | 52 fewer per 1.000 (from 42 fewer to 60 fewer) | VERY LOW | CRITICAL   |

CI: Confidence interval; RR: Risk ratio

Explanations
a. Reporting bias, selection bias (allocation concealment) unclear, attrition bias unclear; b. 1 single-centre US trial (limited generalizibility to other settings/countries); c. Inappropriate eligibility criteria and not controlled for confounding; d. 3 single-centre US trials (limited generalizibility to other settings/countries).
Detailed evidence summary

<table>
<thead>
<tr>
<th>Topic</th>
<th>Patient Blood Management (PBM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtopic</td>
<td>Implementation PBM programs</td>
</tr>
<tr>
<td>Intervention</td>
<td>Decision support systems (DSS) to promote appropriate use of blood products</td>
</tr>
</tbody>
</table>
| Question (PICO)     | Is a specific decision support system [intervention] more effective to improve the appropriate use of blood products or clinical outcomes [outcome] compared to no intervention or another decision support system/behavioural intervention [comparison]?

Search Strategy
We used the evidence from the Cochrane systematic review by Fisher et al. ‘Computer decision support systems to promote appropriate use of blood products.’, which will be published in 2018.

Search date
23 February 2018 (Fisher et al.)

In/Exclusion criteria

| Population: Included: | all people (adults and children) who are considered for transfusion of red blood cells (RBCs), platelets, plasma, cryoprecipitate, or granulocytes in any clinical setting. Excluded: people who receive other blood products e.g. intravenous immunoglobulin, factor VIII. |
| Intervention: Included: | Any electronic/computerised DSS that provides clinicians with recommendations on RBC, platelet, plasma, cryoprecipitate, or granulocyte ordering at the time the decision to order a transfusion is being made based on individual patient characteristics. |
| Comparison: | no DSS |

Outcome: Included:
- Primary outcomes
  - Proportion of participants who receive transfusions
  - Amount of blood product used per participant (number of units in adults and volume in mL in infants and children)
  - Serious adverse event (1) transfusion-related, transfusion-transmitted infection, transfusion-associated circulatory overload, transfusion-associated dyspnea, acute transfusion reactions, (2) bleeding (including WHO grade 3 or 4, or equivalent or bleeding that requires an operation), (3) infection, (4) arterial or venous thromboembolism (including deep vein thrombosis, pulmonary embolism, stroke, myocardial infarction).
- Secondary outcomes
  - Number of transfusions compliant with institutional transfusion guidelines
  - Blood count or coagulation parameter (e.g. haematocrit, haemoglobin, prothrombin time, partial thromboplastin time, or platelet count) preceding and after the transfusion.
  - Length of participant stay (in-hospital)
  - Length of participant stay (ICU)
  - All-cause mortality
  - Clinician workflow (additional time per intervention implemented)

Characteristics of included studies

<table>
<thead>
<tr>
<th>Author, year, Country</th>
<th>Study design</th>
<th>Population</th>
<th>Comparison</th>
<th>Concurrent interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams, 2011, USA</td>
<td>Observational: interrupted time series (retrospective cohort study)</td>
<td>Children (medical, surgical, ICU) after (3492 discharges, 7.18±6.2 years, 51.5% males)</td>
<td>Comparison: after DSS implementation versus before DSS implementation</td>
<td>Details of DSS: None</td>
</tr>
<tr>
<td>Study centre: single centre, tertiary hospital</td>
<td>Study centre: single centre, tertiary hospital</td>
<td>CPOE (Cerner), alerts were created according to the current best-practice recommendations. The CPOE alert was designed to analyse the patient record and hemodynamic status. Variables in the alert algorithm included the patient’s age, diagnosis, most recent serum haemoglobin level and blood pressure. The alert window along with a hyperlink to the supporting evidence was provided if a RBCT order was written in case of appropriate age range (1 month – 18 years), normal blood pressure, and a haemoglobin level &gt;7 g/dL. Overriding the alert was an option if the clinician determined that it was in the patient’s best interest to order the RBCT.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goodnough, 2014, USA</td>
<td>Observational: interrupted time series (retrospective cohort study)</td>
<td>177020 adult inpatient discharges (ED, medical, surgical, obstetrics, and ICU): 10528 (mean age 59.8±17.4, 49.8% males) after versus 3622 (mean age 59.7±17.0 years, 45.7% males) before implementation DSS available</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Comparison: after DSS implementation versus before DSS implementation Details of DSS: CPOE (Epic systems) Orders for RBC units triggered an interruptive alert in patients with the most recent (within 24 hr) Hb level of higher than 7 g/dL (8 g/dL in patients with acute coronary syndrome or post-cardiothoracic surgery).</td>
<td></td>
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</tr>
</tbody>
</table>
| | | Education about the consensus transfusion guidelines was disseminated to providers in various different clinical services via in-person meetings and electronic communication for almost 1
<table>
<thead>
<tr>
<th>Study</th>
<th>Design Type</th>
<th>Study Details</th>
<th>Comparison</th>
<th>Details of DSS</th>
<th>Blood Ordering Products</th>
<th>Follow-up Period Before Implementation</th>
<th>Follow-up Period After Implementation</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kassakian, 2016, USA</td>
<td>Observational: interrupted time series (retrospective)</td>
<td>All adult patients admitted to all services except obstetrics: 71258 admissions (mean age 54.3 years, 53.1% males) after DSS implementation versus 71621 admissions (mean age 53.1 years, 52.4% males) before DSS implementation</td>
<td>Comparison: after DSS implementation versus before DSS implementation</td>
<td>Details of DSS: Htc ≥21% and order for RBC transfusion is followed by an interruptive alert which also allows the user to turn off the alert with common reasons for RBC transfusion in patients with Htc ≥21% such as tachycardia, hypotension, active bleeding, acute coronary syndrome, instability, and imminent surgery.</td>
<td>RBC only</td>
<td>36 months</td>
<td>36 months</td>
<td>Ad hoc education related to appropriate transfusion (6 departmental talks given over a 2-year period)</td>
</tr>
<tr>
<td>Rothschild, 2007, USA</td>
<td>Experimental: randomized controlled trial</td>
<td>453 Junior Housestaff (1st, 2nd and 3rd year)</td>
<td>Comparison: DSS (CPOE system) versus no DSS</td>
<td>Educational intervention (prior to RCT):</td>
<td></td>
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</tbody>
</table>
Residents; medical, surgical, obstetrics, ICU) randomized into the intervention group (DSS) (n=227) and a control group (no DSS) (n=226)

Study centre: single centre, tertiary hospital

Details of DSS:
- Hct level for RBC, Plt count for Plt, PT/INR or APIT for plasma.
- DS-recommended doses were calibrated to patient characteristics and the preceding “trigger” laboratory results for component blood orders
- The DS logic recommended a dose (number of units) of product based on the most recent laboratory values, the patient’s characteristics, and the expected therapeutic result of the product.

Blood ordering products:
- RBC, plasma, Plt only

Follow-up period: 4 months

### Synthesis of findings

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Comparison/Risk factor</th>
<th>Effect Size</th>
<th>#studies, # participants</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriate transfusions</td>
<td>DSS versus no DSS</td>
<td>Statistically significant: 546/1350 vs 503/1546 RR: 1.24, 95%CI [1.13;1.37] (p&lt;0.0001) In favour of DSS</td>
<td>1, 1350 vs 1546</td>
<td>Rothschild, 2007</td>
</tr>
<tr>
<td>Overall RBC usage (RBC transfusions per 100 inpatient days)</td>
<td></td>
<td>Statistically significant: 3/100 versus 2/100 λ (see boxplot 1) (p&lt;0.0001) In favour of DSS</td>
<td>1, 3492 versus 3294 (discharges)</td>
<td>Adams, 2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Statistically significant: 9.5/100 versus 7.5/100 λ (see boxplot 1) (p&lt;0.0001) In favour of DSS</td>
<td>1, 353439 versus 361686 (in-patient days)</td>
<td>Kassakian, 2016</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Statistically significant: 15.5/100 versus 12.5/100 λ (see boxplot 1) (p&lt;0.0001) In favour of DSS</td>
<td>1, no raw data available</td>
<td>Goodnough, 2014</td>
</tr>
<tr>
<td>Inappropriate RBC usage (RBC transfusions per 100 inpatient days)</td>
<td></td>
<td>Statistically significant: 18.5/100 versus 16.5/100 λ (see boxplot 2) (p&lt;0.001) In favour of DSS</td>
<td>1, 3492 versus 3294 (discharges)</td>
<td>Adams, 2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Statistically significant: 8/100 versus 6.5/100 λ (see boxplot 2) (p&lt;0.001) In favour of DSS</td>
<td>1, 353439 versus 361686 (in-patient days)</td>
<td>Kassakian, 2016</td>
</tr>
<tr>
<td>Endpoint</td>
<td>Statistically significant: 8.5/100 versus 3.5/100 λ (see boxplot 2) (p&lt;0.001)</td>
<td>1, no raw data available</td>
<td>Goodnough, 2014</td>
<td></td>
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<tr>
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<td>--------------------------------------------------------------------------------</td>
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<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>Statistically significant: 347/10528 versus 199/3622 RR: 0.60, 95%CI [0.51;0.71] (p&lt;0.00001)</td>
<td>1, 10528 versus 3622</td>
<td>Goodnough, 2014</td>
<td></td>
</tr>
<tr>
<td>30-day readmission</td>
<td>Statistically significant: 894/10528 versus 496/3622 RR: 0.62, 95%CI [0.56;0.69] (p&lt;0.00001)</td>
<td>Goodnough, 2014</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

λ data extracted from graph

Box plot 1. Pre-post results – Interrupted time series (3 studies – x-axis). Overall RBC usage: number of RBC transfusion per 100 inpatient days (y-axis). Analysis (meta-regression) from upcoming/unpublished Cochrane review by Fisher et al. (confidential information).
Box plot 2. Pre-post results – Interrupted time series (3 studies – x-axis). Inappropriate RBC usage: number of RBC transfusion per 100 inpatient days (y-axis). Analysis (meta-regression) from upcoming/unpublished Cochrane review by Fisher et al. (confidential information).
### Quality of evidence

**Experimental studies**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Random sequence generation and allocation concealment (selection bias)</th>
<th>Blinding of personnel and participants (performance bias) and blinding of outcome assessors (detection bias)</th>
<th>Missing data or incomplete outcome data (attrition bias)</th>
<th>Selection of reported results or selective reporting (reporting bias)</th>
<th>Other limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rothschild, 2007</td>
<td>Randomization Low risk of bias  A computerized program generated the randomization scheme for each block (according to clinical specialty and year of training) Allocation concealment: Unclear</td>
<td>Participants: Low risk of bias  Junior housestaff were not told which group they were assigned.  Outcome assessors: Low risk of bias  Abstractors were blinded to the physician randomization. A sample of 50 charts was reviewed by all three chart abstractors to assess inter-rater reliability</td>
<td>Unclear</td>
<td>High risk of bias  No report of drop-out of physicians or whether intervention and control groups ordered similar amounts of products.</td>
<td>Concurrent intervention (education) prior to the randomization</td>
</tr>
</tbody>
</table>

### Observational studies

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Inappropriate eligibility criteria</th>
<th>Inappropriate methods for exposure and outcome variables</th>
<th>Not controlled for confounding</th>
<th>Incomplete or inadequate follow-up</th>
<th>Other limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adams, 2011</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No data reported on the frequency of the alert</td>
</tr>
<tr>
<td></td>
<td>No time-matched controls</td>
<td>Objective outcomes</td>
<td>Controlled for severity of illness (Case-Mix)</td>
<td>Data from specified time</td>
<td></td>
</tr>
</tbody>
</table>
There was a significant difference in patients admitted for diseases of the circulatory system (207 vs 168; P<0.009), ear, nose, mouth, and throat (473 vs 424; P<0.006), respiratory system (288 vs 412; P<0.0001), and endocrine, nutritional, and metabolic disorders (135 vs 217; P<0.0001) in the control versus study cohort.

retrieved from hospital CPOE

No other potential confounding factors were taken in to account

periods in CPOE

<table>
<thead>
<tr>
<th>Goodnough, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No statistical analysis in demographic variables between 2 cohorts (after versus before DSS), cohort that received DSS seems to be older, more males and increased patient discharge volumes,</td>
</tr>
</tbody>
</table>

No |
| Primary data collected from the laboratory data repository (Rhodes) and Midas (a proprietary clinical database). Microsoft Access was used to merge these data. |

Yes |
| Not controlled for confounding variables but unsure if these differences affect the effect estimate. |

Yes |
| Hb data from Rhodes were analyzed only after July 2009 as the data integration and validation for the Rhodes database occurred after this time point; clinical outcomes data from Midas continued to be available |

One limitation of our study is that within our own EMR, CDS and BPA could not be designed so that the option chosen by the user at the alert (“accept”/”cancel“) automatically triggered a downstream action such as canceling or continuing the original RBC product order. Thus, measuring
<table>
<thead>
<tr>
<th></th>
<th>patient-days-at-risk, case-mix complexity, volumes of selected surgeries, and solid organ and stem cell transplant procedures.</th>
<th>before this point.</th>
<th>only the rate of accept versus cancel as success in an override can be a misrepresentation of the end-user action.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kassakian, 2016</td>
<td>No</td>
<td>No</td>
<td>DSS intervention was implemented +/- 2 years later in the general surgery and bone marrow transplant unit (August 2013) compared to the implementation in the other units (October 2011)</td>
</tr>
<tr>
<td></td>
<td>Similar amount of admissions and inpatient days in both groups, demographic characteristic (age/gender) were different</td>
<td>Transfusion data, lab values, and patient characteristics were extracted from the clinical database using Structured Query Language. No significant changes in either the laboratory or blood banking systems or methods in which those were recorded. Secondary use of operational electronic health record data has potential limitations and pitfalls.</td>
<td>Rates of platelet transfusion served as a control variable (from November 2008-July 2013) at which time a separate CDS tool for inappropriate platelet transfusion was implemented + wash-in period of 1 month (+ sensitivity analysis using a 2-month wash-in period) However, significant differences in groups from pre/post intervention on age and sex and did not adjust for confounders and may affect internal validity</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>Less than 1% (836 of 84,518) of the transfused units of red blood cells had missing haematocrit value in the 24 hours prior to transfusion administration. The sensitivity analysis showed a negligible (&lt;1%) difference in the point estimates and CI of the results between the 2 analyses.</td>
</tr>
</tbody>
</table>

Certainty of the body of evidence: see GRADE Evidence tables

| Conclusion | See Evidence-to-Decision template |
| Reference(s) | See overview list included studies |
| Evidence used for | Guideline |
| Project | ICC-PBM 2018 |
| Reviewer(s) | Hans Van Remoortel |