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TIMELY INDIVIDUAL AUDIT AND FEEDBACK SIGNIFICANTLY IMPROVES TRANSFUSION BUNDLE COMPLIANCE - A COMPARATIVE STUDY

Marjon Borgert, Jan Binnekade, Frederique Paulus, Astrid Goossens, Margreeth Vroom and Dave Dongelmans

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ABSTRACT

Objective. To investigate the difference in effect on transfusion bundle compliance between two Audit and Feedback (A&F) strategies to implement the transfusion bundle.

Design and setting. This implementation study was conducted in an ICU of a university hospital from May to December 2014. The ICU consists of two nursing teams containing 63 and 62 nurses.

Participants. All ICU nurses participated in this study.

Intervention. Monthly A&F on team level versus a combination of monthly A&F on team level plus timely individual feedback.

Measurements. The primary outcome was bundle compliance. Compliance was measured after every single transfusion.

Results. Monthly A&F on team level with timely individual A&F significantly improves bundle compliance during implementation compared to monthly A&F on team level alone. The overall effect of compliance during the study period was significantly higher with an OR of 4.05 (95% confidence interval, CI: 1.62 to 10.08), $P < 0.001$. This indicates that when using the combined A&F strategy nurses are more likely to be compliant to the bundle than when monthly A&F was used alone.

Conclusions. Compared to monthly team A&F alone, providing timely individual A&F plus monthly A&F on team level significantly improves the success of implementing a transfusion bundle on the ICU during the implementation period. Providing timely individual A&F plus monthly A&F on team level might also be effective for the implementation of other bundles in healthcare. Future research could elaborate on longer duration of the intervention, the use of information and computer technology to lower costs of the intervention, and to enhance sustainability.

INTRODUCTION

Transfusion of blood products is a frequently used life-saving therapy in critically ill patients. Besides the positive treatment effects, it can cause serious complications such as pulmonary oedema, infections and transfusion-related acute lung injury (TRALI).[1,2] Although reported incidences of these complications are low, they are an important cause of transfusion-related morbidity and mortality.[3,4] Results from the UK have shown that risks of morbidity from transfusion is 1 in 322 580 components transfused.[3] In the last decade, changes have been made in transfusion practice to further reduce these complications. For instance, screening of donors to reduce infections[5] or excluding female donors to reduce the incidence of TRALI.[6]

However, it is known that most transfusion-related incidents are caused by human errors.[3] The blood transfusion process is complex and involves multiple disciplines.[7] This results in multiple moments in which errors could occur.[7] Estimates of the risks of transfusions were calculated in the UK.[7] The risk of an error during blood transfusion is estimated at 1:16 500 units transfused, transfusion a wrong blood product at 1:100 000 and the risks of death in case a wrong blood product was transfused at 1:1 500 000.[7,8] However, the true incidence may be higher since not every error is reported. Most errors are made during the collection and labelling of blood samples or at the final bedside checks.[3,4] For instance, identifying the wrong blood product patient combination could lead to transfusion of incompatible blood.[7]

To improve transfusion practice and to reduce errors, guidelines should be used.[9] However, despite intensive implementation programs, it is known that guidelines are not followed consistently.[10,11] In order to improve guidelines adherence, the Institute for Healthcare Improvement (IHI) has developed the concept of care bundles.[12] They consist of three to five evidence-based interventions for a predefined patient population or clinical process.[12] The strength of bundling interventions in care bundles is to ensure that evidence-based care will be uniformly applied and improve clinical outcomes.[12] Care bundles have already proven to be effective in improving clinical outcomes.[13,14]

In order to improve transfusion practice, we have developed a care bundle for the transfusion of red blood cells (RBCs). We used the IHI process steps to design the transfusion bundle and included five evidence-based interventions (Supplementary File 1).[12,15,16] All interventions are aimed to reduce unnecessary, incorrect or unsafe transfusions.

The implementation of care bundles is challenging. Different implementation strategies are described with varying success rates.[17] A frequently used strategy is Audit and Feedback (A&F). Although A&F tends to be effective, there is a great variability in the effectiveness on implementation.[18]

Several frameworks and theories have been designed in order to understand how A&F could change professionals' behaviour. Zajonc showed that the combination of A&F strategies on group and individual level has positive effects on performance.[19] Hysong *et al.* developed a model in which it is postulated that feedback should be given timely, individualized and non-punitive in order to be effective.[20] An important difference between our study and the study of Hysong *et al.* is that they have chosen a month as a threshold for timely feedback. We considered timely feedback as given within a maximum time span of 72 hours. The reason behind this shorter time span is that it would ensure nurses to clearly remember their actions and gave them the possibility to change their behaviour before the next transfusion occurred. This is in line with Sinuff *et al.* who also found that the timeliness of feedback is an important factor in changing behaviour.[21] Ivers *et al.* suggested that implementation studies should focus on comparing different A&F strategies and on how to optimize their effectiveness.[22] In this present study, we aim to investigate the difference in effect on transfusion bundle compliance between monthly team level A&F versus monthly team level A&F with the addition of timely individual A&F.

METHODS

This implementation study with a quasi-experimental comparative study design was conducted from May to December 2014. We implemented the transfusion bundle from May to August. This implementation period denotes the transition period and post-implementation refers to the period in which the intervention is considered fully implemented as intended.

Context

The study was conducted in a 28-bed mixed medical-surgical ICU of a university hospital. The ICU is a 'closed format' department with four units in which patients are under the direct care of the ICU team. The ICU team consists of 10 full-time intensivists, 8 subspecialty fellows, 12 residents and 125 ICU nurses. The ICU has a stable nursing staff and all nurses were qualified as critical care nurses. Fellows rotate on a yearly basis and

residents half-yearly. Depending on the estimated workload and the severity of illness, the nurses are assigned to one or two patients. The ICU is divided into two nursing teams, working on two units each. Nurses are working in either one of the two teams.

Study subjects

The study included ICU nurses of two nursing teams who transfused at least one unit of RBCs from May to December 2014. Per nursing team a different A&F strategy was used to introduce the transfusion bundle. One team was randomly assigned to the intervention group and the other to the control group. Nurses' individual performances, i.e. transfusion bundle compliance, was measured. Nurses' compliance to the bundle was measured by the researcher after every transfusion. In both teams, nurses were excluded from the analysis with long-term illness, pregnancy leaves, and newly employed during the study period. Transfusion in patients for whom hemapheresis was indicated or for whom the massive blood transfusion protocol was activated were excluded due the urgency of the situation. The massive blood transfusion protocol was activated in case of the presentation of the following signs or symptoms: (i) decrease in blood pressure; (ii) not responding to fluid therapy; and (iii) existence of a high suspicion for bleeding. Furthermore, blood products other than RBCs were excluded.

Introduction of the transfusion bundle

The ICU consists of two nursing teams containing 63 and 62 nurses. Both teams work separately of each other and have their own nursing management. In both teams, we first provided education about the transfusion bundle in order to explain the rationale behind each element. During the implementation period, A&F was provided. Both teams received monthly A&F. On top of this, timely individual A&F was provided in only one of the two teams.

Education

Since we introduced a new transfusion bundle in our ICU, we provided education to both teams in order to explain the concept of care bundles in general, the risks of transfusion and the reasons for using the transfusion bundle. Education was provided in April and May 2014. The way the information was provided and the content of the information was equally in both teams. Nurses first received information by email containing the following items: (i) explanation of the concept of care bundles; (ii) aim of the transfusion bundle; (iii) explanation of the background/evidence per element. By explaining the risks of transfusion in combination with the aims of the transfusion bundle and the importance of the bundle interventions, we expected this would help to stimulate bundle compliance. Subsequently, nurses were asked to fill out a web based

questionnaire containing information and questions about the transfusion procedure including the transfusion bundle. Online participation was registered to ensure nurses had read the information and answered the questions. Two senior ICU researchers, an intensivist and one junior researcher, the head nurse and five ICU nurses were involved in the development process of this educational program. The content was pilot tested by two physicians and two ICU nurses. Furthermore, two information sessions were held for ICU nurses. A presentation about the transfusion bundle was given during hand over meetings to inform residents and physicians.

Audit and feedback intervention

In this study, we used A&F as the intervention to implement the transfusion bundle. In both teams monthly A&F was provided. On top of this, individual A&F within 72 hours after transfusion was provided in only one of the two teams. The definition of A&F was in accordance with the Effective Practice and Organisation of Care (EPOC) taxonomy: 'A summary of health workers' performance over a specified period of time, given to them in a written, electronic or verbal format. The summary may include recommendations for clinical action'.[23]

Team A: monthly provided A&F on team level

In team A, monthly A&F was provided. At the end of each month, the team received a standardized feedback report by email. This report contained the compliance levels per team for that given month. Feedback was provided by the researcher from the ICU together with the intensivist. Simultaneously, posters were used to show compliance levels. Posters were updated each month. Posters were used as a method to visualize the feedback on compliance levels and to further stimulate compliance.

Team B: monthly provided A&F on team level plus timely individual A&F

In Team B, the same A&F strategy was used as in Team A. Additionally, individual A&F was provided to the nurse within 72 hours after each RBC transfusion, i.e. further referred as timely individual feedback. Feedback was provided by the researcher and was given either by face-to-face contact or by email in case personal contact was not possible within 72 hours. A standardized report was used. This contained compliance levels of the complete bundle and compliance per element. The time span of 72 hours was chosen so that nurses would still remember the actions they had performed.

Study of the intervention

Data was collected prospectively from the electronic registration system (Patients Data Management System, PDMS). The occurrence of a RBC transfusion was audited by the researcher three times daily in the PDMS during week days. Transfusions that occurred during the weekends were audited on Mondays. Bundle checklists were used to track compliance (see Supplementary File).

Measures

Compliance with the completion of each element of the bundle was assessed during the eight study months. Each administered unit of RBC was counted as one inclusion. Compliance was calculated by using the all-or-none (AON)-approach.[24] If one of the interventions was not performed, the nurse was considered as non-compliant. Moreover, if checklists were not found, nurses were considered as non-compliant. The denominator is the total number of RBC units administered per month. The numerator is the total number of applied transfusion bundles per month. Bundle checklists were available in prominent places in the ICU. These places were equal in both teams. Bundle checklists were collected daily by the researcher during weekdays or on Mondays after weekends. Compliance data was entered in a database by the researcher. Compliance levels were calculated at the end of each month per nursing team.

Analysis

Continuous normally distributed variables will be expressed by their means and standard deviations or when not normally distributed as medians and their interquartile ranges. Categorical variables will be expressed as n/N (%). To test groups Student's t-test will be used, if continuous data is not normally distributed the Mann-Whitney U-test will be used. Categorical variables will be compared with the Chi-square test or Fisher's exact test. The goal of the primary analysis was to quantify the net effect of the A&F intervention on transfusion bundle compliance, controlling for other variables. Exploration of interaction (effect modification) and confounding was considered methodologically relevant. We first focussed on the crude (uncorrected) effect of A&F (independent variable) on transfusion bundle compliance (dependent variable). Then statistical and clinically relevant covariates were added as an interaction term (implementation and post-implementation period, nurses' characteristics: age, gender and work experience, and patient characteristics: Apache IV, ICU mortality). If the interaction term appeared to be significant ($P < 0.05$), this would indicate that the relation between A&F and transfusion bundle compliance could be different for various levels of the covariate. This indicates the need for separate models for the levels of the covariate. As a significant

interaction was not found, the model was examined for confounding. Confounding was defined as ≥ 10% change in the coefficient of the central determinant (transfusion bundle compliance) as a consequence of adding a covariate.

Because each nurse can be responsible for the performance of one or more transfusions for the same or different patients we accounted for dependence of transfusion bundle compliance data within nurses by including the nurses as a random effect in the model. Statistical significance is considered to be at $P < 0.05$. When appropriate statistical uncertainty will be expressed by the 95% confidence levels. All data were entered into a Microsoft Access database. Analyses were performed using R (version: 3.1.3; R Foundation for Statistical Computing, Vienna, Austria). We used Stata software (version 14) for the multilevel logistic regression analysis.

Ethical considerations

The study was approved by the Medical Ethics Committee of the Academic Medical Center of Amsterdam, the Netherlands and the need for informed consent was waived.

RESULTS

Nurses demographics

In total, 120 of the 125 nurses participated in this study, 59 in Team A and 61 in Team B. Five nurses were excluded. There were no significant differences in age between the nursing teams, neither in gender or years of work experience (Table 1). In team A, 61% (36/59) of the nurses followed the web-based educational program, compared to 100% (61/61) in Team B (difference 39% (95% CI: -51 to -27, $P < 0.001$).

Individual A&F

In Team B, feedback was given in 32% (40/124) via face-to-face contact. In 68% (84/124), a personal feedback report was sent by email. Emails were sent when face-to-face contact was not possible due to the following reasons: change of shifts in 35% (29/84), too busy in 2% (2/84), days off/holiday in 63% (53/84).

Patient demographics

During the implementation period 101 patients received at least one unit of RBCs and 116 post-implementation. Table 2 shows that the cohorts were similar in both groups with respect to age, gender, severity of illness (Apache IV), ICU LOS and ICU mortality.

Table 1. Nurses demographics

	Team A	Team B	95% CI of difference, *P*-value
Number of nurses, n/N (%)	59	61	-
Gender (female), n/N (%)	44/59 (75)	46/61 (75)	-0.008 (-16.33 to 14.67), 0.92[a]
Age, median (IQR)	41 (32-50)	44 (32-49)	0.99 [b]
Work experience (yrs), median (IQR)	10 (4.5-18.5)	14 (6-20)	0.44 [b]

[a] Chi-square test; [b] Mann-Whitey U-test

Transfusion bundle compliance

Implementation period

The overall compliance rate during the four months of implementation was 67% (83/124) in Team B versus 36% (58/160) in Team A (difference -31%, 95% CI: 20 to 42, P < 0.001). Figure 1 shows the compliance over time. In Table 3 the compliance levels per month are shown, including the differences per Team. Compliance significantly differed between the Teams, except for May and August 2014.

Post-implementation period

The overall compliance rate during the post-implementation period was 58% (94/162) in Team B versus 22% (47/216) in Team A (difference -36%, 95% CI: 22 to 58, P < 0.001). Although compliance gradually decreased in both teams, there is still a significant difference in compliance between both teams at the end of the post-implementation period, difference -36% (95% CI: -52% to -18.5%, P < 0.001).

Difference of compliance within the teams

The difference in compliance within Team B between the implementation period and post-implementation period was 9% (95 CI: -2.33 to 20.15, $P = 0.124$). In team A, a difference of 14.5% was observed (95% CI: 5.25 to 23.75, $P = 0.002$).

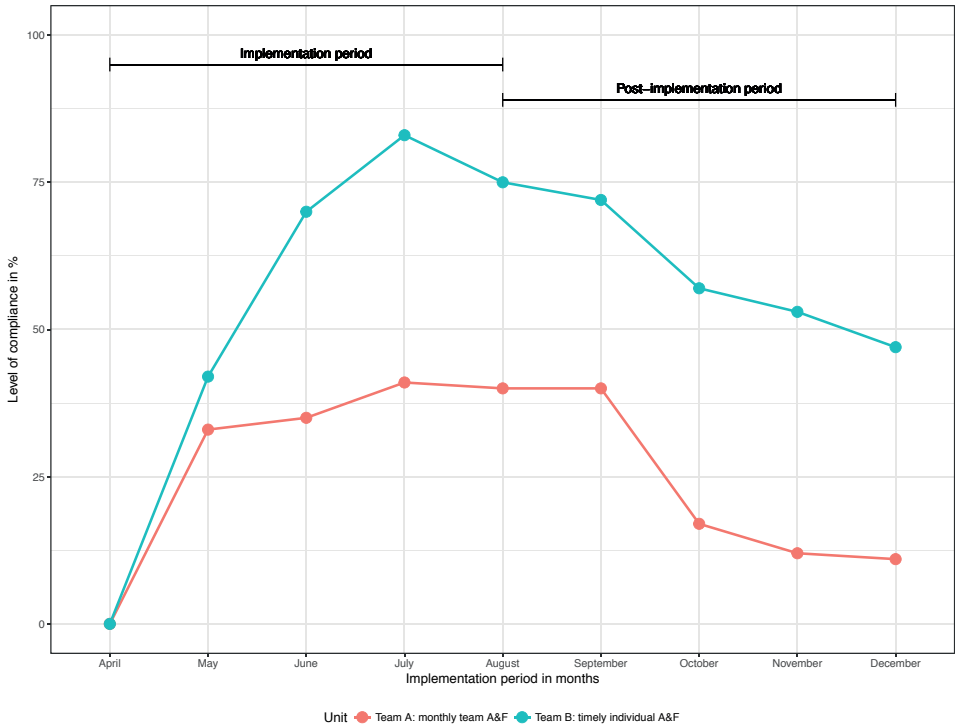

Figure 1. Compliance levels per team during the implementation and post-implementation period.

Multilevel logistic regression analysis

In Table 4, the results from the univariate model are shown. We found a significant interaction between the 'type of A&F' and 'time of intervention'. Therefore, we analysed two models. One for the implementation period and one for the post-implementation period. Both models show a large difference in compliance effect between the implementation period with an OR 4.05 (95% CI: 1.62 to 10.08), $P < 0.001$)) and the post-implementation period, OR 12.51 (95% CI: 4.1 to 38.13), $P < 0.001$. Both models were corrected for confounding for the nurses response to the educational questionnaire.

Table 2. Patient demographics

	Implementation period				Post-implementation period			
	Team A	**Team B**	**95% CI of difference**	***P*-value**	**Team A**	**Team B**	**95% CI of difference**	***P*-value**
Number of unique patients (N)	57	55	-	-	67	61	-	-
Number of transfused RBCs [a]	160/284	124/284	12.7 (4.5 to 20.7) [a]	0.0025	216/378	162/378	14.3% (7.2% to 21.2%) [a]	< 0.001
Age in years, mean (SD)	62.5 (12.2)	58.8 (16.7)	3.70 (-1.8 to 9.2) [b]	0.19	59.4 (17.1)	63.3 (14.44)	-3.90 (-9.5 to 1.6) [b]	0.16
Gender (male), n/N (%) [a]	33/57 (58)	31/55 (56)	1.5% (-16.3 to 19.2) [a]	0.87	35/67 (52)	36/61 (59)	-6.8% (52.2 to 59.0) [a]	0.44
Apache IV, median (IQR)	57 (51-81)	62 (48-83)	-	0.66 [c]	66.5 (47-75)	76.5 (63-97.5)	-	0.17 [c]
ICU LOS in days, median (IQR)	6 (3-12)	6 (3-12)	-	0.63 [c]	4 (2-14)	7 (3-13)	-	0.57 [c]
ICU mortality, n/N (%) [a]	13/57 (23)	13/55 (24)	-0.8 (-16.4 to 14.7) [a]	0.92	16/67 (24)	12/61 (20)	4.2% (-10.3 to 18.2) [a]	0.57

[a] Chi-square test; [b] Unpaired t-test; [c] Mann-Whitey U-test; LOS: Length of stay; Apache: Acute physiology and chronic health evaluation

Table 3. Transfusion bundle compliance

Time of intervention	**Month**	**Team A** n/N (%)	**Team B** n/N (%)	**95% CI of difference**	***P*-value [a]**
Implementation period	May	16/49 (33)	15/36 (42)	-9% (-28.8 to 11.1)	0.40
	June	20/57 (35)	14/20 (70)	-35% (-53.9 to -9.5)	0.007 [b]
	July	12/29 (41)	33/40 (83)	-41% (-59.2 to -18.1)	0.000 [b]
	August	10/25 (40)	21/28 (75)	-35% (-55.7 to -8.4)	0.01
Post-implementation period	September	28/70 (40)	33/46 (72)	-32% (-47.0 to -13.0)	0.001 [b]
	October	7/41 (17)	25/44 (57)	-40% (-56.0 to -19.0)	0.000 [b]
	November	5/41 (12)	18/34 (53)	-41% (-57.8 to -19.8)	<0.001 [b]
	December	7/64 (11)	18/38 (47)	-36% (-52.8 to -18.5)	0.000 [b]

[a] Chi-square test; [b] significant; no missing values

Table 4. Univariate logistic regression covariates for transfusion bundle compliance

	Compliance	
Covariates	**OR (95% CI)**	***P*-value[a]**
Type of A&F (Team A and Team B)	4.19 (3.01 to 5.82)	< 0.001
Time of intervention (impl. and post-impl.)	0.60 (0.44 to .82)	0.002
Nurses' age	0.99 (0.98 to 1.01)	0.59
Nurses' gender	1.38 (0.98 to 1.96)	0.07
Nurses' years of work experience	0.99 (0.98 to 1.01)	0.54
Response to educational questionnaire	2.17 (1.48 to 3.22)	< 0.001
Patient: Apache IV score	0.99 (0.99 to 0.99)	0.03
Patient: died in ICU	1.21 (0.87 to 1.69)	0.26

[a] significant when *P*-value is ≤ 0.20.

DISCUSSION

Our implementation study has shown that during the active period of implementation the combination of monthly A&F on team level with timely individual A&F, significantly improves short-term bundle implementation, compared to monthly A&F on team level alone. This resulted in significantly higher compliance levels in Team B. Even though significantly more transfusions were given in the team that received monthly A&F, our results also indicates that when using the combined A&F strategy nurses are four times more likely to be compliant to the bundle than when monthly team A&F was used alone.

When we stopped the A&F intervention during the post-implementation period, compliance dropped in both teams. However, even though in both teams compliance reduced in the four months after implementation, compliance levels were still significantly better in in the team that was exposed to the combined A&F strategy. These findings are consistent with Zajonc.[19] He showed that individual knowledge about team performance combined with knowledge on performance on an individual level enhances team performance.[19]

We have shown low compliance levels in the team where monthly A&F was given. This is in contrast to Lawrence and Fulbrook[25] who implemented the ventilator bundle.[25] They reported compliance levels of 68% by using monthly A&F. However, they provided A&F over a longer period of time, i.e. six months. The difference in our compliance data between the nursing teams could be explained by the time span in which feedback was delivered as well as the level on which the data was aggregated, i.e. team or individual

level. This is consistent with the model of actionable feedback.[20] This model posits that A&F is the most effective when it is timely given, individualized and in a non-punitive way. An important difference is that we have used a shorter time span in which feedback was provided compared to Hysong *et al.*.[19] The reason was that nurses would still clearly remember their actions and it gives nurses the opportunity to change their behaviour before the next transfusion occurred. Furthermore, we provided individual feedback in a non-punitive way. Feedback was also given when the performance of an individual was optimal i.e. compliance was 100%. This respectful and non-punitive way may have improved bundle compliance.[20]

Although this study has shown a significant effect on compliance during implementation when using the combination of monthly A&F plus timely individual A&F, there are reasons for not reaching the optimal effect. One of the reasons could have been that it was not always possible to meet the nurse within 72 hours. As per protocol, we then sent personal feedback by email. Even though the report was personalized and written in a non-putative manner, this might have had less impact than actual face-to-face feedback. As there is evidence that providing feedback face-to-face improves implementation.[18] Furthermore, there is evidence that when team members know each other's individual performance levels, this will lead to an improved level of overall compliance.[19] This means that when we showed the compliance level of each individual nurse to the whole nursing team, higher bundle compliance levels would have been achieved for that nursing team. Moreover, by expending the implementation period higher compliance levels could have been achieved. In studies that achieved high levels of bundle compliance periods were used of at least one year.[26] Providing timely individual feedback is labour intensive especially when the teams are large and the implementation period is long. A cost-effectiveness analysis would be recommended for future research.

Cost-effectiveness of A&F could be enhanced using information and computer technology. Zaydfudim *et al.* used an electronic monitoring and compliance system to sustain the implementation effect of the ventilator bundle.[27]

Achieving sustainability is a major challenge in implementation.[28] In our study, compliance gradually decreased in both teams during the post-implementation period. This so-called 'washout phenomenon' is a well-known factor in implementation.[28] Although compliance levels did not significantly decreased between the implementation and post-implementation period. Continuing the combined A&F strategy might have had a sustained effect on bundle implementation.[29]

Limitations

Our study was conducted in a single hospital in a 'closed-format' ICU. This limits the external validity of our results. Although the compliance outcomes of one team were not shown to the other team, the Hawthorne effect could have had influenced our results. This would result in less differences between groups and thus to an underestimation of the effect of our intervention. In this study, we did not measured the quality of the transfusion bundle itself. However, even though evidence-based interventions are added to a care bundle, in theory, this could lead to unforeseen consequences. We used bundle checklists to track compliance as recommended by the IHI.[12] There could be a discrepancy between actual delivered care and the reported care. This may have given an underestimation of compliance levels. Bundle compliance was self-reported by nurses. We did not perform a double check of how well it was done. It might be possible that self-reporting leads to an overestimation of the results. This could especially be the case in the team that received individual A&F, since these nurses knew they would receive comments on their individual performances. Our results show a difference in bundle compliance. Reasons for the differences in compliance might be that barriers exist when changing professional behaviour, affecting knowledge, attitude and behaviour.[10] We attempted to overcome the barrier of knowledge deficit by educating nurses. To create support, nurses were involved in the bundle design and in developing the educational questionnaire. Nonetheless, we did not attempt to determine nurses' knowledge or their willingness to change behaviour. Other barriers could exist which we may not have taken into account, such as leadership.[30] However, nursing management were requested not to stimulate implementation to minimize bias. Moreover, there were differences in the number of nurses who responded to the educational questionnaire. Before nurses answered the questions, they received educational materials by email. Thus, nurses might be educated in the transfusion bundle without filling out the questionnaire.

CONCLUSIONS

Compared to monthly team A&F alone, providing timely individual A&F plus monthly A&F on team level significantly improves the success of implementing a transfusion bundle on the ICU during the active period of implementation, which is expressed in significantly better short-term compliance rates. Providing timely individual A&F plus monthly A&F on team level might also be effective for the implementation of other evidence-based care bundles in healthcare. Future research could elaborate on longer duration of the intervention, the use of information and computer technology to lower costs of the intervention, and to enhance sustainability.

Competing interest

The authors declare that they have no competing interests.

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Supplementary File

Transfusion bundle

Transfusion bundle

Patient data	**Transfusion of Red Blood Cells**
Patient Identification Number:	Date of transfusion: ___-___- 20___
Name:	Time of transfusion: ___:___ hours
Date of birth:	Name of the nurse:

Transfusion bundle	**Yes**	**No**	**If no, give reason**
1. Is the haemoglobin (Hb) result considered reliable?	□	□	
2. Have you verified if the Hb transfusion threshold was reached?	□	□	
3. Have you verified if informed consent was obtained?	□	□	
4. Is the identity of the patient checked by two persons independently before transfusion?	□	□	
5. Is the blood product checked by two persons independently before transfusion?	□	□	