Enhanced feedback interventions to promote evidence-based blood transfusion guidance and reduce unnecessary use of blood components: the AFFINITIE research programme including two cluster factorial RCTs

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Scientific summary

The AFFINITIE research programme

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Scientific summary

Background

Blood components are scarce and costly interventions in hospital practice. Appropriate use of blood defines the necessary use of blood, minimising wastage and transfusions that are not indicated. Successive audits by the National Comparative Audit of Blood Transfusion (NCABT) evaluate clinical care against recognised standards and have continued to report that around one in five transfusions may be unnecessary.

Audit and feedback (A&F) is a common quality improvement strategy incorporated into health-care systems. It improves patient care by comparing performance against explicit standards and, hence, guiding action to address discrepancies. The effects of A&F are variable. A Cochrane review of 140 randomised trials found that feedback modestly improved patient care by an absolute median of 4.3%, but one-quarter of A&F strategies had had negative or null effects. There was also a paucity of head-to-head comparisons of different methods of providing feedback, and an explicit rationale for the choice of a particular feedback strategy was rarely provided.

Aim and objectives

The Development & Evaluation of Audit and Feedback INterventions to Increase evidence-based Transfusion practice (AFFINITIE) programme aimed to design and evaluate enhanced feedback interventions to promote evidence-based guidance and reduce the unnecessary use of blood components. The objectives were to:

- develop, pilot and refine two types of feedback intervention – 'enhanced content' and 'enhanced follow-on support'
- evaluate the effectiveness and cost-effectiveness of the two feedback interventions compared with current standard feedback practice
- investigate fidelity of, delivery of, and engagement with the evaluated interventions
- develop general implementation recommendations and tools for A&F programmes in the wider NHS.

Methods

Workstream 1: developing, piloting and refining feedback interventions

We applied behavioural theory, evidence and principles to specify the content of existing feedback reports from the NCABT and examined the extent to which feedback practice aligned with evidence and theory. Using a case study approach, we conducted semistructured interviews in four purposively sampled hospitals. We interviewed 25 participants with different roles in blood transfusion practice (e.g. transfusion practitioners, nurses, doctors from different clinical specialties, and managers). The interviews drew on the theoretical domains framework (TDF) and investigated who receives feedback, local responses to feedback and the factors influencing these responses. We also observed hospital meetings at which transfusion feedback was discussed. Analyses combined deductive framework and inductive thematic approaches.

Workstream 2: evaluating the effectiveness and cost-effectiveness of the feedback interventions

Workstream 1 findings informed the development of two enhanced feedback interventions. First, 'enhanced content' aimed to enhance the format and content of the feedback reports delivered to hospitals by the NCABT. This included a guidance manual for audit-writing groups on how to prepare

feedback reports for hospital staff that incorporate behaviour change techniques consistent with control theory, evidence-based A&F characteristics and behaviourally specific content. Second, 'enhanced follow-on support' aimed to enable hospital transfusion team members to respond appropriately to feedback using a web-based toolkit, with telephone support.

We evaluated the effectiveness of the enhanced feedback interventions against standard National Comparative Audit (NCA) practice, conducting two linked 2 × 2 cross-sectional cluster-randomised controlled trials embedded in the NCABT. The primary outcome was whether or not all transfusions were categorised as acceptable, which was measured at the patient level based on NCA follow-up audit data. The target sample size for each trial was 152 clusters with a mean size of 45 patients. Trial 1 focused on the audit of surgical patient blood management, including elective scheduled surgery; trial 2 focused on the audit of red blood cell (RBC) and platelet transfusions in haematology patients, largely patients with haematological malignancies and cancer.

Decision-analytic modelling evaluated the costs, benefits and cost-effectiveness of the two feedback interventions in the two trials from the perspective of the NHS. Intervention costs were derived from NHS tariffs and meeting records, whereas those of activity following feedback report receipt were estimated from a staff survey. We intended to model incremental cost-effectiveness ratios using these data and the trials' primary outcomes. We explored uncertainty around model parameters using a sensitivity analysis.

Workstream 3: investigating the fidelity of intervention delivery and engagement

The process evaluation examined the fidelity with which the feedback interventions were delivered as designed and intended, and received, understood and acted on as intended. We further assessed how contextual factors external to the interventions influenced local responses to feedback.

We assessed intervention delivery by carrying out a content analysis, monitoring uploads from the NCA website of enhanced reports and toolkit links, and monitoring and sampling the content of telephone support for enhanced follow-on.

We assessed receipt by examining the extent to which hospital staff who were receiving the feedback interventions initially engaged with the intervention (i.e. downloaded feedback reports, read them, logged in to the online toolkit, completed the tools), and understood and remembered the interventions and their content. We assessed enactment by examining the extent to which intervention recipients engaged in four behaviours targeted by the feedback interventions: disseminating feedback reports to colleagues, setting localised goals, developing action plans and re-monitoring performance locally. We used quantitative web analytics and in-depth, semistructured qualitative interviews with 55 participants (trial 1, $n = 35$; trial 2, $n = 20$; from 21 and 14 clusters, respectively). Interviews also explored internal and external contextual influences on responses to feedback. Interview analysis used inductive thematic synthesis.

Workstream 4: developing general implementation recommendations and tools

This work focused on developing relationships with and offering further advice to a number of national audit programmes, working as much as possible within existing networks. It included engagement with the Healthcare Quality Improvement Partnership (HQIP) and allied national clinical audit programmes; conducting and sharing audits of feedback methods used by national audit programmes ('audit of audits'); international collaborative meetings for audit and feedback providers, commissioners and researchers; and a national dissemination event in partnership with HQIP.

Results

Workstream 1: developing, piloting and refining feedback interventions

Existing NCABT feedback reports lacked behavioural specificity, contained only 50% of behaviour change techniques consistent with control theory, and had only two of eight feedback characteristics shown to be effective in the A&F Cochrane review. This formed the basis for developing the 'enhanced

content' intervention, which proposed six enhancements to the design and content of feedback reports. Our interviews and observations revealed considerable variation in how feedback was received, shared, discussed and responded to in hospitals. Feedback was often initially received by the hospital transfusion team, but then not disseminated to more junior clinical staff or clinicians from other specialties. Whether or not NCABT feedback was discussed in meetings also varied. Some hospitals reported not setting any clear goals or developing action plans. Key barriers to action included receiving lengthy reports that had to be amended or adapted for local use; and lack of time, teamwork and support from colleagues. Key enablers of action across all hospitals observed including having clear lines of responsibility and roles, and having strategies to remind staff about recommendations.

We concluded that hospitals could benefit from support to disseminate feedback more systematically, particularly to front-line staff whose behaviours are being audited, plus tools to enable more efficient and strategic decision-making and planning in response to feedback. Therefore, our subsequent 'enhanced follow-on' intervention involved a web-based toolkit and telephone support for hospitals planning local responses to feedback.

Workstream 2: evaluating the effectiveness and cost-effectiveness of the feedback interventions

In the surgery audit, 135 hospital clusters participated out of 189 screened. The baseline audit comprised a total of 2714 patients (averaging 20 per cluster). We randomised 69 clusters to enhanced content and 66 to standard content, and then 68 to enhanced follow-on and 67 to standard follow-on. At the 12-month follow-up, we analysed 112 (54 in enhanced content and 58 in standard content, and 54 in enhanced follow-on and 58 in standard follow-on). The follow-up audit comprised a total of 2222 patients (also averaging 20 per cluster). About 73% of patients had received a pre- or postoperative transfusion outside guidelines.

For the primary outcome, the unadjusted proportion of acceptable transfusions was 18% in clusters allocated to standard content and 18% in clusters allocated to enhanced content; the adjusted odds ratio was 0.91 [97.5% confidence interval (CI) 0.61 to 1.36]. There was no evidence of a clinically or statistically significant effect. The unadjusted proportion of acceptable transfusions was also 18% for both standard and enhanced follow-on; the adjusted odds ratio was 1.05 (97.5% CI 0.68 to 1.61), providing no evidence of a statistically significant effect. There was no evidence of effects on secondary outcomes from either feedback intervention.

In the haematology audit, 134 hospital clusters participated out of 187 screened. The baseline audit comprised a total of 4372 patients (averaging 33 per cluster). We randomised 66 clusters to enhanced content and 68 to standard content, and 67 to enhanced follow-on and 67 to standard follow-on. At the 12-month follow-up, we analysed 122 (61 in enhanced content and 61 in standard content, and 63 in enhanced follow-on and 59 in standard follow-on). The follow-up audit comprised a total of 3859 patients (averaging 32 per cluster). About 25% of patients had received a RBC or platelet transfusion outside guidelines.

For the primary outcome, the unadjusted proportion of acceptable transfusions was 74% for those allocated to standard content and 71% for those allocated to enhanced content; the adjusted odds ratio was 0.81 (97.5% CI 0.56 to 1.12). There was no evidence of a clinically or statistically significant effect. The unadjusted proportion of acceptable transfusions was 74% for standard follow-on and 72% for enhanced follow-on; the adjusted odds ratio was 0.96 (97.5% CI 0.67 to 1.38), providing no evidence of a clinically or statistically significant effect. There was no evidence of effects on secondary outcomes from either feedback intervention.

For surgery, the incremental cost of enhanced compared with standard content feedback was £219 per site and of enhanced follow-on compared with standard feedback was £18 per site. For haematology, these figures were £248 and £198, respectively, for each pair of interventions. For primary outcomes, the enhanced feedback interventions were dominated by the standard intervention in the cost-effectiveness

analyses (i.e. costing more and being less effective). Sensitivity analyses found marked uncertainty around most of the parameters used.

Workstream 3: investigating the fidelity of intervention delivery and engagement

Both feedback interventions were delivered with high fidelity. Both interventions also had good initial receipt (i.e. exposure and understanding), but subsequent engagement was low, particularly for enhanced follow-on. Enactment appeared good, with hospitals across all trial arms engaging to varying extents in the target behaviours in response to feedback. However, these were driven by contextual factors, particularly the dissemination of national guidelines, rather than by the enhanced interventions themselves. Therefore, the interventions did not appear to produce any benefits over and above background quality improvement activities.

Participants generally preferred enhanced content reports over standard reports. Interviewees in part attributed low engagement with feedback to limitations in the upstream audit processes, whereby doubts about the credibility of the blood transfusion audits undermined the case for change.

Workstream 4: developing general implementation recommendations and tools

Our findings highlighted key methodological issues facing national audits, such as ensuring that there were clear definitions of standards, data validity and promoting local action following feedback. We conducted an 'audit of audits' to compare adherence to a set of evidence-based and good practice criteria for 23 national audit reports in 2015 and 20 reports in 2017. Although we identified a range of improvements over time in the content of audit reports (e.g. in the use of achievable benchmarks and the specification of action plans), we also identified areas for improvement (e.g. reducing time intervals between data collection and feedback).

We led a national symposium with the HQIP to share all findings. Participant suggestions largely echoed findings from the intervention development work and the process evaluation (e.g. ensuring credibility of audit measures, delivering timely feedback and offering proactive support for local teams to act of feedback findings). We then produced guides to enhancing feedback that were provided to the audit report writing groups.

Conclusions

We have undertaken a robust evaluation of ways to enhance feedback as part of a national A&F programme in blood transfusion. We identified considerable variation in how feedback was received, shared, discussed and responded to in hospitals. We designed and implemented two relatively low-cost behaviourally modified interventions aimed at augmenting feedback, at the levels of enhancing the content of the reports and the follow-on support in hospitals. The risk-adapted approaches to participation in the national cluster-randomised trial supported high coverage and increased the generalisability of the findings. However, both of the enhanced feedback interventions were found to be no more effective than standard feedback in reducing the inappropriate use of blood in two linked national cluster randomised trials. Despite reduced power, the 95% CIs excluded the minimally important clinical effects specified in the design for enhanced content. The absence of intervention effects is likely to be due to lack of credibility of both the audit standards and the data validity, variable (and often poor) enactment of feedback at hospital sites, and possibly reduced power. The lack of an effect of the enhancements was driven in part by factors outside the nature of the interventions. It may well be that our low-cost interventions have the potential to enhance feedback, but our robust assessment (as successfully delivered) did not detect any effect in our trial setting of a national audit of blood transfusion.

Limitations included the number of participating clusters and loss to follow-up of clusters, compromising statistical power and validity; incomplete audit and costs data contributing to trial outcome measures; and participant self-selection, reporting and recall biases in the process evaluation interviews.

The algorithm used to assess the appropriateness of transfusions followed standard practices for national audits, but might have failed to correctly assign all transfusions. The economic modelling used a short time horizon and lacked one-way sensitivity analyses on key input parameters.

Implications for health care

Although there remains an evidence base underpinning A&F, including different approaches to enhance the effects of A&F on patient care, and on which national audits can draw, our work has provided insight into the complex range of steps required to support credible national A&F and has demonstrated ways of making feedback reports more accessible to recipients. Although both of our enhancements were feasible, and modelling indicated that they could be relatively inexpensive per hospital site to deliver, they are unlikely to work in the absence of more favourable contexts, for example where audit data are perceived as more valid and reliable indicators of performance. Given that participants generally preferred enhanced content reports over standard reports, there may still be merit in changing report format and content to enhance the comprehension and usability of NCABT feedback.

Recommendations for research

Further head-to-head comparisons of different feedback interventions are needed within national clinical audit programmes to identify cost-effective ways to increase the impact of such interventions. Future studies could develop and evaluate interventions to promote meaningful recipient engagement and support focused local action in response to feedback. Pilot studies to ensure sufficient fidelity and identify likely effective 'doses' of feedback interventions may increase the likelihood of definitive trials being able to investigate cost-effectiveness robustly.

Trial registration

This trial is registered as ISRCTN15490813.

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