

**Can we do better? Bridging the research to practice gap in patient blood management – optimising ‘audit & feedback’ and the challenges of undertaking a national cluster randomised controlled trial**

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On behalf of the AFFINITIE Programme

Institute where the work was conducted: NHS Blood and Transplant / City University London / University of Leeds

Short Title: Optimising ‘audit & feedback’

Disclosure:

No conflicts declared. This paper summarises independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1210-12010). The views expressed are those of the author and do not necessarily those of the NHS, the NIHR or the Department of Health.

Sources of Research Support: Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Grant Reference Number RP-PG-1210-12010).

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Acknowledgements and author contributions: Simon Stanworth is the chief investigator of the AFFINITIE programme, and composed the first draft. Contributions to the manuscript were added by Fabiana Lorencatto, Jill Francis, Stephen McIntyre, Riya Patel and James Smith (School of Health Sciences, City University of London), John Grant-Casey (NCA), Lauren Moreau, Suzanne Hartley, Isabelle Smith, Thomas Morris, Amanda Farrin and Robbie Foy (Clinical Trials Research Unit / Leeds Institute for Health Sciences, University of Leeds) on behalf of the AFFINITIE programme.

## Abstract

Audit and Feedback (A&F) is a frequently used quality improvement strategy, aimed to improve patient care and outcomes. The impact of A&F has been subjected to research scrutiny; systematic reviews document only modest and variable effects, despite the likely high costs of A&F programmes, such as those undertaken nationally. To understand and enhance A&F a programme of research termed AFFINITIE “*Development & Evaluation of **A**udit and **F**eedback **I**nterventions to **I**ncrease evidence-based **T**ransfusion practice*”; <http://www.ccf.nihr.ac.uk/PgAR/about/Pages/Abstract.aspx?ID=12588>) has been completed. AFFINITIE adopted a multidisciplinary approach that applied behavioural theory and evidence to optimise the design and delivery of feedback on transfusion practice. These interventions were then tested by embedding them in the context of transfusion national audits in two national randomized cluster trials. The audit topics were pre-operative surgery management and use of blood in patients with haematological malignancies.

Emerging findings included the scope to improve the design of feedback reports by the inclusion of additional behaviour change techniques and increasing the specificity and relevance of feedback (i.e. clarity around who the feedback is targeted at, providing feedback only on behaviours relevant to audit standards, selecting fewer, more concrete, and relevant standards). Other findings recognised the importance of robust data collection based on agreed and clearly stated standards. Also, given wide variation in how hospital received, shared and responded to feedback, a consequent need was identified to better support hospitals to plan their response to feedback, including disseminating the reports to all relevant stakeholders with agreement on selecting local goals and plans.

ISRCTN Registration: 15490813 <https://doi.org/10.1186/ISRCTN15490813>

## **Introduction**

Every clinician recognises that there are gaps between actual and recommended evidence-based practice. Clinicians are typically on the receiving end of many approaches, which aim to close this gap, and may often be involved in designing and delivering them. Such approaches include clinical guidelines, education, audit and feedback, and computerised decision support, many if not all commonly applied in transfusion practice. (1-3)

As for any type of intervention, they can and should be subjected to research scrutiny as is commonly expected now for new drugs or blood components. So, how effective, are these interventions to change practice, and specifically what do we know about their impact on transfusion practice? Equally important, what do we know about the relative or comparative (cost-) effectiveness of different interventions to practice change? For example, if a hospital has limited resources, which approach to optimise practice should be supported; or which interventions would be considered best value for money? A further consideration is to understand which interventions work best in a resource rich country setting at a hospital, such as backed up by heavy investment in IT, compared to a rural and resource poor setting.

Arguably, given the increasing numbers of completed randomised trials evaluating use of red cells in transfusion (4, 5), questions regarding the broad theme of implementation are now equally, if not more, pressing. How do we stop clinicians giving transfusions to patients when the evidence indicates limited or no benefit (or conversely, although less of a problem, to ensure transfusions are only given to patients when really required)?(6)

## **Research questions**

Two main research considerations follow on from this background, and form the basis of this article. First, which types of rigorous clinical studies can help us understand and compare the effects of different interventions to change practice? The typical individual patient randomised controlled trial provides the highest level of evidence to inform the effects of new drugs, or in transfusion medicine, to understand the benefits and risks of different thresholds of red cell transfusion. However, these study designs cannot be readily applied to interventions that operate at the level of a department or hospital. The

literature is replete with quality improvement reports, typically using uncontrolled designs and describing initiatives to improve practice in self-selected sites, such as the results of audits in transfusion. Most clinicians and health care professionals would readily recognise that there are many limitations to these types of publications as reliable or robust sources of best practice. In the wider research landscape, publications of negative studies are well recognised as equally important for patients. Audit reports, however, are likely to be influenced by publication bias; there may be less motivation to publish unsuccessful audit outcomes.

Second, do we know enough about what forms or constitutes a successful intervention to change and optimise practice, such as in blood transfusion? For example, reporting delivery of 'education' provides insufficient detail. Furthermore, do 'educational' sessions at conferences (including the recent ISBT meeting) directly inform practice? Addressing knowledge deficits by delivering education is rarely the only factor influencing clinical practice, and therefore it seems unlikely that education can function as a sole strategy for implementing change and improving care. Interventions are much more likely to be effective if they target the key factors driving the behaviour of interest, and there are a wide range of influences on clinical practice behaviours that would require additional intervention strategies. (1, 7)

### **Audit and Feedback**

Audit and Feedback (A&F) is a strategy for changing practice. A&F is defined as 'providing a summary of the clinical performance of healthcare provider(s) over a specified time period'. (1) It is one if not the commonest quality improvement strategy, to improve patient care and outcomes. A&F has been incorporated and applied at every level of health care, and ranges from small local audits within individual healthcare departments or organisations to national or indeed international clinical audits. It can be applied in many country settings, from high to low resource. It is very widely used in transfusion medicine. In England, National Comparative Audits (NCA) of transfusion practice have been conducted annually by National Health Service Blood & Transplant (NHSBT) for many years.

A Cochrane and other reviews of 140 randomised trials, conducted worldwide and targeting many different types of healthcare problems, indicates that A&F generally

works. (1, 8, 9) However, it typically has only modest effects on healthcare although these changes can make a real difference at the population or healthcare system level, especially if improvements accumulate over time with repeated audit cycles. Compared with other approaches to improving healthcare, it is potentially cost-effective, especially if routinely collected data are used for audit. However, there is a need for more health economics focused research.

The Cochrane review indicates that A&F had quite large effects on practice in a quarter of studies but little or no effect in another quarter. This finding is problematic for those leading audit programmes, as it is hard to predict when feedback will be more effective. There are still major uncertainties about how to make A&F a more reliable approach to improvement and how to enhance its effects. Equally importantly, the effectiveness of A&F has not improved over time, suggesting that many of the potential limitations to applying more effective A&F are not known. (10)

Moreover, A&F has been designed and delivered in many ways, often without a clear rationale for why a particular A&F strategy has been chosen, detailed description of 'what' comprised the A&F intervention or how it was delivered and engaged with. (11-14) Without such information, it is difficult to confidently and more accurately interpret the effects of A&F, or replicate and scale up interventions in new settings. It has in turn been argued that the design, delivery and evaluation of A&F can potentially be optimised through the application of theories, evidence and principles of behaviour change. (15) Achieving this requires a multidisciplinary approach (7), and in the next section we will describe such an approach that is completed.

## **AFFINITIE**

A large body of research has been undertaken to explore the features and impact of Audit & Feedback. This programme is termed "*Development & Evaluation of **A**udit and **F**eedback **I**nterventions to **I**ncrease evidence-based **T**ransfusion practice*" (AFFINITIE; <http://www.ccf.nihr.ac.uk/PGfAR/about/Pages/Abstract.aspx?ID=12588>). The AFFINITIE research programme focussed on two main areas related to A&F. First, to address the 'active ingredients' of A&F, we adopted a multidisciplinary approach that applied behavioural theory and evidence to optimise the design and delivery of feedback. Second,

we applied these interventions by embedding them in the context of an on-going transfusion NCA, and testing in a (unique) national randomized cluster trial. (see below).

In outline, the AFFINITIE programme of research comprised four workstreams that draw on the systematic, methodological approach recommended in the UK Medical Research Council (MRC) guidance for developing and evaluating complex interventions (Craig et al. 2008)<sup>17</sup>: 1) intervention development; 2) feasibility and piloting; 3) evaluation; and 4) implementation.

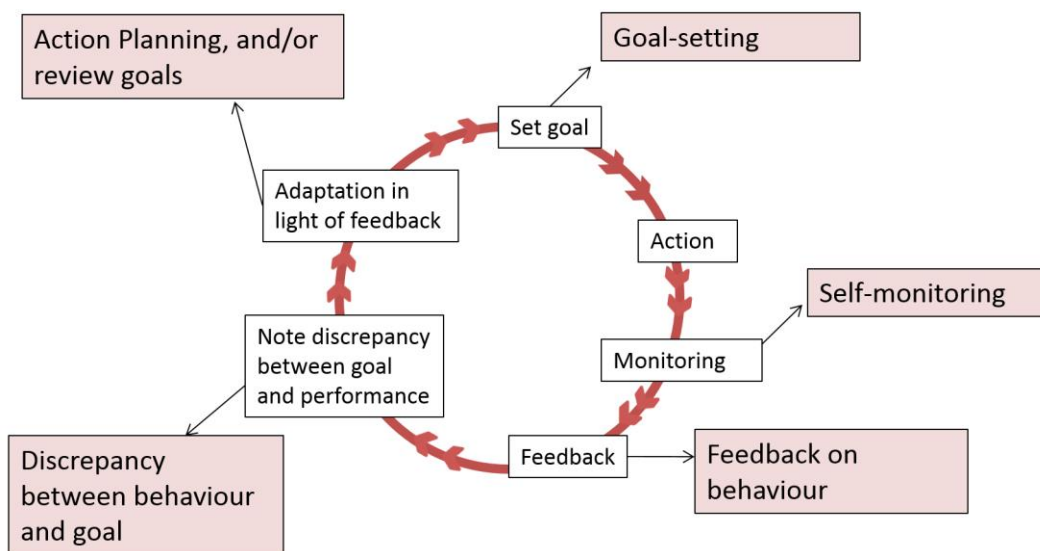
### **Behavioural theory to optimise audit & feedback**

Theory can guide the development of interventions by highlighting activities designed to change behaviour (i.e. behaviour change techniques; BCTs) that are likely to increase effectiveness. (16, 17) There are numerous behavioural theories, some of which have been used to describe how A&F may operate. One such theory is Control Theory (18-20), which has been argued to map onto the typical processes involved in an A&F cycle. (8) According to Control Theory, behaviour is driven by goals. If people perceive a discrepancy between their current behaviour and goal behaviour (or are made aware of this through feedback), they will attempt to reduce this discrepancy by changing their behaviour. This may lead to people eventually achieving their goal or ‘giving up’ if the discrepancy is too great or, for example, they lack the motivation or capability to reduce this discrepancy. This process may operate as a ‘feedback loop’ in which people who are provided repeated feedback on their behaviour may attempt to reduce discrepancies between their actual and goal behaviour in successive cycles.

Figure 1 shows how Control Theory can be applied to A&F interventions, and also illustrates the BCTs associated with each stage. In the first step of a typical A&F cycle, a goal is set (BCT: goal-setting), this involves setting an audit standard against which clinical performance will be assessed. The second step involves auditing current clinical performance (BCT: monitoring of behaviour by self or other). The third step involves preparing and providing feedback on current performance (BCT: feedback on behaviour or outcomes of behaviour), which includes a comparison of current performance against the set audit standard(s) (BCT: discrepancy between behaviour and goal).

Importantly, if standards/goals are not being met, a key step is planning a response to minimise discrepancies, for instance, by developing action plans (BCT: action planning) or identifying

problems causing discrepancies as well as appropriate solutions (BCT: problem solving). (8, 21) After hospitals respond to feedback, additional A&F cycles may occur in which practice is re-monitored and additional feedback is provided so that hospitals may assess whether discrepancies have decreased. There is evidence that interventions containing more BCTs consistent with Control Theory are more effective for changing and maintaining repeated behaviours. (22, 23) Such techniques are also consistent with the Cochrane Review of A&F, which found that feedback is more effective when accompanied by specific action plans and goals. (1) However, it is unclear the extent to which existing A&F interventions delivered by the current NCA of blood transfusion incorporate such theoretically consistent and evidence-based techniques.



**Figure 1 BCTs consistent with Control Theory.**

### **Behavioural theory and transfusion audit & feedback**

One of the first objectives of the first workstream in AFFINITIE was to investigate whether current feedback reports delivered by NCA for blood transfusion audits contain theory-based components, and evidence-based feedback characteristics. (21) This involved conducting a content analysis of twelve feedback reports delivered as part of three previously conducted A&F cycles. We coded for the presence/absence of 11 BCTs consistent with Control Theory using a behavioural science framework- the BCT taxonomy v1 (24) as a coding



framework. On average feedback reports contained 41% of techniques consistent with control theory. The most frequently included techniques corresponded to the first half of the Control Theory loop (i.e. setting goals/standards, providing feedback on behaviour/outcomes; n=11 reports). The least frequent techniques corresponded to the second half of the Control Theory loop, such as providing recommendations, action planning, problem solving, reviewing goals (n=0 reports). (25)

There are also specific feedback characteristics that have been demonstrated to be effective in A&F, these included: provide feedback in verbal and written format; repeated/frequent feedback; inclusion of peer average/achievable bench mark comparators (1). We therefore coded the reports to identify whether these feedback characteristics are used. On average feedback reports contained 23% of these evidence-based feedback characteristics, with most frequently being peer comparison, but least frequently were verbal and written format, peer/supervisor source and repeated/frequent feedback

There is also evidence that guidelines are more likely to be implemented if they are phrased in a behaviourally specific way, i.e., it is clear who needs to what, differently to whom, when/how often and where. This is known as TACTA, which stands for Target, Actor, Context, Timeframe and Action. (26) We therefore examined the behavioural specificity of the wording of any audit standards, feedback on performance and recommendations for change included in the feedback reports. Overall, behavioural specificity was low, and although the action (i.e. 'what) and target group (i.e. whom/ patient group) were often stated, the actor (i.e. 'who;' clinical professional group responsible for performing the action) and time (i.e. 'when') were very rarely stated. (25)

### **Applying behavioural theory to enhance transfusion audit & feedback**

We used these findings to then used to develop the AFFINITIE intervention 1, named 'enhanced content'. This first intervention, termed 'enhanced content', aimed to improve the format and content of the feedback reports delivered to hospitals by the NCA of blood transfusion. It consisted of a guidance manual for audit-writing groups on how to prepare feedback reports for hospital staff that include behaviour change techniques consistent with Control Theory, evidence-based A&F characteristics, and behaviourally specific content.

However, crucially, the effectiveness of feedback interventions depends on hospitals engaging with any feedback that is delivered. For NCA programmes delivering A&F on scale, there is likely to be widespread variability in how different hospitals and individuals respond to feedback. Yet, the majority of A&F research to date has focused on investigating the design and content of A&F (1, 12, 15) rather than how it is received, understood, and responded to. Therefore, we also applied behavioural theory and frameworks to investigate how hospitals in England currently respond to A&F delivered by the NCA of blood transfusion. (21) Using a case-study approach, we conducted semi-structured interviews in four hospitals, purposively sampled to represent hospitals of different sizes, staffing and resource availability. We interviewed 25 participants from the range of different roles involved in blood transfusion practice (e.g. transfusion practitioners, blood bank/lab managers, nurses, and doctors of different levels of seniority from haematology and other clinical specialities, such as obstetrics and anaesthesia). The interviews aimed to investigate who receives feedback, how feedback is responded to locally, and the factors influencing this response. The interview questions were based on the Theoretical Domains Framework of behaviour change. This is another theoretical framework that has combined 33 behaviour change theories into 14 domains and has been widely used to identify factors that can influence clinical practice behaviours (including blood transfusion previously) particularly related to implementation of recommendations. (27-30) In each hospital, we also observed meetings where transfusion feedback was discussed (e.g. hospital transfusion committee meetings). (21)

These findings demonstrated considerable variation in how feedback was received, shared, discussed and responded to in hospitals. Dissemination of feedback was identified as a key barrier. Feedback was often initially received by the hospital transfusion team, but then not disseminated onwards and more widely to more junior clinical staff or clinicians from other specialties. Indeed, many key individuals involved in prescribing transfusions stated that they never received feedback from a national audit. Whether or not feedback from the NCA was discussed in meetings also varied. Some hospitals reported not setting any clear goals or developing action plans. Key barriers to this included receiving lengthy reports that had to be amended or adapted for local use, lack of time and team work, engagement and support from colleagues. Key enablers of action across all hospitals observed including having clearer lines of responsibility and role clarity, plus strategies to remind staff about recommendations.

The second intervention ‘enhanced follow on support’ recognised that hospitals could benefit from support to disseminate feedback more systematically, particularly to frontline staff whose behaviours are being audited, plus tools to enable more efficient and strategic decision making

and planning in response to feedback. Therefore, this second intervention, developed as part of AFFINITIE, aimed to provide such tools. It consisted of a web-based Toolkit, with individual tools that aimed to enable members of the hospital transfusion team to lead an appropriate response to feedback, in their hospital context.

In summary, it was clear that current A&F processes do not reflect current theory and evidence about effectiveness, and response to feedback was variable and limited. There were opportunities to optimise feedback to promote change in transfusion practice. Based on the findings from theoretically-informed analysis of existing feedback reports, and observations of hospital meetings where transfusion feedback was discussed, plus interviews with staff, we developed and tested two novel interventions in a national cluster randomised trial.

1. Intervention 1 ('enhanced content') – guidance for designing feedback reports with theory- and evidence-based content as well as the resulting feedback reports
2. Intervention 2 ('enhanced follow-on') - consisted of practical web-based tools to support hospitals' response to feedback

### **A cluster randomised trial alongside two national audits of transfusion**

A cluster trial design was used to evaluate the effectiveness and cost effectiveness of the two different interventions of enhanced feedback against standard national comparative audit practice. A cluster design was chosen as the target of the intervention is a group of health care professionals working in an individual NHS Trust or Health Board. The national study consisted of two linked 2x2 cluster-randomised controlled trials embedded in national comparative audits of blood transfusion (NCABT). The primary outcome was whether a transfusion was categorised as necessary or not (binary measure) and was measured at the patient level based on NCA follow-up audit data. Full methods are reported elsewhere. (31) Trial 1 audited surgical patient blood management including elective scheduled surgery; trial 2 audited the use of red cell and platelet transfusions in haematology patients.

### **Recruitment strategy and ethics**

The study team considered a range of ethical and resource considerations unique to this type of national cluster study. The study team met with representatives from the Regional

Transfusion Committees across England and the clinical research networks to discuss recruitment to the trial and to identify barriers to participation. Some of the main issues related to ethics and governance, resource at a hospital level, and the need to ensure that procedures were proportionate for this type of study, as follows.

The interventions were not directed at individual patients themselves, but instead designed to assess the eventual impact on patient care as a result of any change in clinician behaviour. Therefore, the interests of patients were guarded by healthcare professionals' normal duty of care. The aim of the study was to change professional practice in line with evidence-based recommendations and did not incur any additional risk above standard practice. The anonymised data used to evaluate the feedback was collected as part of an established national audit programme, which operates within robust information governance arrangements. There was concern that the role of a (traditional) local Principal Investigator could have drawn additional attention to the feedback and hence act as an unintended influence on local transfusion practice, thereby diluting any observed effect size of the interventions. Therefore, for this study, the chief investigator agreed to take on overall responsibility for the research activity at each cluster.

### **Success of the recruitment strategy and interpretation of the analysis:**

Recruitment of NHS Trusts was very good, and high numbers of NHS Trusts participated in the NCA of surgery and haematology. For Trial 1, 152 NHS Trusts agreed to take part in the study, of which 141 participated in the audit; baseline audit cases were collected on 2714 patients. For trial 2, 144 NHS Trusts agreed to take part in the study, of which 138 participated in the audit; baseline audit cases were collected on around 4000 patients.

The results from the trial are currently completed, but the interpretation of these results relies heavily on how the hospitals respond to feedback (some hospital teams might just discard/ignore audit findings, and this could be interpreted as a poorly designed feedback report, but which may not be the case). To address this, alongside the trials we conducted a parallel process evaluation, which will help us to understand whether the developed interventions were delivered and engaged with as intended.

(32)

We have used a mixture of methods to examine the extent to which hospitals received and understood the two interventions (e.g. Did staff read the feedback reports? Access the Toolkit? Understand the feedback provided/purpose of the tools?); perceived acceptability of the two interventions; how the interventions were enacted (e.g. Were the reports adapted? Were the tools in the Toolkit were completed? What goals and action plans were set locally? How have these been subsequently implemented/acted upon?); and lastly, what broader contextual factors influenced response to the interventions (e.g. publication of new guidelines). Methods included a survey administered to all participating clusters, in-depth qualitative interviews with a sub-sample of clusters, and web-analytics (i.e. statistics on number of feedback report downloads, visits to the Toolkit, page views, etc). These findings will support interpretation of observed trial outcomes.

## **Conclusion**

In summary, findings from many audits continue to highlight and document enduring discrepancies with clinical guidelines (33); raising in turn important questions about the effectiveness of current A&F strategies in the context of blood transfusion. AFFINITIE describes a pragmatic approach to enhancing and testing the effectiveness of A&F strategies, using the rigour of cluster-randomised trial design. The risk-adapted approaches to participation in the national cluster trial supported high coverage and increased generalisability of the findings. AFFINITIE provides a framework for implementation research aimed at addressing the often poor and slow uptake of research into patient blood management practice.

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