NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Blood transfusion

Date of Quality Standards Advisory committee post-consultation meeting:
15 September 2016

2 Introduction

The draft quality standard for blood transfusion was made available on the NICE website for a 4-week public consultation period between 23 June 2016 and 20 July 2016. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 20 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

5. For draft quality statement 4: Is there evidence that people are being given prophylactic platelet transfusions unnecessarily when they have a platelet count above 10×10^9, are not having invasive procedures or surgery, and have none of the contraindications?

6. For draft quality statement 5: Is this area of quality improvement sufficiently specific to blood transfusion to merit a statement?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Stakeholders highlighted their support for the prioritised areas.
- Amendments required for the introduction and supporting information sections were highlighted e.g. Prothrombin complex is referred to within the introduction as a blood product rather than a blood component concentrate.
- Additional areas for quality improvement suggested.

Consultation comments on data collection

- Inadequate recording and monitoring processes in many hospitals was highlighted as a potential problem in the implementation of the measures.
- One stakeholder commented that they were unaware of systems in place to collect data for the proposed quality measures.
- Concerns were raised that data linkage between disciplines e.g. haematology and biochemistry may cause problems for data collection.
- A stakeholder commented that the information required to support the measures currently can only be found in patients notes so would have to be collected through clinical audit.
- Outcome measures may be significantly impacted by confounding factors.

Consultation comments on resource impact

- All the draft statements could be achievable with current resources with the possible exception of statement 3.

- The additional resources required for audits to be undertaken, as well as resourcing for education and feedback sessions with clinicians and staff involved with patient management were highlighted.
- For many of the statements there needs to be an effective change management programme including a restructure of systems to enable change to be achieved requiring clinical and stakeholder input.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People with iron deficiency anaemia are offered oral iron before and after surgery.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- Accurately reflects one aspect of the need to address iron deficiency anaemia in iron deficient surgical patients.
- Some concern around data that suggests oral iron is not effective following surgery so routine prescription of oral iron post operatively may unnecessarily expose patients to harm by increased incidence of side effects that are common in oral iron.
- Concerns about stipulating oral iron alone and so it was suggested this should be changed to iron supplementation.
- Suggested inclusion of additional details of what department/staff group is responsible for collecting this information.
- Details around timescales required as offering oral iron only days before surgery would not be deemed appropriate treatment to correct pre-surgical iron deficiency anaemia.
- Clarification about the use of the word infection within the rationale was requested.
- Suggested additional measure around number of patients with anaemia who received a ferritin investigation.

5.2 Draft statement 2

Adults who are having surgery and expected to have moderate blood loss are offered tranexamic acid.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Some stakeholders expressed uncertainty over whether tranexamic acid is recommended in all types of operations for all patients.
- Concerns this statement may have limited impact given that only one third of transfusions are given to surgical patients.
- Need to define contraindications for tranexamic acid use.
- It was requested that moderate blood loss should be defined within the statement instead of in the supporting information.
- It was queried where the responsibility of making sure this happens would lie.
- Outcome measures will be significantly impacted by confounding factors.

5.3 Draft statement 3

People who receive a single-unit red blood cell transfusion, or an equivalent volume, are clinically reassessed and have their haemoglobin levels checked after the transfusion.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Concerns that the value of single unit transfusion policy is not universally accepted, and excludes those receiving a larger transfusion volume.
- Concerns that the statement does not indicate what outcome is required from this assessment, or what the relevant actions should be that are informed by that assessment.
- It is not clear if this quality statement relates to all red cell transfusions or just to transfusions specified as ‘single-unit’.
- A timeframe should be added to the statement for clarity.
- Units referenced should be 70g/L and 70-90g/L.
- Concerns that the wording used in the rationale appears to link the restrictive transfusion and two and single unit transfusions which is not always the case.
- NHS Blood and Transplant highlighted they are already measuring this in their present National Comparative Audit of Patient Blood Management in adults undergoing elective surgery.
- For the outcome measure the infections referred to requires further clarity.

5.4 Draft statement 4

People with a platelet count below 10×10^9 per litre who are not bleeding or having invasive procedures or surgery are offered prophylactic platelet transfusions.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- Concerns that this statement could encourage inappropriate use as prophylactic platelet transfusions are not appropriate for all patients e.g. chronic stable thrombocytopenia without a history of bleeding. Suggested rewording: 'People with a platelet count greater than 10×109 per litre who are not bleeding or having invasive procedures or surgery are not offered prophylactic platelet transfusions.'
- It was suggested that the reference to bleeding or invasive procedures could be removed from the statement. As this is irrelevant if count is below the specified threshold.
- A list of conditions that would exclude people from this statement should be included.
- Rationale and outcome measure requires rewording as 'prophylactic platelet transfusions help prevent serious adverse events associated with bleeding and not associated with transfusion'.
- NHS Blood and Transplant highlighted they are already collecting data around this in the present National Comparative Audit of Patient Blood Management in adults undergoing elective surgery.

Consultation question 5

Stakeholders made the following comments in relation to consultation question 5:

- Overall there was uncertainty about whether or not people are being given prophylactic platelet transfusions unnecessarily with some stakeholders commenting there is a lack of evidence to support this. However, evidence was highlighted from the National Comparative Audit of use of platelets in haematology from 2012 and again in 2016 showing that patients are transfused with platelets unnecessarily.

5.5 Draft statement 5

People who may have or who have had a transfusion are given verbal and written information about the benefits and risks of transfusion.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Suggested reword to 'People who may need or who have had..'.
- It was suggested information on possible alternatives to transfusion should also be included.
- It should be made clear that patient valid consent (which includes the provision of written information about the benefits and risks) must, wherever possible, be obtained pre-transfusion.
- This should highlight that people who have sample taken for other requirements e.g. antenatal screening should be excluded.
- The need to ensure that patient confidentiality is maintained when applying this statement was highlighted.
- Information for the measures would currently be in patients notes so would be hard to measure apart from sporadic clinical audit. However previous difficulties in collecting data around information providing was also highlighted

Consultation question 6

Stakeholders made the following comments in relation to consultation question 6:

- Overall it was felt that sufficient evidence exists to merit a statement on consent specifically for transfusion. It was commented that individuals should, wherever possible, be given this information. It was also felt this would also help to trigger in patient's minds whether they did or did not have a transfusion for later clinical episodes.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- A statement around acute decision making or clinically pressing and important behaviour regarding transfusion practice was suggested e.g. measuring platelet transfusion rate among thrombocytopenic patients with platelet count<50 who have ongoing moderate bleeding or measuring rate of plasma transfusion in massive haemorrhage setting.
- Possible additional statement: “People who receive a blood transfusion must be correctly identified at the time of blood sampling for pre transfusion testing and again at the commencement of each transfusion event.”
- A statement around the observation and monitoring of patients receiving transfusions was also suggested.
- Statements focused on blood transfusion in neonates and preterm infants.
- Monitoring whether patients benefit from their blood transfusion or otherwise (e.g. symptom resolution, functional improvement).

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Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	ABMUHB	General	'Why this quality standard is needed' Para.1 line 2 change to 'Blood donations are collected and stored until needed.'
2	ABMUHB	General	'Why this quality standard is needed', Para.2 line 1 change 'include' to 'are' Prothrombin complex concentrate (PCC) is included as a blood component. PCC is not processed directly from blood donations, but from pooled plasma concentrates. One component which is produced from whole blood donations but is not listed is granulocytes. These are one of the white cell types in the blood and may be used as supportive care in the presence of severe or chronic infections as a consequence of bone marrow failure. Para. 2 line 2, suggest to remove 'prothrombin complex concentrate' and replace with 'granulocytes'. Granulocytes are not directly relevant for these particular quality standards and as such this information may not be required. The addition of a sentence describing specific products used to complement blood component use such as PCC, factor concentrates and fibrinogen concentrate may be appropriate, as PCC is included in NG24, section 1.6. Para.2 line 3 remove 'used in a' and change 'transfusion' to 'transfused' Para.2 line 5 change 'would' to 'may'
3	ABMUHB	General	'Why this quality standard is needed' Para.3 line 4 It is not clear why data from 2002 on the level of issued units should be considered relevant as part of the introduction to a quality standard recommendation for publication in 2016. Presumably if an estimated figure for issues in 2002 can be calculated, then the same would be true for 2015, and would be a more appropriate measure.
4	ABMUHB	General	'Why this quality standard is needed' Inclusion of the year 2015/16 may be unnecessary
5	ABMUHB	General	'Why this quality standard is needed', final paragraph, bulleted list

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments[1]
			The quality standard is expected to contribute to improvements in the following outcomes: □ blood transfusion rates The suggestion that an improvement in blood transfusion rates is an improvement in quality is not justified as there is no direct evidence to support this as a general statement. In fact there is evidence from SHOT that under transfusion is associated with morbidity and mortality. The desirable outcome should be contribute to ensuring appropriate blood transfusion, as the need, or not for blood must be assessed in the clinical context on an individual basis. The desired outcome of improving the adverse event rate related to blood transfusion should be the primary point noted in this list
6	ABMUHB	General	'Coordinated services' sub section, 'Role of families and carers' After 'appropriate' add 'and where possible with the patient's agreement.'
7	ABMUHB	General	The quality statements are drawn from stakeholder feedback on the NICE guidance and as such are appropriate within the scope of the 5 areas highlighted. There are other areas relating to improving transfusion practice that could also be considered such as the fundamental aspect of correct patient identification, and getting the process right first time. The emphasis throughout the standards seems to be on reducing transfusion use, and it would be more appropriate to focus on appropriate use which may not necessarily mean less.
8	British Society for Haematology	General	(Page 3) – there is no number 2
9	British Society for Haematology	General	The phrase "The Health and Social Care Act 2012" on page 4 should be in italics
10	British Society for Haematology	General	Mr Graham Donald is a Ley member – should be Lay member
11	British Society for Haematology	General	Prothrombin complex concentrate is a blood product, rather than a blood component. The two should never be confused.
12	British Society for Haematology	General	Change offered to "investigated and treated as appropriate
13	British Society for Haematology	General	change appropriate to "and assuming patient confidentiality is maintained."
14	British Society for	General	Sue Robinson – should be Dr Sue Robinson

ID	Stakeholder	Statement number	Comments[1]
	Haematology		
15	British Society for Haematology	General	Timothy Walsh – should be Prof Timothy Walsh
16	British Society for Haematology	General	My main overarching concern (relating to the whole of this Quality Standard) is that many hospitals will struggle to measure these standards purely because they have inadequate recording and monitoring processes. Therefore these standards will be significantly hampered and realistically impossible unless a strong recommendation regarding development of IT systems and non paper data entry - with IT infrastructures to enable data reporting and extraction, and also enhance patient safety. Whilst hospitals may strive to meet these standards, their ability to measure and report their success will be near impossible. A different quality statement could be included instead; e.g. use of IT - linked to national indications which can challenge requests outside of these nationally agreed indications.
17	British Society for Haematology	General	Why is this quality standard needed - 2nd paragraph PCC is not a blood component - it is a blood product. A separate definition is needed to make this factually correct.
18	British Society for Haematology	General	Why is this quality standard needed - 3rd paragraph The last sentence references data from 2002 - this data is very old (14 years ago) - is this correct??
19	British Society for Haematology	General	Blood product rather than a blood component?
20	British Society for Haematology	General	Should also refer to BCSH guidelines
21	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
22	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	General	Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? These are reasonable areas for consideration however the data is not necessarily easily obtainable.
23	Institute for Biomedical Sciences – Specialist	General	Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?

ID	Stakeholder	Statement number	Comments[1]
	Advisor for Blood Transfusion		LIMS data can be difficult to write extract routines for (high variation between systems), also linkage between Pathology disciplines (e.g. transfusion and haematology) varies and linkage with clinical systems (patient notes, clinical area data) is often none existent (except for those LIMS which are built into whole hospital information systems (not many of these around the country).
24	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	General	Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any treatment. Please describe any potential cost savings or opportunities for disinvestment. Due to the isolation of the data from each other and that some may not be in electronic format (consent, advice etc. maybe in paper format in patient's notes), these statements would be difficult to prove except by scheduled clinical audit. Most of these would normally be done by Transfusion Practitioners in Hospital Transfusion teams and most of these are already under-resourced and over stretched already. If these standards came with financial incentive/penalty then that might be used to build in the resources to enable the required proof to be collected on a scheduled basis. The benefit of these proposals is that they should lead to more appropriate transfusion prescription and this is likely to have a financial benefit in reducing blood component costs to the hospitals.
25	National Blood Transfusion Committee	General	Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? Yes in general but a standard around the appropriate use of FFP might be included. Suggest include all forms of iron supplementation rather than just oral iron in standard 1
26	National Blood Transfusion Committee	General	Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place? Not for all measures. Some will require quite detailed searches of notes and hospital databases. E.g. Consent will generally require notes review. Use of tranexamic acid requires extensive searching of operations performed and prescription chart review. It may be possible to incorporate use of tranexamic acid into a pre-operative checklist to capture this prospectively in due course (or utilise data collected through electronic prescribing when this is more widely available). To obtain accurate data will require a lot of work without embedded electronic systems in the transfusion and peri-operative process. Often the problem will be accessing records of patients NOT transfused which will be required for standards such as Statement 4.

ID	Stakeholder	Statement number	Comments[1]
			How do you measure if they were 'offered' but refused (vs. 'received') - this is unlikely to be documented
27	National Blood Transfusion Committee	General	Question 3 Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted Some examples have been suggested and the respondents will be advised to provide information to NICE local practice collection
28	National Blood Transfusion Committee	General	Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any treatment. Please describe any potential cost savings or opportunities for disinvestment. Yes, however resourcing would be the biggest barrier to achieving of these quality standards Additional resources would be needed for audits to be undertaken, as well as resourcing for education and feedback sessions with clinicians and staff involved with patient management. Ideally, electronic solutions need to be developed harnessing the data available in the different IT systems to enable meaningful information to be provided to achieve change eg through benchmarking suing a set of KPIs based on the quality standards Clinical and transfusion stakeholder input to undertake the necessary practice changes would also need addressing. For many of the statements there needs to be an effective change management programme including a restructure of systems to enable change to be achieved Eg: • new ways of commissioning anaemia management pathways at the interface between primary and secondary care • moving anaemia assessment to point of listing rather than pre op assessment clinic which is often too close to surgery to allow form time to investigate and correct anaemia • development of electronic decision support at the time of requesting to drive embedding of evidence based practice in order comms • standardisation of transfusion requesting to include a coded reason for transfusion and justification for

ID	Stakeholder	Statement number	Comments[1]
			transfusion using national indication codes which have been developed based on the NICE guidelines Successful implementation and practice of the quality standards could result in the reduction in: • blood component usage and wastage • the inappropriate use of components • The cost of transfusion laboratory resources/transport.
29	NHS Blood and Transplant	General	Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? It accurately reflects one aspect of the need to address iron deficiency anaemia in iron deficient surgical patients and quality improvement. Yes Yes In parts Yes Yes See comments above. Yes
30	NHS Blood and Transplant	General	Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place? We collect it as part of our National Comparative Audits, and most hospitals are able to provide the data. No. All data collection will be reliant on manual systems or manipulation. Appropriate additional resources need to be sourced to ensure that this data can be collected and specific staff groups should be allocated

ID	Stakeholder	Statement number	Comments[1]
			for each standard. No. It would not only require a much more advanced data collection structure to be implemented, it would also require investment in personnel skilled in data collection and data management. This should not become the responsibility of the Trust Transfusion team. They should be partners in the implementation of these and be key stakeholder in reviewing the outcomes. Yes, clinical benchmarking system could be developed nationally for all hospital to collect this automatically (bar consent as this will be depended on electronic notes). No- some hospitals will need to implement systems to produce this information. It may be difficult to obtain data / information around patient information. There are not always systems in place, the most difficult information to collect reliably would be for statement 5 about consent.
31	NHS Blood and Transplant	General	Question 3 Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted. No Yes https://www.nice.org.uk/sharedlearning/audit-of-the-use-of-fresh-frozen-plasma-east-midlands-regional-transfusion-committee No PBM survey Single unit pilot work (awaiting publication)

ID	Stakeholder	Statement number	Comments[1]
			Hospital iron clinics to save transfusion – not aware this is published. No No
32	NHS Blood and Transplant	General	Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any treatment. Please describe any potential cost savings or opportunities for disinvestment. Yes. To make these decisions or record the conversations had with patients is a low cost, low tech solution. Yes I think these statement would be achievable, with the exception of statement 3; full compliance with checking haemoglobin after every single unit transfusion may not. No. It would not only require a much more advanced data collection structure to be implemented, it would also require investment in personnel skilled in data collection and data management. This should not become the responsibility of the Trust Transfusion team. They should be partners in the implementation of these and be key stakeholder in reviewing the outcomes. These standards are for best practice in patient care and should not be driven as a cost saving measure. Yes, it will be good if a central organisation could bring these standard measures together to allow comparison and give support across – NHSBT? Yes I think they are achievable but they may require evidence of cost savings to produce business cases to support this resource requirements. These standards would require financial help for the Trusts, as well as a period of time for them to be implemented. The major resource implication may be collecting information about consent.

ID	Stakeholder	Statement number	Comments[1]
33	NHS Blood and Transplant	General	Prothrombin Complex Concentrate is not a blood component.
34	NHS England	General	Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
35	Royal College of General Practitioners	General	A recent audit in General Practice highlights that the key areas for quality improvement appears to be • Base transfusion decisions on symptoms rather than numbers • It is rare to need to transfuse to over 100g/l • Use iron (oral or iv) for iron deficiency anaemia, • Transfuse only for end organ symptoms • Size of the patient does matter • Consider single unit transfusions in stable non bleeding patients At present the proposed quality statements do not appear to reflect the areas for improvement in primary care.
36	Royal College of General Practitioners	General	At present the RCGP is not aware of systems in place to collect data for the proposed quality measures . The National Comparative Audit of Blood Transfusion (NCABT) is a programme of clinical audits which looks at the use and administration of blood and blood components in NHS and independent hospitals in England and North Wales. At present it does appear to collect this data from primary care.
37	Royal College of General Practitioners	General	The RCGP is not aware of any examples from practice of implementing the NICE guideline that underpins this quality standard.
38	Royal College of General Practitioners	General	A standard coded template and check list in the GP clinical systems may help with data collection but this would need to be piloted.
39	Royal College of Nursing	General	This is just to inform you that the Royal College of Nursing have no comments to submit to inform on the above quality standard consultation.
40	Royal College of Paediatrics and Child Health	General	It is not clear which elements are specific to adults and which are generic and could apply to babies and children. The document requires more clarity than this, or a paediatric version, with expert input
41	Scottish Clinical Transfusion Advisory Committee (SCTAC)	General	<u>Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?</u> • Yes – although not an exhaustive list • Standards 1 & 2 are more relevant • I think standards 1, 3 and 5 represent key areas for improvement.

ID	Stakeholder	Statement number	Comments[1]
			• I am not sufficiently familiar with the use of tranexamic acid in all specialities to comment regarding standard 2. • I do not perceive that we have a problem with inappropriate platelet use. Apart from during major haemorrhage events and in some speciality areas, all platelet requests in our organisation are discussed with, and have to be authorised by, a haematologist. I therefore do not think standard 4 is a priority. • Another key area for improvement that is not addressed here relates to monitoring whether our patients benefit from their transfusion or otherwise (e.g. symptom resolution, functional improvement).
42	Scottish Clinical Transfusion Advisory Committee (SCTAC)	General	<u>Question 2 Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?</u> • Each NHS Board has active Hospital transfusion committees and teams which include a transfusion practitioner. The Better Blood Transfusion Team assists the NHS Boards with Audit and QI projects from a national perspective. However each Board may have additional projects planned so additional work load may be challenging. • As indicated, a number of these standards would have to be measured prospectively or on an individual basis, involving significant time and staff resource
43	Scottish Clinical Transfusion Advisory Committee (SCTAC)	General	<u>Question 3 Do you have an example from practice of implementing the NICE guideline that underpins this quality standard?</u> • Transfusion document for stable post-partum women designed around single unit transfusion (with evidence that this has reduced blood use for this group). • Standard transfusion document that prompts review between units transfused. • Standard transfusion document that prompts the provision of verbal and written information.
44	Scottish Clinical Transfusion Advisory Committee (SCTAC)	General	<u>Question 4 Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them?</u> • This could be a challenge for all NHS Boards and Hospitals • If patient not able to tolerate oral iron, cost and logistical considerations if IV iron is only suitable alternative • Cost implication of increased use of tranexamic acid.

ID	Stakeholder	Statement number	Comments[1]
			• Savings (in terms of health, safety and cost) of reduced component use.
45	Scottish Clinical Transfusion Advisory Committee (SCTAC)	General	2002 data is provided for number of individuals who receive a transfusion – could we use more up to date figure?
46	Scottish National Blood Transfusion Service	General	The areas that have been highlighted are well established improvement dimensions that have formed part of the Patient Blood Management / Better Blood Transfusion agendas for some time The rationale for the exclusion of the vast majority of papers considered by the group should be clearly stated; only 6 or 834 were included according to appendix 2 of the briefing paper Improve clarity around the statement of risks of transfusion. Risks definitely attributed to transfusion have not changed and remain very low; reporting bias and increases in the number of reporting categories contribute to the absolute numbers of adverse events reported to SHOT. Blood use is estimated on the basis of units issued from NHSBT to hospitals not units transfused to patients.
47	Scottish National Blood Transfusion Service	General	Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place? No, the data collection would be resource intensive to gain accurate data which would reflect transfusion decisions in all cases. Outcome measures will be significantly impacted by confounding factors
48	Scottish National Blood Transfusion Service	General	Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? NO
49	Scottish National Blood Transfusion Service	General	Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? See individual responses below to each statement
50	Scottish National Blood Transfusion Service	General	Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them?

ID	Stakeholder	Statement number	Comments[1]
			See individual responses below to each statement
51	The Christie NHS Foundation Trust	General	Does this draft quality standard accurately reflect the key areas for quality improvement? Yes
52	The Christie NHS Foundation Trust	General	If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Yes
53	The Christie NHS Foundation Trust	General	We have implemented the standards that we did not already comply with. Two standards already in the policy and 1 waiting to be implemented on to the trust patient system.
54	UK Transfusion Laboratory Collaborative (UK TLC)	General	This standard needs to include the role of the transfusion laboratory as a key part of the transfusion care pathway, particularly as SHOT has reported that errors originating in the laboratory that cause patient harm or potential for harm are increasing (SHOT Report 2015), and this is due to difficulties within these areas that the UKTLC are trying to address. A short paragraph cross-referencing the *The UK Transfusion Laboratory Collaborative ;Minimum Standard for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014* and the *Blood Safety & Quality Regulations Act 2005, as amended*, would help.
55	Welsh Blood Service	General	Para. 4, final line; Inclusion of the year 2015/16 is unnecessary
56	Welsh Blood Service	General	Para.1 line 2 change to 'Blood donations are collected and stored until needed.'
57	Welsh Blood Service	General	Para.2 line 1 change 'include' to 'are' Prothrombin complex concentrate (PCC) is included as a blood component. PCC is not processed from donations. Sentence needs to be reworded to reflect this. Therefore, Para. 2 line 2, suggest to remove 'prothrombin complex concentrate' and replace with 'granulocytes'. While granulocytes are not necessarily relevant for these particular quality standards it presents incomplete information. Add a sentence here on specific products used to complement blood component use as PCCs are included in NG24, section 1.6. Para.2 line 3 remove 'used in a' and change 'transfusion' to 'transfused' Para.2 line 5 change 'would' to 'may'
58	Welsh Blood Service	General	Para.3 line 4 remove 'An estimated 430,000 patients received a red blood cell transfusion in 2002'. This bears no relevance to 2016.
59	Welsh Blood Service	General	'Why this quality standard is needed', final paragraph, bulleted list

ID	Stakeholder	Statement number	Comments[1]
			Suggest reordering the bulleted list to move 2nd bullet to third place and extend 'adverse events after blood transfusion…due to a reduction in overall transfusion' We would like to make a cautionary observation though that reducing transfusion is not necessarily safer as shown in SHOT reports of under transfusion. These standards as a whole tend towards reduced transfusion rates as being a good thing. Rather, a focus on appropriate transfusion is needed.
60	Welsh Blood Service	General	'Coordinated services' sub section, 'Role of families and carers' After 'appropriate' add 'and where possible with the patient's agreement.'
61	Welsh Blood Service	General	Difficult to comment from our perspective as this will be dependent on the systems held by providers of acute secondary care
62	Welsh Blood Service	General	N/A
63	Welsh Blood Service	General	The quality statements might be achievable, but the quality measures might be difficult to achieve – depending on the frequency of measurement.
64	Welsh Blood Service	General	We have some concerns that the standards lean towards reduction of transfusion as being universally a good thing whilst for some patients it is not. Might there be some balancing in the introductory section 'Why this quality standard is needed' towards appropriate rather than reduced transfusion. Where is the evidence to show what the rate per 1000 of the population should be? We believe that each patient must be treated according to their individual needs and in some cases this may mean more, not less blood components. Attempting to drive down use towards an arbitrary target is potentially as dangerous, if not more so than, inappropriate transfusion.
65	[PREVENTT Clinical Trial Group]	1	We have concerns about the recommendation for oral iron and ask to change this to iron supplementation.
66	[PREVENTT Clinical Trial Group]	1	Following operation data suggest oral iron does not work. There are four RCT's in orthopaedics alone showing that post-operative oral iron has no clinically relevant benefit. The reason is that following operation the inflammation increases hepcidin levels that blocks absorption of iron from the gut by inhibiting the transport protein ferroportin. There is sound mechanistic and level 1 evidence that this recommendation for oral iron postoperatively would not work. Routine prescription of oral iron post operatively may expose patients to harm by increased incidence of side effects that are common in oral iron.
67	[PREVENTT Clinical	1	We do not suggest recommending intravenous iron to patients prior to surgery. This is due to the clinical

ID	Stakeholder	Statement number	Comments[1]
	Trial Group]		trial PREVENTT which is currently running, and gathering large data sets on the effectiveness of intravenous iron in the pre-operative setting. The reason for advising caution on its use, is due to the limited evidence on its efficacy and effect.
68	[PREVENTT Clinical Trial Group]	1	We strongly support the recommendations that patients undergoing surgery should be screened for anaemia, and appropriately investigated for its cause when detected. Further consideration of the cancellation of elective surgery should be made to allow treatment and correction of anaemia. Also in those patients undergoing surgery further Patient Blood Management strategies should be initiated. We encourage the development of PBM/anaemia clinics and anaemia diagnosis pathways in the preoperative setting.
69	ABMUHB	1	This Quality Standard does not include IV iron. Suggest that the standard is extended for oral and IV to address patients who cannot take oral iron, do not tolerate it or may have difficulties in absorbing oral iron. This same comment applies to all sections that reference oral iron. The statement does not distinguish between pre-op and post-op anaemia The statement does not specify type of surgery – would this quality standard also apply to a patient undergoing zero blood loss surgery (e.g. insertion of grommets)?
70	ABMUHB	1	Rationale The use of 'infection' is ambiguous. It is not clear if it relates to transfusion transmitted infection (which although a risk of transfusion, is very rare) or refers to the increased incidence of post operative infections seen in patients undergoing surgical procedures who are also transfused with red cells peri-operatively the evidence for this is increasing across a range of surgical procedures particularly associated with post-operative wound infection.
71	ABMUHB	1	The quality measure outcome 'blood transfusion rates after surgery' should be qualified in relation to type of surgery. Some procedures should never e associated with red cell transfusion
72	ABMUHB	1	The quality measure outcome 'incidence of infections after surgery' is ambiguous, does this relate to surgical wound infection, all infections or transfusion transmitted infection? This comment relates to all references to transfusion related infections
73	ABMUHB	1	While NG24 includes both oral and intravenous (IV) iron the quality standards omit IV iron. If the purpose is to identify the proportion of patients with iron deficiency anaemia who are treated appropriately with iron then exclusion of the IV route will make the numerator wrong.
74	British Society for	1	see before - not "offered" but "investigated and treated as appropriate"

ID	Stakeholder	Statement number	Comments[1]
	Haematology		
75	British Society for Haematology	1	blanket transfusion rates may not be very informative - needs to be adjusted for type of operation, bleeding rate etc
76	British Society for Haematology	1	adjusted to type of operation and starting Hb, extent of bleeding etc
77	British Society for Haematology	1	- as before and highlighted below - not "offered" but "investigated and treated as appropriate"
78	British Society for Haematology	1	Change to 'People with iron deficiency anaemia are investigated and offered oral and/or IV iron as appropriate before and after surgery.
79	British Society for Haematology	1	Service providers - need to change to: Service providers ..... ensure that systems are in place to identify iron deficiency anaemia and to investigate and offer oral and/or IV iron as appropriate ..... c) Incidence of adverse events following surgery - this is very broad - should this be targeted to certain events which are most likely related to transfusion.
80	British Society for Haematology	1.	Oral and/or IV iron - some patients are not tolerant of oral iron, or hospitals have implemented IV iron for certain patient groups / indications - as it is this will not measure overall performance as will not capture those using IV iron. Rationale - Investigating and treating iron deficiency with oral and/or IV iron ..... Quality measures a) A major problem is the initial identification of these patients - blood results are often reviewed against inappropriate 'triggers' (see West Midland Regional Transfusion Committee audit and survey reports). Change a) to: Evidence of local arrangements to ensure people with iron deficiency anaemia are identified, investigated and offered oral and/or IV iron before surgery. If people are not being correctly identified with iron deficiency anaemia correctly, the denominator is incorrect.
81	British Society for Haematology	1	Measures b)what type - all infections or transfusion transmitted ones?
82	British Society for Haematology	1	Measures c)what type - all or related to transfusion?
83	Institute for Biomedical Sciences – Specialist	1	Currently would be in patients notes so would be hard to measure apart from sporadic clinical audit. Rare to have linkage between Pathology IT and Pharmacy IT

ID	Stakeholder	Statement number	Comments[1]
	Advisor for Blood Transfusion		
84	National Blood Transfusion Committee	1	Suggest reword to: *People with iron deficiency anaemia are offered / given iron replacement therapy before and after major surgery*. (to allow for option for use of IV iron instead of oral iron in circumstances outlined in NICE guideline)
85	NHS Blood and Transplant	1	Easy to measure and we are measuring precisely this in our present National Comparative Audit of Patient Blood Management in adults undergoing elective, scheduled surgery. You are welcome to the data. You should add an additional option for patients to be offered IV iron pre and post-operatively, because a) some people cannot tolerate oral iron and b) IV iron is somewhat quicker than oral iron in raising the iron content of blood. Gathering this information may be difficult as there is no standard way to record this information. Transfusion is recorded in the patient's notes. For many Trusts this information cannot be collected automatically and will be a manual search. Details of what department/staff group is responsible for collecting this information should be given as lack of ownership could lead to incomplete measurement of this statement. Times frames should be included, as offering oral iron only days before surgery would not be deemed appropriate treatment to correct pre-surgical iron deficiency anaemia. Who will be responsible for this? The initiative must have ownership through the anaesthetic / surgical teams and NOT haematology / blood transfusion. It must be embedded as a surgical standard and funded accordingly. In order to measure the success of this statement it will require a manual review of patient notes. Information should be available if added to pre op assessment pathways but may require further support if primary care are required to have involvement. No comments.

ID	Stakeholder	Statement number	Comments[1]
			Denominator data may be misleading, for element a) depending on the time of collection. Good practice leading to early identification and management of the iron deficiency could mean patients are not counted. This statement may also need to reflect use of intravenous iron if it is just before surgery as oral iron will not be effective. Therefore suggest use words “offered iron (usually oral) rather than oral iron so oral or intravenous iron could be used whichever is more appropriate for the patient. If this is modified then the quality measures should be modified.
86	Royal College of Anaesthetists	1	We believe that the statement accurately reflects a key area for quality improvement and support the use of oral/intravenous iron in the deserving patient or group of patients. The statement assumes that all patients have their haemoglobin levels assessed and available at the time of booking for elective surgery; this is not universally true. We feel that the statement can be further expanded to include that the following- ‘all patients planned for elective surgery should have their haemoglobin measured and assessed at least two weeks prior to surgery’. This will ensure that iron therapy is offered/instituted (if appropriate), preferably by the GP, well before the patient is admitted to the local hospital for surgery. As regards post-surgery treatment, local protocols could be drawn up to ensure that oral iron is routinely offered to patients whose haemoglobin levels are below accepted levels. A database of all patients who have undergone surgery that includes pre and post operative haemoglobin levels will be a good way to monitor adherence to protocols/ standards. However we recognise and accept this is labour intensive and will require investment in IT and manpower which given the current financial pressure may be viewed less favourably. The use of digital/electronic prescription will help ease the clerical burden, but it is some way away. The statement should also take it account the efficiency and value of oral iron, the time interval between iron therapy and surgery and the need for intravenous therapy in those individuals who cannot for receive oral therapy (for whatever reason). Should it be viewed as unethical to operate of patients who are anaemic? Or is it a step too far?
87	Royal College of General Practitioners	1	The RCGP welcomes this guideline but has some concerns about statement 1. Concerning oral iron was not expected in a guideline about blood transfusion, except that it is explained later that giving oral iron reduces the need for transfusion during surgery. Any doctors – GPs or hospital doctors – already prescribe oral iron for someone with known iron deficiency anaemia. Is there any evidence that this has not happened? It may happen that some patients are admitted to hospital with acute abdominal problems and

ID	Stakeholder	Statement number	Comments[1]
			need emergency surgery. Such patients might be found to be anaemic as part of routine investigations. In that case they might well have the operation before anyone has sorted out the anaemia, but that would be completely reasonable. If there is evidence that patients known to have iron deficiency are not receiving oral iron then please cite it so that we can understand why it has happened.
88	Scottish Clinical Transfusion Advisory Committee (SCTAC)	1	• The timing of surgery relative to pre-operative assessment leaves only a short time for oral iron therapy pre operatively, likely to be too short a time for a response to occur • This should read that people are not "offered" but "investigated" and treated as appropriate • I would agree with this statement in principle however timescales are short and this could be hard to measure without undertaking a case note review. • This would be a labour intensive process to review • Should the standard include contingency for circumstances where the individual cannot tolerate oral iron • Measurement would have to be arranged prospectively or on an individual basis • If we are measuring simply whether iron has been offered or not, the offer and subsequent response would need to be documented – not sure this would currently be done routinely?
89	Scottish National Blood Transfusion Service	1	• Agree, however this standard could have limited impact given that only one third of transfusions are given to surgical patients • Would require timely pre-assessment of patients which may require increased resource / planning • Increased costs associated with investigation of anaemic patients found at pre-assessment clinics • Outcome measures will be significantly impacted by confounding factors
90	Stanningley Pharma Ltd	1	Offering oral iron therapy may, or may not be appropriate depending upon the severity of anaemia and or iron deficiency and anticipated blood loss. If the Hb is low and the anticipated blood loss high then it may be better if possible to postpone surgery or give IV iron. The whole issue should be to both ensure the patients Hb is within the normal range prior to surgery and that they have sufficient iron available in stores to enable them to increase their Hb following blood loss. The current statement is rather too simple and likely to confuse.
91	Stanningley Pharma Ltd	1	Rationale. This would benefit from clarification, as although potentially true it is not always true. Oral iron has many limitations not least being the side effects which contribute to poor patient concordance. If a patient has previously had problems with oral iron it may be that using IV iron therapy should be considered.

ID	Stakeholder	Statement number	Comments[1]
92	Stanningley Pharma Ltd	1	Both the Structure and Process comments have the same limitations. Offering oral iron to all patients with IDA will not always be appropriate. Greater clarification is called for.
93	Stanningley Pharma Ltd	1	It would be helpful to define what is meant by IDA and ID and how to diagnose them. This is especially important in patients with pro-inflammatory conditions where measurement of iron status needs to be interpreted with caution. It is important to note that a patient with iron deficiency and a normal Hb is in just as great a need for iron supplementation as a patient with IDA. The idea of offering oral iron to patients with IDA is but a very small step in the right direction and may fail to address the needs of many patients undergoing surgery.
94	Vifor Pharma UK Ltd	1	This only partly reflects the key areas for quality improvement. This statement should state that "People with iron-deficiency anaemia are offered **iron treatment** before and after surgery" to reflect the acknowledgement in the guidance and briefing paper that IV iron should be considered for the following reasons: 1) cannot tolerate oral iron, 2) diagnosed with functional iron deficiency, 3) interval between diagnosis and surgery is too short for oral iron to be effective. The National comparative audit of blood transfusion (2015) reported that preoperative anaemia was common and was present in half of patients but was often identified relatively late prior to surgery with only half of patients having an Hb level tested at least 14 days preoperatively[1]. The current proposed statement could potentially result in excluding a large proportion of patients from being included in the measures associated with this statement, because as per the guidance they should be considered for IV iron which is not included in the measure.
95	Vifor Pharma UK Ltd	1	All measures should be expanded from oral iron to iron treatment, to reflect the guidance recommendation to consider IV iron for the following reasons: 1) cannot tolerate oral iron, 2) diagnosed with functional iron deficiency, 3) interval between diagnosis and surgery is too short for oral iron to be effective. It would also then give an estimate of the total number of patients who have iron deficiency anaemia, rather than exclude those who were offered IV iron.
96	Vifor Pharma UK Ltd	1	As identified in the briefing paper (section 4.1.3 Current UK Practice) prior to this consultation process only 15% of pts identified as anaemic had a ferritin test[2]. Therefore, an additional measure should be introduced to capture number of patients with anaemia who received a ferritin investigation. The briefing report states the comparative audit highlights the need to increase these figures for the investigation and management of preoperative anaemia in the UK[2]
97	Vifor Pharma UK Ltd	1	Replace "oral iron" with "iron therapy" to accurately reflect the options available in the guidelines.

ID	Stakeholder	Statement number	Comments[1]
98	Vifor Pharma UK Ltd	1	The stakeholder impact should reflect the guidance and make reference to offering appropriate iron therapy before and after surgery.
99	Vifor Pharma UK Ltd	1	This should reflect the guidance and state that services should be commission services that offer oral and IV iron before and after surgery.
100	Welsh Blood Service	1	While NG24 includes both oral and intravenous (IV) iron the quality standards omit IV iron. Additionally the guidelines themselves fall short in that they do not address the underlying cause for iron deficiency anaemia.
101	Welsh Blood Service	1	Rationale In this paragraph 'infection' is used as an example of serious transfusion risks. It is unclear if this is a transfusion transmitted infection (incredibly low risk) or an associated infection such as post-operative wound infection.
102	Welsh Blood Service	1	The quality measure outcome 'blood transfusion rates after surgery' does not account for type of surgery
103	Welsh Blood Service	1	The quality measure outcome 'incidence of infections after surgery' – does this refer wound site infection rates, or transfusion transmitted infection? This comment on infection equally applies to the remaining measures
104	ABMUHB	2	Rationale Is the mode of administration for tranexamic acid relevant here? Is it anticipated that this will be IV therapy given during surgery, or pre, peri and post op administration by IV and or oral route? If the standard is merely to identify how often tranexamic acid is considered, rather than to assess if the use is appropriate or not then this may not be relevant. It may be helpful to clarify if IV, oral, or either route is offered.
105	ABMUHB	2	Rationale Please see earlier comments
106	ABMUHB	2	Outcome a) to e) – these are outcomes already commonly measured so it seems logical that blood transfusion rate can be measured in relation to the outcomes.
107	British Society for Haematology	2	Is tranexamic acid indicated in all types of operations and all types of patients?
108	British Society for Haematology	2	define moderate blood loss here not at the end of the statement ?more than 500mls
109	British Society for	2	Is Tranexamic acid indicated for all operations (?renal operations) and for all patients types? Needs

ID	Stakeholder	Statement number	Comments[1]
	Haematology		professional judgement?
110	British Society for Haematology	2	- as before – define
111	British Society for Haematology	2	- transfusion specific? Tranexamic specific?
112	British Society for Haematology	2	as before ?all types of transfusion related?
113	British Society for Haematology	2	See earlier comments
114	British Society for Haematology	2	- not sure about "offer" as opposed to "consider and take a professional judgement re suitability"
115	British Society for Haematology	2	Need to define 'moderate blood loss' (i.e. >500ml) so standardised and measurable locally.
116	British Society for Haematology	2	Are there any contra-indications to tranexamic acid?
117	British Society for Haematology	2	as previous ?all ?
118	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	2	Currently would be in patients notes so would be hard to measure apart from sporadic clinical audit. Rare to have linkage between Pathology IT and Pharmacy IT
119	National Blood Transfusion Committee	2	Please define moderate blood loss as referenced in NICE Guideline Suggest change to *offered/given tranexamic acid*.
120	NHS Blood and Transplant	2	Easy to measure and we are measuring precisely this in our present National Comparative Audit of Patient Blood Management in adults undergoing elective, scheduled surgery. You are welcome to the data. Gathering this information may be difficult as there is no standard way to record this information. Transfusion is recorded in the patient's notes. For many Trusts this information cannot be collected automatically and will be a manual search.

ID	Stakeholder	Statement number	Comments[1]
			Who will be responsible for this? The initiative must have ownership through the anaesthetic / surgical teams and NOT haematology / blood transfusion. It must be embedded as a surgical standard and funded accordingly. In order to measure the success of this statement it will require a manual review of patient notes. Additional systems will be required to collate this information as this is not currently collected except via audit. No comments. Patients in whom tranexamic acid is contra-indicated need to be excluded; clarification of these contr-indications will ensure comparable results and facilitate benchmarking. Suggest the statement has the caveat of “unless they have a contraindication to prophylactic platelet transfusions”. The quality measures would also need to be altered to reflect the fact that not all people should receive a prophylactic platelet transfusion.
121	Royal College of Anaesthetists	2	We fully support the use of tranexamic acid (TXA) as a blood conservation technique intra-operatively. However the definition of moderate blood loss must be quantified clearly for eg, greater than 500mls. It should be included as part of the WHO surgical safety checklist thus embedding this standard into routine surgical/anaesthetic practice. This will serve as an alert for perioperative use TXA in patients who are likely to experience moderate or greater blood loss during surgery. As with statement 1, monitoring adherence to this standard will be laborious, but in Trusts where the use electronic records and prescriptions is the norm, data collection may be less labour intensive. We would like to stress the importance of patients being made aware of the use of blood conservation techniques including the use of TXA at the time of preoperative visit/consent. The use of TXA is likely to increase significantly and we would like to draw attention to reports of fatalities overseas due to inadvertent use of the drug via the wrong route and urge all necessary precautions are taken when administering this drug.
122	Scottish Clinical	2	• Should the term moderate blood loss be defined for clarity

ID	Stakeholder	Statement number	Comments[1]
	Transfusion Advisory Committee (SCTAC)		• Definition of moderate blood loss is required in order to measure if Transexamic acid has been effective • Is Tranexamic acid indicated for all operations and for all patients, this requires a degree of professional judgement • not sure about "offer" as opposed to "consider and take a professional judgement re suitability" • will this statement indicated that tranexamic acid is required for all types of surgery and all patients • Measurement would have to be arranged prospectively or on an individual basis • If we are measuring simply whether this drug has been offered or not, the offer and subsequent response would need to be documented – not sure this would currently be done routinely?
123	Scottish National Blood Transfusion Service	2	• Agree, however this standard could have limited impact given that only one third of transfusions are given to surgical patients • Need to define contraindications for Tranexamic acid use • Outcome measures will be significantly impacted by confounding factors
124	Welsh Blood Service	2	The statement does not specify mode of administration for tranexamic acid. However, neither does NG24 specify this. One would assume it is IV but needs clarification.
125	Welsh Blood Service	2	Rationale It is unclear as to the type on infection; transfusion transmitted infection or surgical site infection?
126	Welsh Blood Service	2	Outcome a) to e) – these are outcomes already commonly measured so it seems logical that blood transfusion rate can be measured in relation to the outcomes.
128	ABMUHB	3	Rationale Restrictive transfusion practice does not per se reduce the risk of adverse events related to a specific transfusion, although fewer transfusion episodes will reduce risk overall. The statement is somewhat ambiguous. A restrictive transfusion approach does not automatically relate to single unit transfusions. The wording used in the rationale appears to link the two and should be reviewed.
129	ABMUHB	3	Measures It is not clear if this quality statement relates to all red cell transfusions (and how many of these are managed as single-unit transfusion) or just to transfusions specified as ‘single-unit’ (in which case how are these identified). The denominator data might be hard to capture.

ID	Stakeholder	Statement number	Comments[1]
130	ABMUHB	3	The statement requires the patient to be assessed following transfusion of a single unit of red cells, but does not indicate what outcome from this assessment is required, or what the relevant actions should be that are informed by that assessment. Ie on what basis the decision to transfuse further red cells, or not, is made. Reports of adverse outcomes to SHOT highlight that under transfusion is associated with significant morbidity and may be implicated in mortality, so it is important that the standards do not create the impression that only one red cell unit is all that will be needed. Assessing and checking haemoglobin levels without a further decision is not a patient centred outcome. The standard could be extended and reworded thus (or similar). Please note inclusion of brackets as in NG24: 'People who have received a single unit red blood cell transfusion (or equivalent volumes calculated based on body weight) are clinically assessed and the post transfusion haemoglobin levels are considered in the clinical context to inform the decision to transfuse further units of red blood cells.'
131	British Society for Haematology	3	"70g/litre" and "70-90g/litre" should be "70g/L" and "70-90g/L" respectively (and "l" for litre should be "L" throughout).
132	British Society for Haematology	3	Change "have" to "need"
133	British Society for Haematology	3	this needs re-wording
134	British Society for Haematology	3	wouldn't give allergic reaction as an example here - unlikely to ever pick up an allergic reaction due to the elective assessment of a patient at the end of a blood transfusion - such reactions usually manifest themselves acutely and often during the transfusion - such assessments are more likely to pick up potential Transfusion associated circulatory overload for example
135	British Society for Haematology	3	- reword as before and all highlights below
136	British Society for Haematology	3	again - this implies that reassessment will only happen if a patient has been prescribed only one unit - when actually unless bleeding patient should be reassessed after each unit (with or without a repeat Hb as the case may be)
137	British Society for Haematology	3	- most patients will not be prescribed just a single unit - this needs to be changed as to outwith bleeding patients how many are reassessed before continuing with transfusion beyond 1 unit.
138	British Society for	3	as before

ID	Stakeholder	Statement number	Comments[1]
	Haematology		
139	British Society for Haematology	3	- Incidence of infections - as per previous comments - what types of infections
140	British Society for Haematology	3	- see previous comments re types of adverse events
141	British Society for Haematology	3	see previous comments
142	British Society for Haematology	3	in the absence of heart disease and some cancer treatments
143	British Society for Haematology	3	This statement does not give any indication who should/could have a single unit transfusion. Also, ALL patients, not just those who have had a single unit, should be clinically assessed after transfusion. The assessment should be to determine whether the single unit has had the desired effect and whether another unit is clinically required.
144	British Society for Haematology	3	This gives no indication of who should receive a single unit. Also, ALL patients, not just those who have had a single unit, should be clinically assessed after transfusion. The assessment should be to determine whether the single unit has had the desired effect and whether another unit is clinically required. Change to: In non acute bleeding, haematologically stable patients should be given single unit red cell transfusion, followed by a clinical assessment and Hb check before proceeding with another unit (if clinically required).
145	British Society for Haematology	3	Rationale - Allergic reaction is a strange adverse event to include here. Allergic reactions are more commonly seen in platelets or plasma rather than red cells. A better adverse event which is more suitably related to single unit transfusions is TACO (Transfusion Associated Circulatory Overload).
146	British Society for Haematology	3	Process - needs to take account of patients who have received >1 unit, because following the 1st single unit the patient was assessed and a 2nd unit was clinically required. The single unit standard has been followed, even though more units of blood were given. Some hospitals may struggle to extrapolate this data.
147	British Society for Haematology	3	Restrictive red blood cell transfusion threshold and targets - In the absence of co-morbidities, the suggested threshold
148	Institute for Biomedical	3	Currently would be in patients notes so would be hard to measure apart from sporadic clinical audit.

ID	Stakeholder	Statement number	Comments[1]
	Sciences – Specialist Advisor for Blood Transfusion		Linkage between Transfusion and Haematology varies, also many LIMS do not accurately note exactly when the transfusion is given – often only notes when was issued.
149	National Blood Transfusion Committee	3	Suggest the following rewording: *Patients outside a regular transfusion program should receive a weight adjusted red cell transfusion dose to achieve target haemoglobin and should be clinically reassessed and have their haemoglobin level checked after the transfusion.* The value of single unit transfusion policy is not universally accepted, and excludes those receiving a larger transfusion volume. The suggested wording widens the scope of the statement and is inclusive rather than exclusive.
150	NHS Blood and Transplant	3	Easy to measure and we are measuring precisely this in our present National Comparative Audit of Patient Blood Management in adults undergoing elective, scheduled surgery, and our current National Comparative Audit of the use of Red Blood Cells and platelets in adult haematology patients. You are welcome to the data. All patients that have a transfusion should have a post transfusion Hb check. This will be difficult to measure as will rely on a manual data collection methods. Clinical reassessment may not be formally checked and there are no standards to measure the effect of a transfusion. There needs to be consideration regarding the period after transfusion when the reassessment should take place. This standard does not state who is eligible for a single unit transfusion policy – non bleeding stable medical patients. Standard should state that all patients eligible for a single unit transfusion should only receive a further unit if indicated by Hb and clinical symptoms. There will be resistance to this due to taking further blood samples from patients – associated costs and time/manpower. Suggest strong links with use of point of care near patient testing e.g. Hemacue as a standard Hb measure in clinical areas. This does not highlight the fact that a single-unit should be given, just assumes for those that have it there should be an assessment. We need to give the indicator that for those patients who it is appropriate to have a single unit they should be given one.

ID	Stakeholder	Statement number	Comments[1]
			All patients (except those with major haemorrhage, chronic anaemia) should receive a single-unit transfusion, or equivalent volume, and be clinically reassessed and Hb checked after single unit transfusion. This will need to be more indicative of the patient group it may be directed towards. Collating this information will require a change in systems and pathways including education and management. At present this information required manual input. There may be a need to provide information on indications for single unit transfusions. This statement may be hard to measure as it is difficult to define 'A single unit transfusion'. This may be interpreted differently by each organisation / clinician. Does it require a blood sample to be taken before deciding on whether another unit of blood is required – could the patient be visually assessed? The quality statement is misleading and very negative in comparison to the rationale. To achieve compliance clinicians may revert to routine two unit transfusions.
151	Royal College of Anaesthetists	3	This statement appears quite sensible and can be implemented in most elective cases. Intraoperative haemoglobin is frequently measured (if indeed attempted) using bedside equipment or blood gas machines. Therefore this information is largely contained within the anaesthetic charts and will require trawling through patient's notes making it arduous task for those collecting the data. The blood bank database should also contain information on the number of units each patient has had and whether the haemoglobin was measured between units but this will miss out those patients (the majority) who fall into the former group.
152	Scottish Clinical Transfusion Advisory Committee (SCTAC)	3	• The way this reads it implies that only patients where a single unit has been indicated should be re-assessed - what I think it should say is: "Except in cases of major haemorrhage, patients should be re-assessed and have their haemoglobin checked after each unit of red cells transfused to allow a decision to be taken re the need for further transfusion" • Should there be a length of specific time as and when to undertake the haemoglobin checked • In conjunction with the Hb check should we not also be checking the clinical presentation of the patient • In order to measure this retrospectively, you would be able to clarify time of transfusion and time

ID	Stakeholder	Statement number	Comments[1]
			samples taken – but how can we demonstrate that a result has actually been reviewed before a further unit is transfused • Do clinicians always document if they have performed an interim clinical review and the outcome of this
153	Scottish National Blood Transfusion Service	3	• This standard proposed on the basis of the benefits of a restrictive transfusion policy and the suggestion that there is significant over-transfusion of patients. The background document mentions Hb triggers (70g/dl) and targets – these should be included in the process measure. • The proposed solution is to have a clinical assessment and a check Hb after a single unit (that is after every unit as all transfusion take place one unit at a time) to ensure patients are not over-transfused. Confusion may arise as a 'transfusion episode' may comprise 1 or more units depending on the starting Hb and the response. Thus the process measure should be the proportion of all units transfused that have a check Hb done on completion. It would also be useful to know the proportion of patients that go on to have further units. • Exclusions mentioned are patients with coronary disease, bleeding and chronically transfused. Thus impact may be limited as these groups will account for a significant number of transfusions. • Impractical in the outpatient setting • Increased inconvenience and costs of testing
154	The Whittington Health NHS Trust	3	Transfusion threshold for Thalasemia patients are above 100g/L
155	Vifor Pharma UK Ltd	3	Agree this reflects a key area for improvement.
156	Welsh Blood Service	3	This statement suggests assessing people post single unit transfusions, but doesn't include a further action which should be to transfuse or not to transfuse further red cells. Assessing and checking haemoglobin levels without a further decision is not a patient centred outcome. We acknowledge that further action is covered in the later Rationale, and suggest that the standard itself might be extended and reworded thus (or similar). Please note inclusion of brackets as in NG24: 'People who receive a single unit red blood cell transfusion (or equivalent volumes calculated based on body weight) are clinically assessed and have their haemoglobin levels rechecked to inform the decision to transfuse further units of red blood cells.' An additional view is that the statement is amended to 'Haemodynamically stable patients who are inpatient and need blood transfusion for established anaemia (not ongoing blood loss) should receive only one unit of blood transfusion and consequently should have clinical assessment (which may include FBC) before decision for further blood transfusion is made.

ID	Stakeholder	Statement number	Comments[1]
158	Welsh Blood Service	3	Rationale Restrictive red cell transfusion thresholds do not directly translate to single unit transfusions. There are occasions where it is entirely appropriate to work to a restrictive threshold yet transfuse multiple units. The wording of the rationale appears to link the two and needs further clarification. Single unit transfusion has no bearing on early identification of adverse events and does not in itself improve the safety in this context. Observation and monitoring of patients is essential during any transfusion. Inclusion of minimising risk of Transfusion Associated Circulatory Overload (TACO) (www.shotuk.org) will strengthen the rationale
159	Welsh Blood Service	3	Is this quality statement a measure of all red cell transfusions (and how many of these are managed as single-unit transfusion) or just of transfusions specified as 'single-unit' (in which case how are these identified). The denominator data might be hard to capture.
160	ABMUHB	4	Correct platelet count text to ensure superscript 10x**10^9,** and extend sentence to include a statement on the list of conditions that will exclude patients with conditions as in NG24, 1.3.3
161	ABMUHB	4	Rationale The statement is not clear and contradicts the rationale for prophylactic platelets Prophylactic use and restrictive use are not the same, but the wording seems to imply they have the same meaning
162	British Society for Haematology	4	10 x 10^9 per litre should be 10 x 10^9 per litre
163	British Society for Haematology	4	This doesn't read well - suggest change to: "Except where not indicated or where contraindicated (i.e. TTP, chronic bone marrow failure, ITP, HIT) patients with a platelet count less than 10... should be offered prophylactic platelet transfusion even if they are not bleeding or having invasive procedures or surgery".
164	British Society for Haematology	4	Suggest reword this - see Pg5 statement 4
165	British Society for Haematology	4	except in....TTP, HIT, chronic bone marrow failure, ITP
166	British Society for	4	I think prophylactic platelet transfusions help prevent serious adverse events associated with bleeding and

ID	Stakeholder	Statement number	Comments[1]
	Haematology		NOT associated with transfusion
167	British Society for Haematology	4	reword as before
168	British Society for Haematology	4	need to exclude all pts with platelets below 10 where there is chronic bone marrow failure, TTP, ITP, HIT
169	British Society for Haematology	4	as per previous comments
170	British Society for Haematology	4	reword as before - and below
171	British Society for Haematology	4	change "and" to "even"
172	British Society for Haematology	4	Incorrect nomenclature 10 x 10^9 Prophylactic platelet transfusions are not appropriate for all patients e.g. chronic stable thrombocytopenia without a history of bleeding. All national standards and guidelines must be consistent. This standard could encourage inappropriate use! Most platelet transfusions in this group are haematology patients, or under the care of a haematologist, and so a very discreet group.
173	British Society for Haematology	4	Prophylactic platelet transfusions are not appropriate for all patients Prophylactic platelet transfusions can therefore help to prevent serious adverse events associated with BLEEDING (not transfusion).
174	British Society for Haematology	4	Denominator data needs to take account of those where prophylactic platelets are NOT indicated (e.g. chronic bone marrow failure).
175	British Society for Haematology	4	'Yes' (National Comparative Audit and Regional Transfusion Committee Audits).
176	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	4	Currently would be in patients notes so would be hard to measure apart from sporadic clinical audit
177	Institute for Biomedical Sciences – Specialist	4	Could be gathered from lab data but would need data extract routines to be written (this may not be possible for all LIMS)

ID	Stakeholder	Statement number	Comments[1]
	Advisor for Blood Transfusion		
178	National Blood Transfusion Committee	4	Suggest the following reworking: *People with a platelet count **greater than** 10×109 per litre who are not bleeding or having invasive procedures or surgery are **not** offered prophylactic platelet transfusions.* This ensures that those groups with low platelets who do not warrant platelet transfusions are not included inappropriately in the standard and measures over-transfusion, which is viewed as a more common problem than under-transfusion in this group. .
179	National Blood Transfusion Committee	4	Yes there is evidence from National Comparative Audit of use of platelets in haematology from 2012 and again in 2016 that patients are transfused with platelets unnecessarily in these groups
180	NHS Blood and Transplant	4	Easy to measure and we are measuring precisely this in our current National Comparative Audit of the use of Red Blood Cells and platelets in adult haematology patients. You are welcome to the data. You should consider enhancing this statement so that it applies only to those who are being given prophylactic transfusions because they have reversible bone marrow failure or because they have aplastic anaemia or myelodysplasia and are receiving no other treatment than transfusion. The wording of this statement needs to be changed to reflect the rationale. Transfusion may not be indicated in all patients with a platelet count below 10x109 for example in a clinically stable haematology patient the decision may be made not to transfuse at 10 x 10^9. This wording could be interpreted as though it promotes transfusing everyone under 10 x 109 rather than avoiding inappropriate transfusion over it. The statement should say People with a platelet count below 10×109 per litre who are not bleeding or having invasive procedures or surgery are offered prophylactic platelet transfusions ***if clinically indicated*** No comments.

ID	Stakeholder	Statement number	Comments[1]
			Misleading quality statement; remove reference to bleeding or invasive procedures etc. as irrelevant if count is below the specified threshold.
181	NHS Blood and Transplant	4	Easy to measure and we are measuring precisely this in our current National Comparative Audit of the use of Red Blood Cells and platelets in adult haematology patients. You are welcome to the data. Yes – National Comparative Audit data and Regional Transfusion Committee Audit data. Yes- local and national audit data reflects that this is happening. No comments. Is this the true objective i.e. to discourage use when platelet count is above the threshold, if so bleeding etc. is relevant. Yes, The most recent national comparative audit that is due to be published in July still shows unnecessary use. It also shows a large number of people are receiving prophylactic platelet transfusions when they have chronic bone marrow failure. This was the biggest obvious issue within the audit.
182	Royal College of Anaesthetists	4	It is a sensible statement. The information should be available from the blood bank database and therefore measurable. That said, these patients form a small subgroup of the overall numbers requiring blood or blood product transfusions and the question is, 'Is it worth including this quality standard at all?'
183	Royal College of General Practitioners	4	The RCGP is not aware of any evidence that this is occurring.
184	Scottish Clinical Transfusion Advisory Committee (SCTAC)	4	• Clinical judgment dependant, as some patients with haematological conditions this may not be contraindicated. • Patients who have for example Thrombotic thrombocytopenic purpura should not receive platelets unless they are bleeding, although this is capture in the contraindications section this should be highlighted in the statement • This would be a challenge to monitor • Could giving platelets to all patients potential not increase adverse events rather than decrease • Measurement would have to be arranged prospectively or on an individual basis

ID	Stakeholder	Statement number	Comments[1]
185	Scottish Clinical Transfusion Advisory Committee (SCTAC)	4	• I would expect that there would be limited evidence without this being monitored and audited
186	Scottish National Blood Transfusion Service	4	• Exclusions need to be given more prominence in the wording as per the topic document and these patients should be removed from the denominator ie the process measure should be of 'eligible' patients • Outcome measures will be significantly impacted by confounding factors **Question 5** - For draft quality statement 4: Is there evidence that people are being given prophylactic platelet transfusions unnecessarily when they have a platelet count above 10×10^9, are not having invasive procedures or surgery, and have none of the contraindications - Would require clinical audit to ascertain
187	Welsh Blood Service	4	Correct platelet count text to ensure superscript 10x**10^9,** and extend sentence to include a statement on the list of conditions that will exclude patients with conditions as in NG24, 1.3.3
188	Welsh Blood Service	4	Rationale The rationale appears to contradict itself: - the last sentence does not make sense; The first 2 sentences appear to say that:- Prophylactic platelets will reduce risk of bleeding in patients with platelet count below $10x10^9$ and withholding platelet transfusions in patients with platelet count above $10x10^9$ reduces exposure to risks of transfusion The final sentence seems to imply that prophylactic is the same as restrictive? The NICE briefing paper does make this a little clearer in that it suggests use of prophylactic platelets will reduce need for other components. This needs to be captured somehow to make sense of the rationale
189	Welsh Blood Service	4	The denominator data might be hard to capture.
190	Welsh Blood Service	4	This statement suggests measuring Length of stay (LoS), rate of infection, morbidity & mortality. In the last few years there have been a few studies looking at these outcomes as direct outcomes of transfusion, but a contributor to this comment believes it is still too early to measure success or failure of transfusion procedure with outcomes such as LoS or infection rate. Even regarding mortality, majority of studies have not shown direct relationship between transfusion procedures and mortality for red cell transfusion. The contributor also suggests that this is even more striking for platelet transfusion. He continues, that

ID	Stakeholder	Statement number	Comments[1]
			assessment of outcomes of platelet transfusion have not been measured by LoS, infection rate or morbidity.
191	Welsh Blood Service	4	There is evidence of unnecessary platelet transfusion when platelet count is >10 and capturing this information should demonstrate areas to improve quality and safety of transfusion practice.
192	ABMUHB	5	Reword sentence, 'People who may **need** or who have had…..'
193	British Society for Haematology	5	Change "have" to "need"
194	British Society for Haematology	5	suggest change "have" to "need" - and all highlighted below
195	British Society for Haematology	5	- how will this be defined?
196	British Society for Haematology	5	- need to make sure that exclude all patients where the group and save is purely for blood group information e.g. all pregnant patients pre labour
197	British Society for Haematology	5	- the way this is worded it suggests that patients need to be made aware that if they receive blood they will lose out on their ability to donate blood - the message should be given in the vein that if they themselves need a transfusion then their need comes first, and they will not remain suitable to donate blood for public health purposes.
198	British Society for Haematology	5	- Yes
199	British Society for Haematology	5	- need to ensure that patient confidentiality is maintained.
200	British Society for Haematology	5	- Also the BCSH guidelines re transfusion
201	British Society for Haematology	5	Mr Mike Murphy – should be Dr Mike Murphy
202	British Society for Haematology	5	This standard suggests information can be given retrospectively post-transfusion. It is important that this quality standard makes it clear that patient valid consent (which includes the provision of written information about the benefits and risks) must, wherever possible, be obtained pre-transfusion (as per SaBTO recommendations). Where this is not possible (for justified reasons) post-transfusion information should be provided.

ID	Stakeholder	Statement number	Comments[1]
203	British Society for Haematology	5	This standard suggests information can be given retrospectively post-transfusion. It is important that this quality standard makes it clear that patient valid consent (which includes the provision of written information about the benefits and risks) must, wherever possible, be obtained pre-transfusion (as per SaBTO recommendations). Where this is not possible (for justified reasons) post-transfusion information should be provided.
204	British Society for Haematology	5	Need to be able to exclude patients who have sample taken for other requirements e.g. antenatal screening.
205	British Society for Haematology	5	Yes, but better if more closely related to SaBTO Consent for Transfusion recommendations
206	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	5	Currently would be in patients notes so would be hard to measure apart from sporadic clinical audit
207	Institute for Biomedical Sciences – Specialist Advisor for Blood Transfusion	5	Yes – individuals should, wherever possible, be given this information. It would also help trigger in patient's mind whether they did or did not have a transfusion for later clinical episodes (possibly in different hospitals)
208	National Blood Transfusion Committee	5	Suggest add : *and possible alternatives for transfusion.* At the end of the statement This covers the recommendations on consent following the Montgomery ruling where alternatives should be discussed
209	National Blood Transfusion Committee	5	All but one responder agreed there was sufficient evidence to merit a statement on consent specifically for transfusion.
210	NHS Blood and Transplant	5	We have audited this on a number of occasions, and have produced an audit report (2014) on Patient Information and Consent, which we did on behalf of the Department of Health's SaBTo committee. This showed that it is very difficult to capture this information. There may or may not be a record in the patient's written record, and patients could be given this information or explanation and one or more points in their journey through their healthcare experience. Healthcare professionals and patients recollection is unreliable, and I would say that this is not worth auditing until we can access all primary, secondary and tertiary care records and there is a more strongly stated requirement to record what information was given

ID	Stakeholder	Statement number	Comments[1]
			and what explanation on risks, benefits and alternatives was given. This is almost impossible to measure as requires clinical staff managing the patient to deliver the information. Even if a “tick box” system is required it is impossible to know the standard of information delivered and whether the patient understood. Trusts must give a higher priority to patient information in blood transfusion. This may be easy to measure in terms of providing information but it does not reflect the quality of verbal information given and therefore will be an unsatisfying indicator of the end point which is consent. This statement should include: …..verbal and written information about the benefits, risks and alternatives to transfusion. No reference to alternatives which is now a legal requirement (Supreme Court 2015).
211	NHS Blood and Transplant	5	Yes. It’s a very important issue for people to understand why they are being given a transfusion and not an alternative. Yes – There are specific information needs and risks associated with transfusion of a human blood product including transmission of transfusion transmitted infections and informing patients they can no longer donate blood themselves. Yes. Blood transfusion must be considered as a separate therapy within the overall picture of the patients care package and consent for use must be discussed with the patient. Yes – this is a key measure to support the safety of the blood supply, i.e. told not to become donors, and gives a chance to discuss risk and patients to refuse a transfusion. This is also easy to measure and is definitive as to it was recorded in notes or not. This will be a good KPI for the transfusion training and education element too. Yes Not sure.
212	Novartis	5	We understand the rationale behind this quality statement. However, this statement needs to be more

ID	Stakeholder	Statement number	Comments[1]
			specific otherwise it will be difficult to measure. The quality of information provided to patients may vary between different localities and centres. We recommend that standard blood transfusion forms include the risks of blood transfusions such as iron overload to ensure that all patients receive adequate information about the benefits and risks of transfusion. This is a key area for quality improvement. For many patients, red blood cell transfusions are essential and a vital intervention in managing their disease. This includes patients with β- thalassaemia, sickle cell disease and myelodysplastic syndromes amongst others. For example, β-thalassaemia major patients are by definition transfusion dependent.[1] However, each transfused red cell unit contains up to 250 mg of iron.[1] When thalassaemia major patients receive regular blood transfusion, iron overload is inevitable because the human body lacks a mechanism to excrete excess iron. Iron accumulation is toxic to many tissues, causing heart failure, cirrhosis, liver cancer, growth retardation and multiple endocrine abnormalities. [2] Iron overload may damage the heart, liver, and other organs[3] and the consequences of iron overload may be life-threatening [4, 5]. After as few as 10 units of packed red blood cell transfusions, patients may be at risk of iron overload[6, 7]. As disorders of iron excess are much less common than disorders of iron deficiency, not all healthcare care professionals are familiar with transfusional iron overload. In addition, some health care professionals are unaware of the clinical significance of iron overload, the associated risk of organ dysfunction and damage, and when the risk begins.[8] Patients may not experience symptoms as excess iron accumulates in vital organs and iron overload may be asymptomatic for years. Non-specific early symptoms of iron toxicity such as abdominal discomfort and fatigue may delay the diagnosis until severe organ damage and dysfunction are clinically apparent.[8] Consequently, iron overload is often undiagnosed or misdiagnosed. Despite this, standard transfusion consent forms do not typically warn blood transfusion recipients of the potential risk of iron toxicity. As patients don't often feel 'iron overloaded' immediately, it is very important that they are made aware of the risks of receiving multiple transfusions. They should be provided with verbal and written information explaining the risks of iron overload.

ID	Stakeholder	Statement number	Comments[1]
			All standard transfusion forms should include the risk of iron overload. This should be a quality measure. Iron overloading is a complex clinical problem which can be difficult to treat. Increased awareness of the risks of iron overload from chronic transfusion therapy should result in more effective management of iron overload and prevent serious complications. References: 1. Dr Derek Norfolk. Handbook of Transfusion Medicine. United Kingdom Blood Services. 5th edition. January 2014 2. Cappellini et al. Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT), 3rd edition. Thalassaemia International Federation; 2014. ISBN-13: 978-9963-717-06-4 3. Kushner et al. Secondary iron overload. Hematology Am Soc Hematol Educ Program. 2001:47-61. 4. Darbari et al. Circumstances of death in adult sickle cell disease patients. Am J Hematol. 2006; 81(11):858-863. 5. Malcovati et al. Prognostic factors and life expectancy in myelodysplastic syndromes classified according to WHO criteria: a basis for clinical decision making. J Clin Oncol. 2005;23(30):7594-7603. 6. Cid et al. Clinical characteristics and management of iron overload in 631 patients with chronic transfusion dependency: results from a multicentre, observational study. Blood Transfus 2014; 12 Suppl 1: s119-23 10.2450/2013.0173-12 7. Poggiali et al. An update on iron chelation therapy. Blood Transfus 2012; 10: 411-22 DOI 10.2450/2012.0008-12 8. Shander et al. Iron overload and toxicity: the hidden risk of multiple blood transfusions. International Society of Blood Transfusion, Vox Sanguinis (2009) 97, 185–197
213	Royal College of Anaesthetists	5	Once again we support this standard. Most places now have leaflets in several languages but one cannot be certain if patients actually read the information contained within. Consent is contained within the surgical notes/anaesthetic charts making it quite challenging to tease out the relevant information. Some centres have dedicated consent forms signed by patients prior to undergoing surgery; not certain how widespread this practice is. A national agreed consent form listing benefits and risks (including that they can never be donors again) maybe a way forward. It will also be an opportunity to discuss blood conservation strategies with the patient for eg, the use of TXA, cell salvage etc. It will likely help patients who are anaemic and who may require iron therapy. It is also a convenient time to discuss various

ID	Stakeholder	Statement number	Comments[1]
			treatment options with the patient, including delaying surgery until anaemia has been investigated and corrected, albeit this is bit late in the pathway. One area where prior discussion/consent cannot be had is in Intensive Care Units, except in those circumstances where the patient may have had expressed his/her wish clearly and is recorded in the notes, eg for Jehovah witnesses. Additionally discharge summaries could include a prompt (like a tick box) if the patient has had blood products as part of their overall treatment. All staff must undergo updates on blood transfusion and this is probably the case in most Trusts, if not all, as part of their mandatory training requirements.
214	Royal College of General Practitioners	5	Patient information is important for them and their carers and it would help if there was a standard national booklet that could be printed off to give patients with an easy read accessible version available.
215	Scottish Clinical Transfusion Advisory Committee (SCTAC)	5	• It is likely that this is happening, however it can be difficult to find evidence that this has occurred e.g. in patients' case notes or electronic records • I expect that this does happen in most cases due to better information /training being available. However to evidence would require an audit of case notes or transfusion records to be undertaken. • This recommendation was introduced into NHS Scotland as part of the NHS Quality Improvement Scotland Standards 2006 and a similar recommendation for SABTO. However the Standards are now classed a business as usual. • Measurement depends on reliability of documentation that this has occurred. Our findings from previous audit work are that patient and staff recollection of whether this has occurred does not always tally – and that recollections do not always match what had been documented.
216	Scottish Clinical Transfusion Advisory Committee (SCTAC)	5	• I would think that for all interventions that carry a risk, patients should get verbal and written information about the risks and benefits and therefore this is not specific to blood transfusion, however it is an area that in the past has tended to be overlooked • This is a generic issue but, in order to measure and monitor effectively, we presumably do need to look at this as separate from other aspects of care where this is also pertinent.
217	Scottish National Blood Transfusion Service	5	• This recommendation was introduced into NHS Scotland as part of the NHS Quality Improvement Scotland Standards (2006) and as part of the SABTO recommendations (2014). **Question 6 –** whilst this is not only specific to blood transfusion patients can have a choice and therefore agree Note the definition of patients who may have a transfusion (p29) includes anyone having a sample sent to

ID	Stakeholder	Statement number	Comments[1]
			the transfusion lab for blood group or antibody screening. This will include a significant number of pregnant women who are never transfused. The information being given to them includes their exclusion from being a blood donor – if they are not transfused this would not be the case. This may have an adverse impact on donation.
218	Vifor Pharma UK Ltd	5	Agree this reflects a key area for improvement. This quality statement is sufficiently specific to blood transfusion to merit a statement.
219	Vifor Pharma UK Ltd	5	The measures are appropriate for this quality statement.
220	Welsh Blood Service	5	Reword sentence, 'People who may **need** or who have had…..' Alternatively, emphasise thus, 'People who **may** have or who **have** had…..' This comment will apply throughout the standards where this sentence is used Additionally, consider extending the statement to include consent as specified by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).
221	Welsh Blood Service	5	Change to 'People who may **need** or who have had a transfusion…..'
222	Welsh Blood Service	5	Change sub heading to 'People who may **need** a transfusion Also under the subheading, Verbal and written information, change the sentence to 'People who may **need** or who have had a transfusion…..'
223	Welsh Blood Service	5	Yes, we believe so. We know that provision of patient information in relation to blood components is performed poorly. Provision of patient information to enable informed decision making is recommended by SaBTO and also expected by the General Medical Council. This statement could go a step further and include consent and documentation of that consent. Monitoring this as a quality standard should improve quality of care and patient satisfaction. In addition to consent and informed decision making, people who have been transfused need to be aware that they can no longer donate blood and therefore represents a wider public health issue.
224	Royal College of Paediatrics and Child Health	Additional statement	The guideline does not include neonates and preterm infants - is there an intention to develop this? There is a guideline from the British Committee for the Standards in Haematology that was released this year, "Guidelines on transfusion for fetuses, neonates and older children". (April 2016) Should the draft include a statement of where to find more information on this?
225	Royal College of Paediatrics and Child	Additional statement	The guideline does not include neonates and preterm infants - is there an intention to develop this?

ID	Stakeholder	Statement number	Comments[1]
	Health		There is a guideline from the British Committee for the Standards in Haematology that was released this year, “Guidelines on transfusion for fetuses, neonates and older children”. (April 2016) Should the draft include a statement of where to find more information on this?
226	Welsh Blood Service	Additional statement	As in comment 6 above, this Quality Standard does not include IV iron. Suggest that the standard is extended for oral and IV to address patients who cannot take oral iron, do not tolerate it or may have difficulties in absorbing oral iron. This same comment applies to all sections that reference oral iron. The statement does not distinguish between pre-op and post-op anaemia The statement does not specify type of surgery – would this quality standard also apply to a patient undergoing zero blood loss surgery (e.g. insertion of grommets)?
227	Welsh Blood Service	Additional statement	As the quality statements are drawn from stakeholder feedback and are limited to 5 areas, it appears that those prioritised in this document are reasonable. Other suggestions from contributors are: • It is prudent to measure and document more acute decision making or clinically pressing and important behaviour regarding transfusion practice. This urgent decision making process have potentially more impact on clinical outcomes directly related to transfusion. This could include measuring platelet transfusion rate among thrombocytopenic patients with plat count<50 who have ongoing moderate bleeding or measuring rate of plasma transfusion in massive haemorrhage setting. • The major cause of transfusion misadventure is still transfusion the wrong blood component which has been identified since the inception of SHOT. A major cause of this is patient misidentification at the time of blood sampling (for pre transfusion testing) or at the time of the transfusion event. It would be ideal if there was a quality statement which read as follows. “People who receive a blood transfusion must be correctly identified at the time of blood sampling for pre transfusion testing and again at the commencement of each transfusion event” • In addition, there needs to be a quality statement about the observation and monitoring of patients receiving transfusions. This will ensure that any adverse event is rapidly detected.

Registered stakeholders who submitted comments at consultation

- Abertawe Bro Morgannwg University Health Board (ABMUHB)

- British society for Haematology
- Department of Health
- Institute for Biomedical Sciences
- National Blood Transfusion Committee (NBTC)
- NHS Blood and transplant
- NHS England
- Novartis
- Royal College of Anaethetists (RCOA)
- Royal College of Nursing
- Royal College of Paediatrics and Child Health (RCPCH)
- Scottish Clinical Transfusion Advisory Committee
- Stanningley Pharma
- The Christie
- UCL REVENTT
- UK Transfusion Laboratory Collaborative (UK TLC)
- Vifor Pharma
- Welsh Blood Service
- Whittington NHS Trust

Appendix 2: Quality standard internal checks table

Comment number	NICE Team	Statement number	Comments
1	QS team	1	Further information needed around timing and dosage of oral iron.
2	QS team	2	Further information needed around timing and dosage of tranexamic acid.
2	QS team	4	Is there evidence that this is not already happening?
3	QS team	5	Could be reworded to improve the clarity