National Institute for Health and Clinical Excellence

Transfusion
Scope Consultation Table
7th February 2013 - 7th March 2013

	Type	Stakeholder	Order No	Section No	**Comments** Please insert each new comment in a new row.	Developer's Response Please respond to each comment
1.	SH	Addenbrookes Hospital	1	4.3.1a	There is no comment in the draft regards the cost/benefits of the investigation and treatment (who is going to treat how should it be treated, the role of intravenous iron, risk of harm if all anaemic patients are treated with iron pending further investigations) of anaemia if it is detected e.g. in pre-operative elective surgical patients. The possibility of exemptions from iron treatment should be addressed (ongoing infections, inflammatory conditions etc).	Thank you for your comment. In light of stakeholders' comments, we will now include oral iron/IV iron/erythropoietin for treatment of anaemia in surgical patients. However, we will not include any investigations and treatment of anaemia in medical patients. The scope has been amended accordingly.
2.	SH	Addenbrookes Hospital	2	4.3.1b	There is no comment on the stratification of patients who may/may not benefit from blood transfusion e.g. age groups, demands of post-operative rehabilitation (for example successful achievement of physiotherapy exercise targets following joint replacement which influence length of stay), pre-op physical fitness (regular exercisers versus poor exercisers). This is an opportunity to consider the evidence to move away from global haemoglobin targets and move towards tailoring transfusion to specific subgroups who may poorly tolerate anaemia (symptoms, delayed rehabilitation, discharge)	Thank you for your comment. If these are appropriate subgroups that require specific consideration in a recommendation, they will be specified as a group in the review protocol by the GDG and covered in individual clinical reviews. The GDG will make decisions for predefined subgroups, related to the evidence reviewed.
3.	SH	Addenbrookes Hospital	3	4.3.1c	There is good evidence already that tranexamic acid reduces blood loss. What is unclear and needs review is	Thank you for your comment. The guideline will focus on the effectiveness of tranexamic acid

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					time of treatment in relation to blood loss/or anticipation of blood loss, the best dosage and duration of treatment and possible exemptions particularly for patients susceptible to DIC.	in reducing transfusion in surgical patients. However, we will not be able to cover further detail of time/dosage/duration of tranexamic treatment, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood.
4.	SH	Addenbrookes Hospital	4	4.3.1c	There is a need to review commonly stated contraindications to cell salvage e.g. cancer, contamination and to provide best evidence guidance whether these contraindications still hold.	Thank you for your comment. We agree that this would be useful information to include and where appropriate contra-indications will be highlighted.
5.	SH	Addenbrookes Hospital	5	4.3.2	Consideration should be given to address usage of products(prothrombin complex concentrate and fibrinogen concentrate) instead of components..	Thank you for your comment. In light of the stakeholders' comments; we will now include prothrombin complex concentrate in the scope along with other blood components (RBC/platelets/FFP/cryoprecipitate). However, we will not be able to include fibrinogen, as this is not licenced to use in the UK other than for treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency.
6.	SH	Addenbrookes Hospital	6	general	Address possible benefits/risks of usage of new technologies to improve safety(electronic blood tracking systems)	Thank you for your comment. The benefits/risks of new technologies such as electronic patient identification systems to improve safety will be considered. However we will not be able to include electronic blood tracking system, as this is a cross cutting topic focussing broadly on the general principles of transfusion and the appropriate use of blood.
7.	SH	Barnsley	1	4.3.1b	To ensure patient safety - When you cover the	Thank you for your comment. We agree this is

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		Hospital NHS Foundation Trust			administration section - could we make sure there is a clear statement that recommends **against** transfusing at night unless patients are clinically symptomatic? (as per SHOT recommendations)	an important topic. We intend to include certain aspects of patient safety, however, we will not be able to cover transfusing specifically at night as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas.
8.	SH	Barnsley Hospital NHS Foundation Trust	2	4.3.1b	?? can we highlight benefits of single unit transfusion (regular Hb and patient clinical assessment) to prevent un-necessary or over transfusion of RBCs administration	Thank you for your comment. We agree over-transfusion is an important topic and we intend to include this in the section on appropriate use of red blood cell transfusion (section 4.3.1).
9.	SH	British Committee for Standards in Haematology / The British Society for Haematology	1	3.1c	In relation to adverse effects of transfusion: In addition to more tangible adverse events reported to haemovigilance schemes should also allude to potential other risks that are of concern but which need more study eg Acheson AG, Brookes MJ, Spahn DR.Effects of allogeneic red blood cell transfusions on clinical outcomes in patients undergoing colorectal cancer surgery: a systematic review and meta-analysis. Ann Surg. 2012 Aug;256(2):235-44 Murphy GJ, Reeves BC, Rogers CA, Rizvi SI, Culliford L, Angelini GD Increased mortality, postoperative morbidity, and cost after red blood cell transfusion in patients having cardiac surgery. Circulation. 2007 Nov 27;116(22):2544-52. Should perhaps also allude to publications of age of blood and outcomes again stating that this is currentl a subject of ongoing research	Thank you for your comment and the information provided. We intend to include serious adverse events as one of the outcomes. The outcomes listed are examples suggested for questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review. The guideline development group will finalise the list and we will include your suggestions in the options that we will consider. Thank you for your comment. We note the studies you mention. We will consider these as part of the evidence based review if relevant during our systematic searches of the evidence.

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10.	SH	British Committee for Standards in Haematology / The British Society for Haematology	2	4.1.1c 4.3.2e	Consider changing the wording to reflect that the overall principles eg around patient identification, administration, monitoring for reactions, patient information and consent within the guideline cover the majority of patients transfused but more detailed guidance for specific patient groups is beyond the scope of these guidelines.	Thank you for your comment. We agree and have amended the scope accordingly.
11.	SH	British Committee for Standards in Haematology / The British Society for Haematology	3	4.3.1a	Suggest include another bullet point stating the cause of anemia should be identified wherever possible	Thank you for your comment. We recognise that determining causes of anaemia are required for the care of these groups of patients. However, we will not be able to include this topic, as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas.
12.	SH	British Committee for Standards in Haematology / The British Society for Haematology	4	4.3.1b	Include additional bullet point emphasising the need to give oral and if needed Iv iron rather than blood for iron deficiency anaemia and similarly to replace other haematinics if deficient eg vitamin B12 or folate	Thank you for your comment. In light of the stakeholders' comments we are now including oral iron/IV iron as alternatives to transfusion in the treatment of anaemia in surgical patients. However, we will not be able to include any investigations and treatment of anaemia in medical patients, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. The scope has been amended accordingly.
13.	SH	British Committee for	5	4.3.1c	Consider including erythropoetin – some hospitals are using this piecemeal as part of their pre-op protocols so	Thank you for your comment. In light of the stakeholders' comments we are now including

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		Standards in Haematology / The British Society for Haematology			important to review evidence and include recommendations on whether or not should be used and safety	erythropoietin as one of the alternatives to transfusion in the treatment of anaemia in surgical patients.
14.	SH	British Committee for Standards in Haematology / The British Society for Haematology	6	4.5.3a	Strongly recommend including cost effectiveness of IV iron	Thank you for your comment. IV iron has been included in the scope and the GDG will consider whether to prioritise this area for additional health economic modelling.
15.	SH	British Committee for Standards in Haematology / The British Society for Haematology	7	4.5.3a	Consider including cost effectiveness of erythropoetin use in surgery	Thank you for your comment. Erythropoetin has now been included and the GDG will consider whether to prioritise this area for additional health economic modelling.
16.	SH	Department of Health – Sponsor branch	1	general	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you. For information, we have received comments from a separate section of the Department of Health and we have responded to these separately.
17.	SH	Gloucestershire Hospitals NHS Foundation Trust	1	4.1.1c	Jehovah's Witnesses are a patient subgroup that requires special consideration, as they cannot benefit from autologous blood transfusion. As a result new strategies for avoiding blood products have been initiated and	Thank you for your comment. We are aware of equality issues for some subgroups such as Jehovah's Witnesses, and this will be addressed by the GDG when reviewing the

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					developed for this group. These strategies may be applicable to a wider population. Their clinical and cost effectiveness should therefore be considered. Also the risk/benefit and cost/benefit ratio for certain management strategies is altered for JW patients compared to others. Examples include the pre operative administration of erythropoietin or the use of intraoperative cell saver in surgery for malignacy where the risk of death from blood loss outweighs the risk of dissemination of cancer cells.	evidence. We have included in the scope some alternatives to blood transfusion such as oral iron/IV iron/ erythropoietin/tranexamic acid/cell salvage therapy and we will consider your comments about these patients when making these recommendations.
18.	SH	Gloucestershire Hospitals NHS Foundation Trust	2	4.5.1a	REVIEW QUESTIONS. Clinical and cost effectiveness of testing for anaemia at different times before surgery. This question needs to be qualified i.e. what interventions are taken if anaemia is detected. Further investigation, haematinics? For example, recent studies suggesting that use of Erythropoietin in Orthopaedic Joint replacement may now be cost effective due to reduction in transfusion, length of stay and mortality. Haematinics and Erythropoietin should have their own section for consideration for this to be a useful guide for clinicians. Limitations of the review Q: cancer surgery now has reduced waiting times and therefore constrains the timing of preoperative testing to surgery.	Thank you for your comment. In light of the stakeholders' comments, we will now include oral iron/IV iron/erythropoietin for treatment of anaemia in surgical patients. However, we will not be able to include any investigations and treatment of anaemia in medical patients, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at the detail of testing for anaemia. The scope has been amended accordingly.
19.	SH	Gloucestershire Hospitals NHS Foundation	3	4.5.2a	These subsections are almost identical questions. Even in a more easily studied population (CRITICAL CARE PATIENTS) where outcome data is more reliable	Thank you for your helpful comment. The GDG are able to consider a variety of evidence when making their recommendations e.g. trial data,

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		Trust		4.5.2c 4.5.2d 4.5.2e	the level of evidence for recommendations based upon HB level is poor. E.g "Guidelines on the management of anaemia and red cell transfusion in adult critically ill patients Andrew Retter et al and British Committee for Standards in Haematology Dec 2012" They were only able to make recommendations with good evidence for the general critical care population (transfusion triggers 70-90g/l) based upon the TRICC study 1999). The other recommendations were based upon a very weak evidence base. Non-crtitical care patients are likely to have LESS robust data. Very generalised recommendations based upon low levels of evidence by NICE are unlikely to aid clinicians in transfusion management.	patient views, cost effectiveness information and their own consensus opinion. Whilst the data may be of poor quality in the direct populations we are examining they can choose to include indirect populations. They will take the quality of the data into account when making their recommendations, and even if the data are considered to be poor it may still be possible to make a useful recommendation for the NHS that will improve blood transfusion.
20.	SH	Gloucestershire Hospitals NHS Foundation Trust	4	4.5.2b	Symptoms of anaemia are very non specific and not helpful. Is this question relating to other co-morbidities e.g. IHD	Thank you for your comment and suggestion. In light of the stakeholders' comments, we will take co-morbidities in to consideration and to reflect this. We have amended the scope accordingly (section 4.5.2 b).
21.	SH	Gloucestershire Hospitals NHS Foundation Trust	5	4.5.4a 4.5.4b	This is already established good practice that is partly responsible for the good safety record mentioned 3.1e)f).	Thank you for your comment. We will be including, monitoring of acute transfusion reactions and electronic patient identification systems, to ensure patient safety during blood transfusions.
22.	SH	Gloucestershire	6	4.5.5	Please liaise with the Advisory Committee on the Safety	Thank you for your comment and the

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		Hospitals NHS Foundation Trust			of Blood, Tissues and Organs (SaBTO). Their 14 recommendations and action plans (patient consent for transfusion) is not accompanied by robust centralised accessible information for NHS providers. I hope that NICE can provide this in this review.	information provided. We will be considering the provision of patient information and support specific to blood transfusion, but will not be revisiting the issue of consent. Every guideline includes standard wording about the importance of consent.
23.	SH	Gloucestershire Hospitals NHS Foundation Trust	7	4.1.1c 4.5.2e	Obstetric patients should be considered as a special subgroup as normal Hb changes throughout gestation. Other unique issues affect target Hb values e.g Antepartum Haemorrhage with risk of re-bleeding and risk to the foetus requires higher target Hb than a non pregnant patient.	Thank you for your comment. We agree that Hb changes and antepartum haemorrhage in obstetric patients is an important issue, however we will not be able to cover this as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas.
24.	SH	Medicines and Healthcare products Regulatory Agency (MHRA)	1	general	The document should refer to the Blood Safety and Quality Regulations 2005 for the correct definitions of blood and blood components. The document is incorrect in its statement that "platelets, fresh frozen plasma and cryoprecipitate" are blood products. They are blood components and as such perhaps consideration should be given to including these in the guidelines.	Thank you for your comment. We agree with your definitions. In light of the stakeholders' comments we are now including the following blood components: RBC, platelets/FFP/cryoprecipitate/ prothrombin complex concentrate in the guideline. We have amended the scope accordingly
25.	SH	Northern Ireland Blood Transfusion Service	1	3.2a	Please note, issues of red cells per 1,000 population for Northern Ireland are 30/1,000 and this result has been achieved for each of the years from 2006/7. Major regional audit "Appropriate use of Red Cells in Northern Ireland" concluded inappropriate use 19% and over transfusion 29%. This led to publication of clinical	Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline

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					guideline recommending thresholds below which red cell transfusion may be appropriate. Guideline may be accessed www.gain-ni.org.	
26.	SH	Pharmacosmos UK Ltd	1	4.3.1	Our comments are as follows: We suggest adding "what to test for" as a bullet here. Few simple test in addition to haemoglobin might improve management of the anaemic patients and help avoid unnecessary transfusions.	Thank you for your comment. We will now be including treatment of anaemia in surgical patients. However we will not be including any investigations and treatment of anaemia in medical patients, as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas. The scope has been amended accordingly.
27.	SH	Pharmacosmos UK Ltd	2	4.3.1	We suggest adding "IV iron therapy" as a bullet as IV iron may help reduce unnecessary transfusions in this setting.	Thank you for your comment. We agree this is an important topic. We will now include IV iron, which will be specifically considered in the treatment of anaemia in surgical patients. The scope has been amended accordingly.
28.	SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. The draft scope seems comprehensive.	Thank you for your comment.
29.	SH	Royal College of Nursing	2	3.1b	Is there not a more up to date figure than 2002?	Thank you for your comment. Unfortunately there are no more up-to-date figures available than what is already mentioned in the scope.
30.	SH	Royal College of Nursing	3	4.3.2e	These are the main uses of red blood cells in medicine. By removing these from the scope it means the concentration will be looking at surgical patients and as the document recognises, this is already reducing. It is the use of red cells in medicine that is increasing.	Thank you for your comment. The patient groups you refer to are included in the scope, but we will not go into the detail management of each of these groups as this is a cross cutting guideline focussing on the general

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						principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. We have amended the scope to make this clearer.
31.	SH	Royal College of Nursing	4	General	The proposals all look very worthwhile; however, we wonder if it is duplicating the BCSH guidelines? The BCHS guidelines are not mentioned in the document.	Thank you for your comment. We are aware of these existing guidelines and agree that there will be some overlap and duplication, however to make a NICE clinical guideline recommendation we will have to look at the evidence independently.
32.	SH	Royal College of Nursing	5	General	It would be worth looking at strategies to support implementation as audits consistently show that people do not often follow guidelines.	Thank you for your comment. Following publication of the guideline, the NICE implementation team will work with stakeholders to develop implementation tools.
33.	SH	Royal College of Obstetricians and Gynaecologists	1	General	A decision has recently been taken regarding the date duration for group & save in pregnancy. For the last few years we have worked with a specific requirement in obstetrics that cross-matching will only be done on samples up to 7 days old. This relates to the risk of sensitisation in pregnancy due to Fetomaternal haemorrhage. A decision has been made (apparently without consultation with RCOG) that this is now to be reduced to three days. Is there an evidence base to justify the substantial inconvenience this presents to women, particularly those attending for a planned caesarean section. The scope excludes antibody testing which is disappointing and will limit the relevance of the guideline.	Thank you for your comment. We recognise that antibody testing is very important to specific groups of patients including obstetric patients, however we will not be able to cover this topic as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas

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34.	SH	Royal College of Obstetricians and Gynaecologists	2	General	No mention of certain "at risk" groups – e.g. Jehovah's Witnesses – who may decline blood products	Thank you for comment. We considered religious groups when writing the scope and the GDG will continue to do so in developing the recommendations. We did not feel that we needed to highlight these groups particularly in the scope, but are intending to consider them during development.
35.	SH	Royal College of Obstetricians and Gynaecologists	3	General	Massive obstetric haemorrhage is a huge issue but is not covered and neither is the transfusion of blood products which further limits the relevance of the guideline. The RCOG produces guidance on blood transfusion in obstetrics (and postpartum haemorrhage and antepartum haemorrhage); these guidelines will therefore continue to be revised.	Thank you for your comment. We agree that massive obstetric haemorrhage is a huge issue, however we will not be able to cover this as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas.
36.	SH	Royal College of Paediatrics and Child Health	1	general	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the Transfusion draft scope. We have not received any comments from our members.	Thank you for your comment.
37.	SH	Royal Devon and Exeter NHS Foundation Trust	1	4.3.1	Need to address: perioperative physiology – normothermia, normovolaemia , acidosis correction	Thank you for your comment. This was not an area prioritised for inclusion following the scoping exercise.
38.	SH	Royal Devon and Exeter NHS Foundation Trust	2	4.3.1	Perioperative anticoagulation management	Thank you for your comment. This was not an area prioritised for inclusion following the scoping exercise.

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39.	SH	Royal Devon and Exeter NHS Foundation Trust	3	4.3.1	Antiplatelet management	Thank you for your comment. This was not an area prioritised for inclusion following the scoping exercise.
40.	SH	Royal Devon and Exeter NHS Foundation Trust	4	4.3.1	Biological haemostats	Thank you for your comment. This was not an area prioritised for inclusion following the scoping exercise.
41.	SH	Royal Devon and Exeter NHS Foundation Trust	5	4.5.3	Biological haemostats	Thank you for your comment. This was not an area prioritised for inclusion following the scoping exercise.
42.	SH	Scottish Clinical Transfusion Advisory Committee (SCTAC)	1	3.2a 3.2b	We have excellent up to date data in Scotland from Account for Blood showing RBC use across various surgical specialties and across Boards/ Trusts which may help to inform guidelines process	Thank you for your comment and information. The guideline development group will be made aware of this information when developing the guideline.
43.	SH	Scottish Clinical Transfusion Advisory Committee (SCTAC)	2	4.3.2c	May impact on peri-operative decision making in 4.3.1 (a) + (b)	Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.
44.	SH	Scottish	3	4.3.2e	Exclusions severely restrict the overall scope of the	Thank you for your comment. The patient

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		Clinical Transfusion Advisory Committee (SCTAC)			guidelines, which seems to leave only non – traumatic and major blood loss surgery and some "medical" indications (elderly/ non – bleeding/ non – renal). This is likely to be minority of transfusion recipients!	groups you refer to are included in the scope, but we will not go into the detail management of each of these groups as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. The scope has been amended to make this much clearer.
45.	SH	Scottish Clinical Transfusion Advisory Committee (SCTAC)	4	4.5.3a	Are there other interventions that could be considered? What about effective management of anticoagulation/ anti - platelet drugs?	Thank you for your comment. This is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. Effective management of anticoagulation and anti-platelet therapy will be beyond the scope of this guideline.
46.	SH	Scottish Clinical Transfusion Advisory Committee (SCTAC)	5	General	Scope seems quite broad at first glance – would 4.5.4 and 4.5.5 sit better as separate guidelines ie. one for assessment and one for management – while also quite restrictive – see 4.3.2 (e) & comments in Sec.3 above	Thank you for your comment. This is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas.
47.	SH	Sheffield NHS Teaching Hospitals Foundation Trust	1	3.1b	This whole line is a little random. 'In 2002 an estimated…' the rest of document cites 2011 as the date period.	Thank you for your comment. Unfortunately there are no more up-to-date figures available.

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48.	SH	Sheffield NHS Teaching Hospitals Foundation Trust	2	4.3.2	The title of the scope is transfusion. Disappointed it has become another red cell document. Will other blood components from Blood Bank (Plts, FFP and Cryo) be covered by another document?	Thank you for your comment. We agree this is an important topic. In light of the stakeholders' comments we are now including the following blood components in the guideline: RBC, platelets/FFP/cryoprecipitate, prothrombin complex concentrate. We have amended the scope accordingly.
49.	SH	Sheffield NHS Teaching Hospitals Foundation Trust	3	4.5.3	Should oral/IV iron not be promoted as an alternative to red cells especially if advising for medical patients	Thank you for your comment. In light of the stakeholders' comments we are now including oral iron/IV iron as alternatives to transfusion in the treatment of anaemia in surgical patients. The scope has been amended accordingly.
50.	SH	Sheffield NHS Teaching Hospitals Foundation Trust	4	4.3.1e 4.5.5a 4.5.5b	Mentions patient information. Have we deliberately stayed away from the issue of consent?	Thank you for your comment. We will be considering the provision of patient information and support specific to blood transfusion, but will not be revisiting the issue of consent. Every guideline includes standard wording about the importance of consent.
51.	SH	Sickle Cell Society	1	General	**Climate Change & Risks:** We think the draft scope should consider the emerging and real threat of climate change and its likely impact on Transfusion, especially safety of blood supply, and tenuously adequacy of supply.	Thank you for your comment and suggestion. We will not be able to include the topic on climate change and its impact on transfusion, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas.
52.	SH	Sickle Cell	2	Genera	**Excess Iron Removal:** The scope should consider the	Thank you for your comment. We recognise

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		Society		l	issues in relation to safety resulting from the build up of Iron (hence need for chelation or other removal) as a result of repeat/ frequent transfusion. Eg in sickle cell, thalassaemia and haemophilia.	that this is an important issue for haemoglobinpathy patients. However we will not be able to include issues in relation to safety resulting from the build-up of iron as a result of repeat transfusion, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas.
53.	SH	Sickle Cell Society	3	General	The Scope should also so look at : **Allo-immunisation**, which relates to the fact that patients receiving blood products may produce antibodies against some antigens (proteins) that are expressed on the red cell (or white blood cell, for that matter) of the donors. From our understanding the more frequently transfused the more chance that patients will be immunized against antigens from the blood products.	Thank you for your comment. We recognise that this is an important issue for people with haemoglobinopathy. However we will not be able to include allo-immunisation, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas.
54.	SH	UK Thalassaemia Society	1	General	• Thalassaemia patients are very untypical of the usual patient having a blood transfusion in the NHS. The majority of people are transfused due to trauma, surgery or during treatment for an illness they have developed during life. Thalassaemia patients are exceptional in that blood transfusion is not an unusual event but a way of life for them. In order to manage their condition they are transfused every 3-4 weeks throughout life from babyhood onwards. Despite the onerous demands of thalassaemia treatment, thalassaemia is a condition that can be successfully	Thank you for your comment and the useful information provided. People with thalassemia are included in the scope, but we will not go into the detail of managing of these groups, as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. The scope has been amended to make this much clearer.

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					managed. The UK Thalassaemia Society encourages all patients to achieve their full academic and career potential and become adults who are both socially and economically integrated into society. • Many hospitals which treat thalassaemia patients do not provide any facilities which would allow them to be transfused outside "office hours" (9am-5pm Monday-Friday). This is a huge problem for our patients and the main complaints we have been hearing from them for years centre around the difficulties of getting a job when they are forced to take time off for frequent transfusions. If essential services such as transfusions are only available during normal "office hours" how can patients successfully balance the demands of their treatment with the demands of a full time job, family life etc.? • Interestingly, some hospitals are able to solve this problem and accommodate the patients' needs by creative ways of working. For example, Coventry & Warwickshire Hospital has an arrangement whereby they open their day unit every fourth Saturday, which does not impose huge extra costs or demands on the staff but enables all their patients who are in work to be transfused without taking time away from their jobs. If some hospitals can do this why not others?	
55.	SH	UK Thalassaemia Society	2	4.1.1c	• The document states under *Population: Groups that will be covered* (Section 4.1.1 c) "No patient subgroups have been identified as needing specific	Thank you for your comment. People with thalassemia are included in the scope, but we will not go into the detail of managing of these

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					consideration." We strongly feel that NICE should reconsider this point; as thalassaemia patients and other multi transfused groups clearly need to be considered separately. • There are numerous transfusion guidelines, at national, regional, local and individual hospital level; and some hospital managements use the fact that transfusions "out of hours" are statistically less safe to refuse to consider providing this essential service for thalassaemia patients. However as stated in the first point, the majority of "out of hours" transfusions are given in emergency situations rather than the routine, elective procedure which applies to thalassaemia patients. • We are concerned that local transfusion policies are widely variable, not evidence based for this patient cohort and more related to cost and liability considerations.	groups, as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. The scope has been amended to make this much clearer.
56.	SH	UK Thalassaemia Society	3	4.3.2e	The NICE draft scoping document on transfusion should provide an opportunity to amend guidelines to accommodate the need of multi transfused patients such as those with thalassaemia; however the document specifically excludes them. Under *Clinical issues that will not be covered* (Section 4.3.2 e) it states "Red cell transfusions is specific conditions, such as: malignancy or haematology". We strongly urge NICE to reconsider this position to bring thalassaemia patients within the remit of this document.	Thank you for your comment. People with thalassemia are included in the scope, but we will not go into the detail of managing of these groups, as this is a cross cutting guideline focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. The scope has been amended to make this much clearer.

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					The NICE transfusion clinical guideline development offers a unique opportunity to address these equity issues and provide robust clinical evidence to the efficacy and safety of flexible transfusion regimens for this cohort, mindful of these patients' Quality of Life too.	
57.	SH	British Blood Transfusion Society.		4.5.3	There are other alternatives that should be considered especially iron-oral/intravenous	Thank you for your comment. We are now including oral iron/IV iron as alternatives to transfusion in the treatment of anaemia in surgical patients. The scope has been amended accordingly.
58.	SH	NHS Blood and Transplant	1		Transfusion is a huge subject and you will have to make some choices. The scope as written is not achievable in the time and duplicates many excellent guidelines elsewhere. The question for NICE is- where are the biggest gains to be made for healthcare by this new document. It seems clear from national audits and benchmarking of the UK against other countries that the focus of the NICE guidance should be on **prescribing of blood components (red cells, platelets, FFP, cryoprecipitate).** The rationale is that these are donated by voluntary blood donors in UK and should therefore be used only when indicated. I suggest that the following be EXCLUDED: albumin, recombinant factor VIIa, Immunoglobulin (which, although	Thank you for your comment. In light of the stakeholders' comments we are now including the following blood components: RBC, platelets/FFP/cryoprecipitate, prothrombin complex concentrate in the guideline. The scope has been amended accordingly. We agree with your suggestions for exclusion. These blood products have been included in the section clinical issues that will not covered (section 4.3.2 a)

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					a blood product, is not used for transfusion as such).	
59.	SH	NHS Blood and Transplant	2		The scope should include the following in relation to the blood components listed: triggers, dose, target values and alternatives (which may include some plasma products eg fibrinogen concentrate).	Thank you for your comment. We agree. These issues will be included when the appropriate use of blood is considered (section 4.3.1).
60	SH	NHS Blood and Transplant	3		There should be a prioritised list of clinical scenarios in which these are considered. Since surgical blood use has decreased so much, I suggest you focus on medical scenarios first. I don't understand the rationale for excluding neonates and infants – they are highly transfused and will live long enough to be susceptible to any long term complications.	Thank you for your comment. We agree that neonates and infants are an important group in relation to transfusion, however we will not be able to cover such a specialist and complex area as part of this guideline as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas. These groups would require separate guidance.
61	SH	NHS Blood and Transplant	4		Safe administration of transfusion should not be a major focus (well covered elsewhere), but there needs to be clear guidance on the use of electronic systems to reduce errors of identification. They also have great potential as a tool for appropriate prescribing and for that reason should be included.	Thank you for your comment. We will be including electronic patient identification systems to ensure patient safety during blood transfusions.
62.	SH	NHS Blood and Transplant	5		The following topics should be **excluded**, as they are well covered elsewhere, although the NICE document could cross-refer:- a. Monitoring of the transfused patient (BSCH) b. Patient information (SaBTO and UK Blood Services)	Thank you for your comment and suggestion. We feel it is important to include monitoring of transfused patients and patient information and support specific to blood transfusion. We will need to look at the evidence to make NICE guideline recommendations for the development of Quality Standards.

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					c. Laboratory procedures (BSCH, UK Guidelines for Transfusion Services, which are also used by hospitals) d. Detailed review of near patient testing (this could be the subject of separate guidance) e. HLA sensitisation in transplantation – too specific.	Unfortunately, NICE guidelines do not cross refer to information not produced by NICE. We need to review the evidence and consider the cost effectiveness independently.
63	SH	Department of Health	1	general	The Department of Health (DH) Blood Policy Team welcomes the development of a NICE guideline on blood transfusion. It has the potential to improve significantly the clinical and cost effectiveness of transfusion practice, to the benefit of both patients and health services. However we believe the scope as currently drafted will not achieve the degree of benefit possible, and suggest it is amended. The level of inappropriate use of blood / blood components is currently a major concern of blood and transfusion services. Inappropriate use is estimated at 20% or more, which puts patients at unnecessary risk of a transfusion-related adverse outcome, incurs considerable unnecessary cost and wastes a (limited) resource donated for the benefit of patients, which the health services have a duty to the donors to use well. A number of factors are acting to drive up the use of blood transfusion, such as the ageing of the population and the development of new techniques in cancer, cardiac surgery	Thank you for your comment and useful information, we agree with your comment. This is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas. Having considered the information provided by the stakeholders we are now including the following blood components in the guideline: RBC, platelets/FFP/ cryoprecipitate/, prothrombin complex concentrate. We will further include the following topics: alternative treatments to blood transfusion in surgical patients including oral iron, IV iron, recombinant erythropoietin, tranexamic acid and cell salvage therapy; monitoring of acute transfusion reactions; electronic patient identification systems; and patient information and support specific to blood transfusion. We have amended the scope accordingly.

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					and transplantation. In order to manage this pressure and maintain the supply of blood for all essential clinical uses, as well as reducing the avoidable risk to patients, the level of inappropriate use in both medical and surgical treatment must be reduced. If the NICE guideline is to achieve this, it will need to include red blood cells, platelets, fresh frozen plasma (FFP) and cryoprecipitate, rather than just red blood cells. To make the scope manageable, this will necessitate removing from scope some areas currently included, where good guidance is already available. The programme of national comparative audits carried out by NHS Blood and Transplant (NHSBT) and the Royal College of Physicians provides widespread and detailed evidence of variation in transfusion practice between hospitals, and inappropriate use of blood components. The audits give an indication of the reasons for inappropriate use, which the NICE guideline could usefully address. For example, a 2010 audit of platelet transfusions found 28% were inappropriate, including patients being transfused above the recommended threshold, prophylactic use in inappropriate patients, inappropriate pre-operative use, and double doses being used when single dose had been shown to be equally effective.	

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					A 2009 audit of the use of FFP found widespread prophylactic use in non-bleeding patients and use for reversal of anticoagulation in patients without severe bleeding, both contrary to guidance; and found much FFP use resulted in little or no improvement or correction in coagulation abnormalities. A recent study (*Cryoprecipitate for transfusion: which patients receive it and why? A study of patterns of use across three regions in England.* H Tinegate, S Allard, J Grant-Casey et al. Transfusion Medicine 2012, **22,** 356-361) of the use of cryoprecipitate concluded that 'Wide variation in practice and dose suggest inconsistent practice and uncertainty in the evidence informing optimal use of cryoprecipitate'. Despite the improvements brought about by initiatives such as Better Blood Transfusion, the work of the National Blood Transfusion Committee and Blood Services, the level of inappropriate use remains unacceptably high. In addition, insufficient use is being made of techniques which might avoid or reduce the need for transfusion. These include, for example, pre-operative anaemia management, intra-operative cell salvage, restrictive blood transfusion strategies and the use of tranexamic acid. These issues were discussed at the event in June 2012, 'Patient Blood Management: the Future of Blood	

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					Transfusion', jointly hosted by NHSBT, the National Blood Transfusion Committee and DH, and the papers provide further detail. It would be helpful for the NICE guideline to include use of these techniques, to optimise patient care and reduce the use of blood components where appropriate. As noted above, the inclusion of platelets, FFP and cryoprecipitate as well as red blood cells will make the scope of the NICE guideline unmanageable, unless areas currently in scope are dropped. We would recommend that lower priority should be given to areas where good guidance already exists. The British Committee for Standards in Haematology, for example, is accredited (or is in process of being accredited) as a producer of guidance through NICE's NHS Evidence scheme. The Committee has produced guidance on a number of aspects of transfusion practice, including the administration of blood components, pre-transfusion compatibility testing and the investigation and management of acute transfusion reactions. This makes it less necessary for the NICE guideline to cover these areas in detail. In addition, action by the National Blood Transfusion Committee, the Blood Services and others will continue to be focused on these areas, as a result of the evidence	

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					provided by Serious Hazards of Transfusion's analysis of the data it collects on transfusion-related adverse outcomes. This highlights the main types of adverse outcomes arising, allowing action to be specifically targeted on reducing them, an approach that has proved successful in the past and that will continue. Guidance is also available on correct patient identification – which is an issue going beyond blood transfusion – following initiatives such as the National Patient Safety Agency's Right Patient - Right Blood, so this too is a lower priority for the NICE guideline. If the Guideline Development Group has the capacity, however, it would be useful to provide cost-effectiveness guidance on electronic patient identification systems, because of their potential value. We also consider the information to be given to patients is a lower priority. Leaflets are available from the Blood Services, which are developed with input from patients; and the Better Blood Transfusion Toolkit includes helpful material, drawn up following work by the Advisory Committee on the Safety of Blood, Tissues and Organs. Apart from platelets, FFP and cryoprecipitate, we agree with the items noted as being out of scope of the guideline.	

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					In summary, we believe that to achieve the greatest improvement in the clinical- and cost-effectiveness of patient care, the guideline should seek to ensure that patients are transfused only when that is the most appropriate treatment for them; and if there is an alternative treatment that would be more effective, or a supplementary treatment that would minimise their transfusion, they should receive it. This would optimise their care, and avoid putting them at risk of transfusion-related adverse outcomes. It would have the additional benefit of avoiding wastage of a valuable and limited resource, protecting the supply at a time when demand is rising for other clinical uses. The guideline should highlight the accredited guidance available on other areas (such as administering the blood components, and monitoring the patient for adverse reactions) rather than covering them in detail.	
64	SH	Serious Hazards of Transfusions (SHOT)	1		Why have neonates and infants been left out? Neonates receive transfusions and there is very variable practice around the country	Thank you for your comment. We agree that neonates and infants are an important group in relation to transfusion. However we will not be able to cover such a specialist and complex area as part of this guideline as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical areas. These groups would require separate guidance
65	SH	Serious	2		Assessment of anaemia is clearly important.	Thank you for your comment. We will now

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		Hazards of Transfusions (SHOT)				include treatment of anaemia in surgical patients. However, we will not include the investigation and treatment of anaemia in medical patients, as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues/areas.
66	SH	Serious Hazards of Transfusions (SHOT)	3		The other piece is assessment of all patients immediately before transfusion which is not being done properly due to changes in medical practice with shifts and also patients being transferred between different departments (emergency room to medical admissions unit to another medical ward all within a few hours - add in poor communication and the impossibility of being clear about who is in charge and the risk of adverse incidents goes up and up).	Thank you for your comment. We intend to include certain aspects of patient safety such as monitoring for acute transfusion reactions and electronic patient identification systems, however, we will not be able to cover assessment of patients before transfusion as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood and not looking at specific clinical issues.
67	SH	Serious Hazards of Transfusions (SHOT)	4		Transfusion in surgical patients is better managed than in medical patients, and there is good evidence for use of tranexamic acid.	Thank you for your comment and the information provided. We will look at the clinical and cost effectiveness of tranexamic acid.
68	SH	Serious Hazards of Transfusions (SHOT)	5		A general comment: NICE should not be looking to reinvent the wheel where good guidelines are already in place.	Thank you for your comment. We will need to look at the evidence independently to make NICE guideline recommendations in transfusion related areas prioritised for inclusion by the stakeholders.
69	SH	Serious Hazards of	6		Avoidance of harm is very important - clearly identification of the patient at all stages is very important, but the other	Thank you for your comment. We agree patient safety is an important topic and we will include

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		Transfusions (SHOT)			piece here is communication of specific requirements from clinical to laboratory area. Poor handover and inadequate communication results in many reports to SHOT every year. This does not seem to feature in the scope.	some aspects of patient safety including monitoring of acute transfusion reactions and electronic patient identification systems, However we will not be able to cover all the aspects of patient safety as this is a cross cutting topic focussing on the general principles of transfusion and the appropriate use of blood.
70	SH	Serious Hazards of Transfusions (SHOT)	7		Patient information - guidance on consent has been published by SaBTO and the Transfusion Services have worked on this over several years.	Thank you for your comment. We will be considering the provision of patient information and support specific to blood transfusion, but will not be revisiting the issue of consent. Every guideline includes standard wording about the importance of consent.
71	SH	Serious Hazards of Transfusions (SHOT)	8		I am surprised that platelets, FFP and cryoprecipitate are not part of the scope. There is misuse of these components, particularly FFP and it would be good to address this.	Thank you for your comment. We agree this is an important topic. In light of the stakeholders' comments we are now including the following blood components in the guideline: RBC, platelets/FFP/cryoprecipitate/prothrombin complex concentrate. The scope has been amended accordingly.
72	SH	Serious Hazards of Transfusions (SHOT)	9		Main outcomes - quality of life: this is a huge and complex area. The transfused patients are extremely variable - how will this be assessed?	Thank you for your comment. We plan to look for details of quality of life recorded in the published trials in each of the areas that we are reviewing, but we will be guided by the guideline development group in determining the exact protocol for each question. The outcomes listed are examples suggested for

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						questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review.
73	SH	Serious Hazards of Transfusions (SHOT)	10		Adverse events - it is very important to obtain more information on these. Currently 98.9% of NHS hospitals/health boards across the UK are registered to report to SHOT but the number of incidents reported varies considerably. We would be very interested to work with the guideline group in this area.`	Thank you for your comment. The guideline development group will consider serious adverse events when reviewing the evidence. Thank you for sharing the useful information, we may get in touch with you during the course of the guideline development, if the GDG would like any further information regarding this topic.
74	SH	Serious Hazards of Transfusions (SHOT)	11		Questions 4.5.4 - I am puzzled by these. Monitoring for acute transfusion reactions is essential and may prevent death. I am not clear how this translates into cost effectiveness.	Thank you for your comment. For each clinical question, the GDG is required to consider the best available evidence of both clinical and cost effectiveness. We are able to capture the benefits of the intervention alongside the cost when we analyse the data and for some areas the cost may be low but the benefit high.
75		National Blood Transfusion Committee		General	Blood transfusion is an essential part of modern healthcare. Over 2.5 million blood components (red cells, platelets, plasma , cryoprecipitate) are transfused to over 400,000 patients in England each year; the cost for the provision of blood components by NHS Blood & Transplant to hospitals in England is around £400 million (not accounting for the cost of blood transfusion services in hospitals). Blood transfusion, like most therapies, is also associated with significant clinical risks.	Thank you for your comment. This is a cross cutting guideline which will be focussing on the general principles of transfusion and the appropriate use of blood. We will also be including some elements of patient safety such as monitoring of signs and symptoms of acute transfusion reaction and electronic patient identification systems. We have amended the scope to reflect this.

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					Minimising the risks and optimising the benefits of transfusion depend on close collaboration throughout the transfusion chain from blood donors, blood transfusion centres, hospital blood transfusion laboratories, clinicians to patients in need of transfusion. There have been numerous initiatives in the UK over the last 15 years to improve transfusion safety, including national guidelines from the British Committee for Standards in Haematology (BCSH) on the administration of blood, compatibility testing, and the investigation and management of acute transfusion reactions; three Better Blood Transfusion initiatives in 1998, 2002 and 2007 led by the UK Chief Medical Officers; National Patient Safety Agency (NPSA) initiatives on 'Right Patient - Right Blood' and the Provision of blood in emergencies ; and the recent Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recommendations on patient consent for transfusion. In addition, national regulations for blood transfusion cover hospitals as well as blood centres, and include adverse incident reporting, blood traceability, staff training and quality management.	

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					These initiatives have led to a demonstrable improvement in transfusion safety. Data from the UK haemovigilance scheme, the Serious Hazards of Transfusion (SHOT), in 2011 indicate that the risks of transfusion-related death and major morbidity were 2.7 and 39.9 per million blood components issued, respectively, and that the proportion of adverse incident reports resulting in death or major morbidity has reduced from 34% in 1996/97 to 6.9% in 2011. While there was a decline in the use of red cell transfusions in England in the 2000s, the use of red cell transfusions remains higher than other countries such as Northern Ireland and Canada, and the use of platelets and plasma is increasing. The Royal College of Physicians and NHS Blood & Transplant in England have established a national comparative audit initiative for blood transfusion, and conducted as series of national audits on blood usage. These show considerable variation between hospitals in blood usage, and indicate that the inappropriate use of all blood components is 20% or higher. These data suggest that overall blood usage could be further reduced	

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					without compromising patient safety. Surveys of the implementation of the recommendations of the Better Blood Transfusion initiatives found that few hospitals had implemented blood conservation strategies e.g. pre-operative anaemia management and intra-operative cell salvage. In summary, there have been numerous initiatives over the past 15 years in the UK which has had a demonstrable effect on improving transfusion safety. Further efforts are needed to improve transfusion safety and NICE guidelines and quality standards for basic transfusion practice e.g. patient identification, monitoring of transfused patients, staff training etc would be helpful, but is not urgent because there are continuing initiatives to improve practice. The main current concern for transfusion (both for the NHS and patients) is the evidence for the very significant level of inappropriate use of blood components, which is wasteful of a scarce and costly resource and puts patients at unnecessary risk. In addition, there are potential drivers for increased blood use in the near future including the ageing population and new therapies in cancer, transplantation and many other fields of	

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					medicine. Efforts are needed to promote evidence-based strategies for measures to reduce the inappropriate use of blood components, and increase the use of alternatives to transfusion, sometimes now called Patient Blood Management . These will both improve patient care and reduce NHS costs. NICE guidelines and quality standards are needed in this area as soon as possible. Transfusion Safety and Patient Blood Management are important issues for the NHS and for patients, and deserving of NICE guidelines and quality standards. They are both huge pieces of work; trying to combine both in one guideline will inevitably significantly delay their publication. It is the view of the National Blood Transfusion Committee that Patient Blood Management should have the top priority for the NICE guideline on blood transfusion.	

These organisations were approached but did not respond:

Advisory Group on Hepatitis

Aintree University Hospital NHS Foundation Trust

Allocate Software PLC

Amgen UK

Association of Anaesthetists of Great Britain and Ireland

Association of British Insurers

Barts and the London NHS Trust

British Infection Association

British Medical Association

British Medical Journal

British National Formulary

British Nuclear Cardiology Society

British Psychological Society

Cambridge University Hospitals NHS Foundation Trust

Capsulation PPS

Care Quality Commission (CQC)

Croydon Health Services NHS Trust

Deltex Medical

Department of Health, Social Services and Public Safety Northern Ireland

Diamond Blackfan Anaemia Support Group

East and North Hertfordshire NHS Trust

Faculty of Intensive Care Medicine

Five Boroughs Partnership NHS Trust

Health Quality Improvement Partnership

Healthcare Improvement Scotland

Humber NHS Foundation Trust

Institute of Biomedical Science

ITP Support Association, The

Leukaemia & Lymphoma Research

Luton and Dunstable Hospital NHS Trust

Maquet UK Ltd

Medtronic International Trading Sarl

Mid Yorkshire Hospitals NHS Trust

Ministry of Defence

National Collaborating Centre for Cancer

National Collaborating Centre for Mental Health

National Collaborating Centre for Women's and Children's Health

National Institute for Health Research Health Technology Assessment Programme

National Patient Safety Agency

National Treatment Agency for Substance Misuse

NHS Commissioning Board

NHS Connecting for Health

NHS Direct

NHS Plus

NHS Sheffield

NICE TLOC GDG

North West London Perinatal Network

Nottingham City Council

Novartis Pharmaceuticals

Oxford Health NHS Foundation Trust

Public Health Wales NHS Trust

Public Health Wales NHS Trust

Royal Brompton Hospital & Harefield NHS Trust

Royal College of General Practitioners

Royal College of General Practitioners in Wales

Royal College of Midwives

Royal College of Pathologists

Royal College of Physicians

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Surgeons of England

Royal Liverpool and Broadgreen University Hospitals NHS Trust

Royal Pharmaceutical Society

Sandoz Biopharmaceuticals

Scottish Intercollegiate Guidelines Network

Sheffield Childrens Hospital

Social Care Institute for Excellence

South London & Maudsley NHS Trust

South West Yorkshire Partnership NHS Foundation Trust

Southport and Ormskirk Hospital NHS Trust

St Mary's Hospital

Stanningley Pharma Ltd

Teenagers and Young Adults with Cancer

TERUMO BCT

The Childhood Cancer Parents Alliance

The Intensive Care Society

The Whittington Hospital NHS Trust

Trauma Audit & Research Network

Walsall Local Involvement Network

Welsh Government

Welsh Scientific Advisory Committee

Western Sussex Hospitals NHS Trust

York Hospitals NHS Foundation Trust