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GUIDELINE

BSH Guideline

The use of predeposit autologous donation: Guideline prepared by the BSH Blood Transfusion Task Force

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clinical transfusion medicine, predeposit, red cells, transfusion

INTRODUCTION

A guideline for predeposit autologous transfusion was published in 2007.[1] Practices have changed in the intervening years, and in line with British Society for Haematology (BSH) guidelines processes, this guideline required review and revision. The increasing safety of allogeneic transfusion has reduced the need for autologous collection. In addition, disadvantages have been noted, which are discussed below.

METHODOLOGY

This guideline was compiled according to the BSH process at (https://b-s-h.org.uk/media/16732/bsh-guidance-development-process-dec-5-18.pdf). The Grading of Recommendations Assessment, Development and Evaluation (GRADE) nomenclature was used to evaluate levels of evidence and to assess the strength of recommendations.[2] The GRADE criteria can be found at http://www.gradeworkinggroup.org and are summarised in appendix 3 of the guidance document linked above.

LITERATURE REVIEW DETAILS

An updated search covering articles published from January 2006 (end date of search for previous guideline) to June 2020 was applied to Medline (PubMed), Embase and the Cochrane library using the following keywords (and alternative spellings and abbreviations): 'pre-deposit autologous blood', 'pre-deposit autologous red cells', 'preoperative autologous collection', 'preoperative autologous donation', 'autologous transfusion', 'autotransfusion'. These keywords were combined with AND using the keywords 'elective surgical procedures', 'preoperative care', 'cardiac surgical procedures', 'cardiovascular surgical procedures', 'thoracic surgical procedures', 'orthopaedic', 'arthroplasty', 'prostatectomy', 'hysterectomy', 'digestive system surgical procedures', 'urologic surgical procedures', 'neurosurgical procedures'. Filters were applied to include only publications written in English and to include only studies carried out in humans. The searches, after filtering, produced 339 results, including systematic reviews, meta-analysis and clinical studies. The majority of clinical studies were retrospective cohort studies and retrospective analytical studies.

REVIEW OF THE MANUSCRIPT

A review of the manuscript was performed by the British Society for Haematology (BSH) Transfusion Task Force and the BSH Guidelines Committee. The draft guideline was also posted on the members section of the BSH website for comment.

SCOPE AND DEFINITION

Predeposit autologous donation (PAD) is the collection and storage of blood from a person prior to elective surgery so that it can be transfused to the same person in the event that a transfusion is required due to blood loss or anaemia.[3–5] This guideline does not cover other forms of autologous donation, such as cell salvage, acute normovolaemic haemodilution and emergency autotransfusion. PAD is no longer recommended except for the exceptional circumstance outlined below.

BACKGROUND AND CURRENT CONTEXT

PAD came into being at a time when one of the largest concerns about blood transfusion was the risk of transmission of infection, in particular human immunodeficiency and hepatitis viruses in the 1980s. PAD was a means of decreasing infection risk.[3]

In the last 30 years, the management of preoperative anaemia and blood loss during surgery has changed significantly. There remains a small group of patients who, despite clinicians utilising patient blood management techniques, may still require intraoperative or postoperative red cell transfusion and where the blood services cannot provide compatible allogeneic blood. It must, however, be borne in mind that the greatest risks of transfusion relate to administrative error. The risk of such errors will be increased by introducing such a rarely performed variation from normal practice, as would be the case for PAD. One infectious risk of blood component transfusion is bacterial contamination, which may also be paradoxically increased by a non-standard process and longer storage.

REQUESTS FROM PATIENTS FOR OTHER SPECIFICATIONS

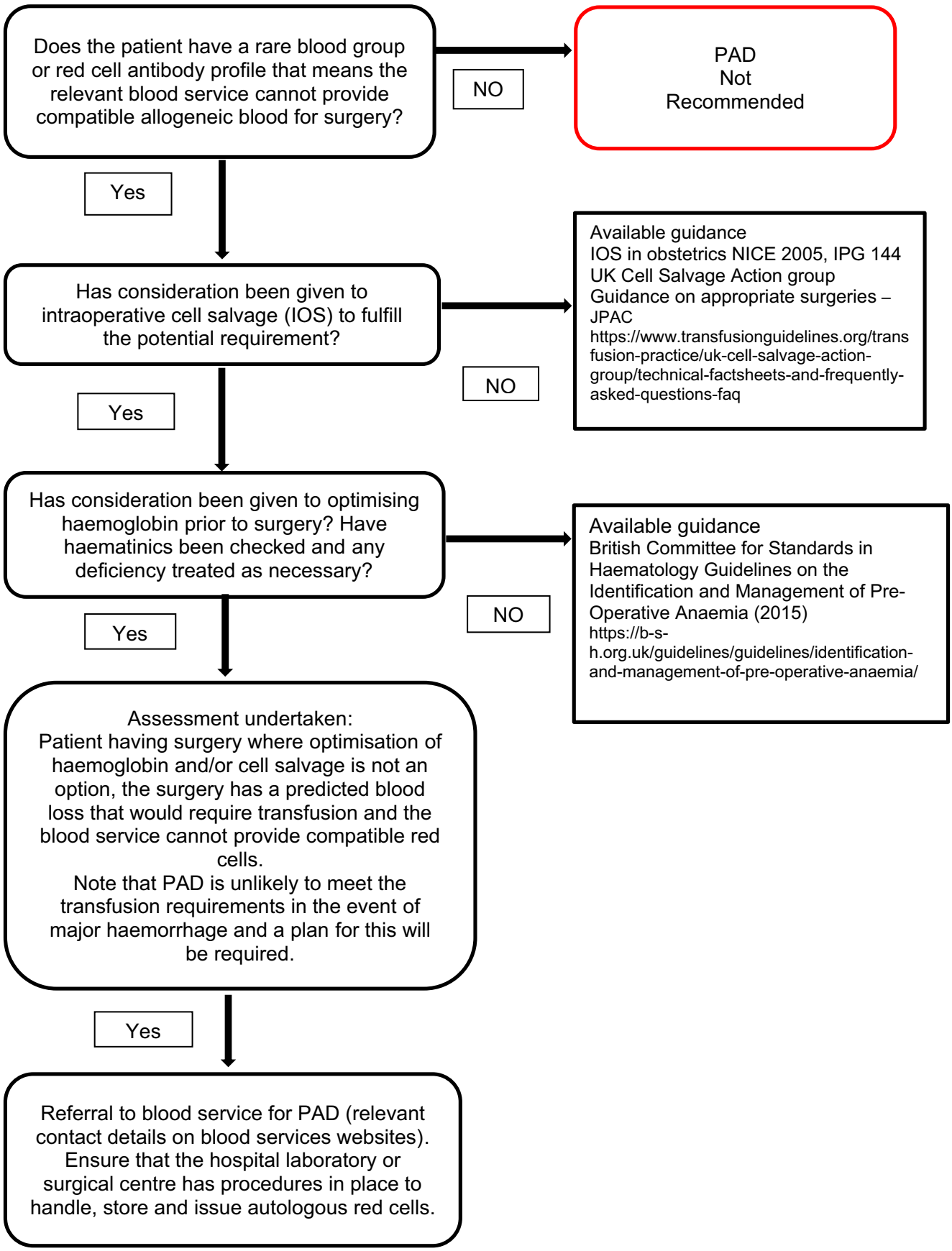
Recent concerns around the COVID-19 vaccination status of donors have resulted in an increase in requests for PAD. In July 2023, the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) published a position statement stating that COVID-19 vaccines approved in the UK present no risk to the safety of the blood supply or to patients who receive transfusions from vaccinated donors and are therefore not an indication for PAD.[4] JPAC states that 'UK Blood Services, in common with other blood services internationally,[6] cannot provide information about the vaccine status of donors to recipients or their treating clinicians. There are no clinical reasons regarding the safety and efficacy of transfusion to justify gathering and supplying this information. Although donors are asked about recent immunisations at the time of donation, this information is required to check the donor's eligibility to donate. It is not possible or practical to test for mRNA in donated blood'.

Information collected regarding donor sociodemographics, for example about their religion, sexual orientation or dietary practice, is not collected. Any other information is confidential and not available to hospitals; information collected from donors is to assess suitability to donate. The only factors considered when red cells are made available to a recipient are blood group compatibility of the component and the likelihood of causing a transfusion reaction.

Key recommendation

- **PAD is only recommended for patients with rare blood groups or who have multiple blood group antibodies, which make compatible allogeneic (donor) blood difficult to obtain (Grade 1B)**

Assessment of PAD requirement and patient eligibility



EVIDENCE FOR CLINICAL BENEFIT OF PAD

PAD is reported to be of low clinical efficacy and is not cost-effective for most patients in the UK. PAD is time and circumstance dependent. Other ways of avoiding allogeneic transfusion should always be considered.

The previous BCSH (now BSH) guideline[1] only recommended the use of PAD in exceptional circumstances with the examples given below. In 2023, we have addressed whether these exceptional circumstances still justify the use of PAD.

Patients with rare blood groups or multiple blood group antibodies can also have autologous units frozen and stored; this would require discussion with the relevant national blood service.

Exceptional circumstance 2007	Review 2023
Patients with rare blood groups or multiple blood group antibodies where compatible allogeneic (donor) blood is difficult to obtain.	This is now the only exceptional circumstance and with this comes the recommendation to optimise the patient haemoglobin to decrease the requirement for PAD.
Patients at serious psychiatric risk because of anxiety about exposure to donor blood.	This recommendation was informed by a Cochrane review[5] which noted that some members of the public have concerns about the risks of allogeneic blood and the risk of contracting an illness from transfusion. However, this anxiety may no longer be justified due to the reduction in exposure risks. In 2020 & 2021 there were no confirmed reports of bacterial or viral transmission.[7,8] Requests for PAD due to concerns about receiving blood from a donor who has received the COVID-19 vaccine have been addressed by JPAC and PAD was not recommended for conscientious objections to donor blood.[4] Other methods of reducing exposure to donor blood should be considered as outlined in the PAD assessment above.
Patients who refuse to consent to donor blood transfusion but will accept PAD.	This recommendation came from 'A National Blood Conservation Strategy' which itself was informed by the same Cochrane review.[5] The context of refusal to consent in this review was centred around viral risks. Since the review, viral risks have reduced with no confirmed viral transmissions in 2020 or 2021.[7,8] Other Patient Blood Management (PBM) measures should be considered as outlined in the PAD assessment above.
Children undergoing scoliosis surgery.	Leading clinicians in UK centres performing scoliosis surgery were contacted and PAD is no longer undertaken.

In 2023, these indications have been updated, and it is now recommended that PAD is only used in the following circumstance:

- Patients with rare blood groups or who have multiple blood group antibodies where compatible allogeneic (donor) blood is difficult to obtain.

To confirm restriction to this recommendation in relation to scoliosis surgery, contact was made with seven leading scoliosis consultants and the British Scoliosis Society to establish the current use of PAD. The centres were contacted directly as the literature search found very few recent papers on the use of PAD in scoliosis surgery, and all reported that it was no longer used.

CLINICAL INDICATIONS AND LIMITATIONS

The clinical indications for collecting and using PAD are limited. For patients undergoing elective surgery of a nature likely to require transfusion to treat surgical and postoperative blood loss, PAD is only recommended when allogeneic blood cannot be obtained. There are no large, high-quality randomised controlled trials, so it is impossible to judge whether the benefits of PAD outweigh the potential harm. Non-infectious transfusion risks are not mitigated by autologous donation, particularly transfusion-associated circulatory overload (TACO).

Published studies do not show a convincing benefit of PAD. Iatrogenic anaemia post-PAD is a risk, and while some studies have suggested PAD may reduce exposure to allogeneic blood transfusion,[9,10] PAD has been associated with an increase in overall transfusion rates.[11,12]

PAD is not recommended for children less than 10 years of age, mainly because of technical difficulties (large bore needle in veins of limited size) and it can be difficult to gain sufficient co-operation.

PAD is no longer recommended in obstetric practice. Following donation, a patient's haemoglobin concentration (Hb) may not return to baseline before delivery, leading to a decrease in maternal iron stores and exacerbating anaemia.[13] In addition, the need for transfusion cannot always be predicted. Therefore, preoperative autologous donation is no longer recommended in obstetric practice except in the rare circumstance outlined above, where allogeneic blood cannot be obtained.

PATIENT ELIGIBILITY ASSESSMENT

Patients with serious cardiac disease (depending on the clinical setting of blood collection) or active bacterial infection are not suitable for PAD.[14] Decisions about eligibility for PAD should be undertaken by a qualified health professional

in a blood service in conjunction with the patient's clinician. The risks and benefits for the individual patient should be considered. The possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual, whether as a donor or recipient of the autologous blood or blood components, should be explained to the patient.[14]

Patients with anxiety about acceptance of allogeneic donor blood should be provided with appropriate counselling and psychiatric advice. JPAC also offers the following advice: 'Patient Blood Management strategies should be discussed and considered as part of a wider blood conservation approach, tailored to the patient's status and the nature of any planned surgery'.[4]

BARRIERS TO IMPLEMENTATION AND PRAGMATIC ASPECTS OF THE PROCEDURE

PAD is not without risk, and indeed, it has the same risks for errors as allogeneic transfusion. The procedure is outside normal practice and carries the risk of errors occurring in the labelling, recording and storage of components.[15] SHOT (Serious Hazards of Transfusion) reporting demonstrates that PAD does not protect patients from incorrect blood component transfusion. In 2005, a patient who had undergone PAD and had autologous blood available was issued and administered allogeneic blood in error.[16] In 2018, SHOT made a key recommendation relating to the transfusion of autologous blood. This stated that institutions must have the same guidelines in place for autologous blood administration and management of reactions as those for allogeneic transfusion.[17]

The practical aspects of PAD include timing, assessment of the patient's fitness to donate, provision of information to the patient about the donation process and the use of donated components, regulatory requirements and storage of components, potential wastage of autologous components, cost effectiveness, communication and the involvement of stakeholders. A written policy and standard operating procedure are recommended for hospitals and blood establishments, which should cover all aspects from the management of the potential donor to the issue of autologous blood components from the transfusion laboratory.

TIMING OF THE PROCEDURE

Patients considered for PAD must be candidates for elective surgery where the need for blood transfusion is anticipated. The Association for the Advancement of Blood & Biotherapies (AABB, formerly the American Association of Blood Banks) guidance states that PAD should only be considered when the likelihood of transfusion is more than 10% and elective surgery can be scheduled at least several weeks in advance. The admission and surgery dates must be guaranteed. Sufficient time should be given from the date and time of the ultimate PAD collection prior to surgery for the patient to make a full circulatory and volaemic recovery. However, the time between PAD and surgery should not exceed the licensed time for storing the collected blood component. There should be a minimum interval of 72 h between collection and surgery.[18]

COST EFFECTIVENESS/ WASTAGE RATES

Many reports suggest that PAD can be associated with wastage rates from 41% to 55% of autologous blood units collected.[11,19] As allogeneic blood becomes safer, the intended benefit of PAD reduces, but the disadvantages of wastage and reduction in Hb prior to surgery remain.

UK BLOOD REGULATIONS

Autologous donations must be clearly identified and stored separately from allogeneic donations.[14] PAD units not transfused to the donor must be discarded and must not enter the allogeneic blood stock.[14] Traceability and notification of defined serious adverse reactions and events apply to autologous blood. Blood services undertaking PAD must have the activity outlined on their Blood Establishment Licence. Blood establishments and hospital transfusion laboratories must maintain the records pertaining to the full traceability of the blood for not less than 30 years.[14]

PATIENT/DONOR COUNSELLING

Patients should be assessed for their fitness to donate and advised of the possibility of deferral and reasons why the donation procedure would not take place in the presence of a health risk to the individual. The patient should be informed that the autologous blood may not suffice for the intended transfusion requirements (dependent upon individual circumstances and particularly if there is a major haemorrhage). They should also be informed that any unused autologous blood and blood components will be discarded and not transfused to other patients, and the reasons why.

INVOLVEMENT OF STAKEHOLDERS

Following discussion with the patient, a clear and timely plan should be communicated to all stakeholders, including the treating clinicians, the transfusion laboratory and the blood service/licensed blood establishment.

In summary, barriers to the use of PAD include a lack of evidence of clinical efficacy, the need for fixed timings and the exclusion of certain patient groups. Other concerns include donor anaemia, a lower transfusion threshold because

units are available and staff prefer not to waste them and are therefore likely to transfuse at a higher Hb, and indications that autologous donors are more likely to require perioperative blood transfusions than those who do not undergo PAD.[11] PAD is therefore rarely appropriate.

IRON SUPPLEMENTATION AND PAD

A study of 501 patients undergoing radical prostatectomy found that treating anaemic PAD donors with IV iron plus erythropoietin (EPO) in the context of anaemia reduces the requirements of allogeneic blood transfusion.[20]

Patients scheduled to undergo PAD who are iron deficient should have underlying causes investigated and treated so that patients are iron replete prior to collection and surgery.[21] A systematic review of more recent literature[22] found no evidence that refutes this, and hence, it is still recommended in line with good patient blood management practices.

ERYTHROPOIETIN (EPO) AND PAD

There has been an increase in the number of studies on the role and efficacy of EPO in PAD since the publication of the 2007 guidelines,[1] especially when used in conjunction with iron.

Specifically in the PAD setting, there is strong evidence to show that the use of EPO can increase PAD yield and, in some cases, can also reduce the need for allogeneic transfusion in the perioperative and postoperative periods.

A meta-analysis and systematic review of the use of EPO in total hip arthroplasty and knee arthroplasty involving 4159 patients concluded that EPO was effective in increasing the Hb in the perioperative period.[23] When the use of PAD and EPO were compared, EPO use was associated with a reduced exposure to allogeneic blood transfusion.

This is supported by a retrospective observational study of 56 patients undergoing surgery to correct spinal deformity. This study also supported the use of EPO to reduce the requirement for allogeneic transfusion where patients had undergone PAD.[24] Thus, growing evidence supports the use of EPO to improve predonation Hb and PAD collection yield. However, as there is an increased risk of thromboembolic events associated with EPO, a risk-versus-benefit approach should be considered.[25]

One study recommended that use of EPO be restricted to patients with moderate anaemia (haemoglobin concentrations between 100 and 130 g/L) without iron deficiency who are expected to undergo procedures with moderate blood loss (900–1800 mL).[23] EPO is also licensed to increase the yield as part of a PAD collection program. EPO has also been recommended for patients who refuse blood or have multiple blood group antibodies where compatible allogeneic (donor) blood is difficult to obtain.[25,26]

CELL SALVAGE AND PAD

The use of cell salvage and tranexamic acid in the perioperative phase, along with improved surgical techniques and the increased use of less invasive techniques, have contributed to the continued reduction in red cell use during surgical intervention.[5,27,28] Intraoperative cell salvage should be considered during the perioperative phase rather than PAD.

TOPICS FOR AUDIT

Patients referred to the relevant blood service will meet the criteria for a PAD request. In hospitals where PAD has been performed, the relevant procedures and documentation will be in place.

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DECLARATION OF INTERESTS

The BSH paid the expenses incurred during the writing of this guidance. All authors have made a full declaration of interests to the BSH and Task Force Chairs, which may be viewed on request. None of the authors have any relevant conflicts of interest to declare.

REVIEW PROCESS

Members of the writing group will inform the writing group Chair if any new evidence becomes available that would alter the strength of the recommendations made in this document or render it obsolete. The document will be reviewed regularly by the relevant Task Force and the literature search will be re-run every 3 years to search systematically for any new evidence that may have been missed. The document will be archived and removed from the BSH current guidelines website if it becomes obsolete. If new recommendations are made, an addendum will be published on the BSH guidelines website (www.b-s-h.org.uk/guidelines).

DISCLAIMER

While the advice and information in this guidance is believed to be true and accurate at the time of going to press, neither the authors, the BSH nor the publishers accept any legal responsibility for the content of this guidance.

AUDIT TOOL

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