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*EDITOR: David Ross*

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#### ARCHIVE CLIP OF EXPLOSIONS

MAN: In one tiny underground cave in the central rock, there were four men having blood transfusions. It's no exaggeration to say that blood transfusion on a big scale is one of the biggest and finest medical service developments in this war.

CURWEN: Ever since World War II, blood transfusion has been saving the lives of people who are bleeding to death. But it's not just these patients who get donated blood, and now doctors are beginning to ask whether the risks of transfusion in many cases might outweigh the benefits.

GAVIN MURPHY: Almost every evaluation that's ever been done of blood transfusion has shown it to be harmful in some way, and in fact the difficulty is not finding evidence that blood transfusion is harmful, the difficulty is actually finding evidence showing that blood transfusion is good for you outside of the setting of life threatening bleeding.

CURWEN: Tonight, File on 4 examines the debate that's been raging in medical circles, and asks what that means for the way the UK runs its blood services.

## SIGNATURE TUNE

## ACTUALITY IN INTENSIVE CARE

WALSH: We're here in the Intensive Care Unit of Edinburgh Royal Infirmary. We admit about a thousand patients every year with various types of critical illness. Patients who come in here require blood transfusions for a number of reasons. One would be major trauma – road traffic accidents, that sort of thing.

CURWEN: Consultant Tim Walsh checks on a patient in the intensive care ward.

WALSH: This lady actually was admitted after giving birth, unfortunately lost her baby and bled a large amount in relation to her delivery. At that time she was very sick and would have died without a blood transfusion. These are good examples, these sorts of patients where there's no question that receiving a blood transfusion is life-saving. There's no question of that.

CURWEN: There is a consensus among doctors that giving donated blood to patients who bleed severely is vital in saving their lives. And that's part of the reason why more than two million people willingly give up their time to go to blood donor centres.

## ACTUALITY IN BLOOD DONOR CENTRE

WOMAN: Roll your top up for me, I'm going to give your arm a clean.

CURWEN: This one is just a short distance away from the intensive care unit at Edinburgh Royal Infirmary.

WOMAN: Just a gentle prick here. That's fine. And then open the clips and the blood will flow into the sample pouch.

CURWEN: Just a few doors away, in the same building, every donation of blood is screened for various possible infections. The blood is processed into its separate elements, which may be used for patients with a wide variety of illnesses.

#### ACTUALITY WITH CENTRIFUGE

MCCLELLAND: I'm closing the lid which will lock electronically. So twelve of the packs are put into this big centrifuge thing here which will spin them around at quite a high speed. The result of that is that the red cells, which are heavier, go to the bottom of the pack, the plasma goes to the top and the white cells and the platelets are in the middle.

CURWEN: Dr Brian McClelland is the strategy director of the Scottish National Blood Transfusion Service. The blood components most commonly used are the red blood cells, which can be stored for up to thirty-five days in the UK.

MCCLELLAND: So this is a large walk-in cold room and through that door we can see there are large quantities of individually wrapped blood packs. They're sitting in ..., it's really quite chilly in here.

CURWEN: So we're surrounded by hundreds of bags of red blood cells?

MCCLELLAND: Yes.

CURWEN: It's these red blood cells that may be transfused into people who lose large amounts of blood, like the woman in the intensive care ward.

MCCLELLAND: There are situations in which a patient clearly has to have a transfusion if they're going to survive - major trauma or surgical haemorrhage where the patient loses a lot of blood acutely. Transfusion is absolutely essential and unavoidable in patients with leukaemia. The ability to treat with chemotherapy is fundamentally dependent on having blood transfusion support available. So those are the situations when transfusion is doing definitely good and is essential.

CURWEN: Dr Brian McClelland estimates that about two-thirds of red blood cell transfusions are vital, leaving a third that are not. But it is not clear-cut. Other experts we've spoken to make a different judgement. Some think the majority of transfusions are not life-saving. Red blood cells are certainly given to many different types of patients. All of them have a low blood count, a below normal level of the protein haemoglobin, which carries life-giving oxygen around the body. The chief aim of giving someone red blood cells is to boost the amount of oxygen getting to their organs.

WALSH: Many patients become anaemic and the levels of haemoglobin in the blood, which is what's measuring anaemia, are not in the normal ranges, and doctors like to see things in normal ranges.

CURWEN: Professor of Critical Care, Tim Walsh, in Edinburgh.

WALSH: Only 10% of the blood in our hospital, which is a major teaching hospital undertaking a lot of complex surgery, went directly to the operating theatre for patients in theatre who were probably bleeding. Of that 90% that was left, only just over 20% of that went to patients who we call surgical patients. So 75% of it went to this group that we call medical patients – they haven't come in for an operation, they're not having a planned operation or an emergency operation. They've got conditions like heart trouble, pneumonia, chest trouble, a whole host of conditions.

CURWEN: Would most of them be elderly?

WALSH: A lot of these patients will be elderly and the majority will be elderly, and as we know, elderly patients have a far higher incidence of anaemia, a low blood count, when they come into hospital. It can be difficult for a doctor who sees the patient who is feeling unwell, who has the symptoms that are consistent with anaemia and who is anaemic not to feel that the best they can do to that patient is give them a blood transfusion.

CURWEN: It's a view shared by Dr Brian McClelland of the Scottish National Blood Transfusion Service.

MCCLELLAND: If a transfusion of red cells is given just to correct a number in the patient's lab results, then giving red cells is unlikely to offer the patient any benefit. Nowadays quite a high proportion of all the red cells that are transfused are given to a group of patients who tend to be older, who often have quite a number of conditions, and where it actually becomes much more difficult to assess the probable benefits as opposed to the possible risks of giving the patient a transfusion. If any treatment is not going to do a patient some good, then really it's not acceptable to expose the patient to any level of risk.

CURWEN: And there are risks involved with blood transfusion.

DAVIES: I got a phone call off the hospital – could I get to the hospital straightaway? Margaret was on oxygen. We got there, I think she was in shock then, she was really breathing very fast, and shortly after, she died.

CURWEN: Malcolm Davies's wife, Margaret, died in Whiston Hospital in St Helens last year. She was a cancer patient who had contracted a hospital infection, became anaemic and was given a transfusion of red blood cells.

DAVIES: Two consultants that was in charge of the ward which she was in and chemo told us that she'd received the wrong blood. She'd received A blood and she was O. We looked it up on the internet and different things and it said that within twenty-four hours you'd die, and actually there was two Margaret Davies.

CURWEN: In the same place?

DAVIES: In the same place. She got the other Margaret Davies' blood. It's just a big, terrible mistake.

CURWEN: Do you remember actually seeing your wife being transfused from the bag of blood?

DAVIES: I do remember her being on the bag, it just didn't go through my mind at the time, like, you know.

CURWEN: Your wife was very ill.

DAVIES: I do think the blood finished her off.

CURWEN: The hospital trust says, although there is no conclusive evidence Mrs Davies died as a result of the blood transfusion, the two nurses involved have been dismissed for not following hospital procedures. This kind of event is rare; UK figures for 2006 report fifty-four instances where patients received a blood component intended for a different person, or of the wrong blood group. But it is one of a number of known risks of transfusion, which blood services try hard to minimise.

#### ACTUALITY WITH SCREENING MACHINES

MCCLELLAND: What you can see here is actually a very large machine into which we put samples from each donation and they are tested for the main transfusion transmissible infections – that's HIV, Hepatitis B, Hepatitis C and ...

CURWEN: Today the risks of such infections are very rare. But while millions of pounds have been spent on screening UK blood to make it safer, comparatively little has been spent on trying to establish the benefits of giving some patients red blood cells. In fact, it is a treatment that has never been tested anywhere in the world, for safety and efficacy, as a new drug would be. Professor of Critical Care, Tim Walsh in Edinburgh.

WALSH: I think it's remarkable that, given that blood transfusion has been a, almost a standard part of treatment of patients for many years, since the Second World War, we've managed to accrue so little evidence about who really needs it, particularly as the majority of blood transfusions go to patients where the risk benefit profile is really uncertain. And it's perhaps unique in medicine in that respect.

CURWEN: So why do physicians give blood transfusions if there's no clear benefit?

WALSH: It's a very difficult question to understand, why the clinicians give blood to patients when there aren't any strong research studies saying they should get it. It's probably fair to say there's a general belief that blood should at worst do no harm and at best do good, and that's one of the issues that clearly we now worry about – that maybe receiving someone else's blood that's been stored could possibly do some harm.

CURWEN: And it's the effects of storage on red blood cells which now lie at the centre of a hot debate in the medical world.

KOOK: Our study findings suggested that patients who receive older blood – that is blood stored longer than fourteen days old – these patients had more complications after heart surgery.

CURWEN: Dr Colleen Kook from the Cleveland Clinic in Ohio. She looked at the records of thousands of patients who had undergone heart surgery, comparing those who had been given red blood cells stored for more than two weeks with those who had fresher blood.

KOOK: They had more in-hospital death, they had more kidney failure, more infections. The patients' survival was also lower, meaning that their risk of death was higher.

CURWEN: So from your study, can you actually prove that older blood is causing harm?

KOOK: You can't ever prove a causal association with an observational cohort investigation, so no. However, our findings were very persistent.

CURWEN: What do you think should be the consequences of what you found?

KOOK: We're not recommending to throw out older blood at this time. We really are recommending funding for randomised control trials in this area of medicine, because it has huge ramifications on the blood bank inventory.

CURWEN: Her study, which was published in the respected New England Journal of Medicine, has proved contentious. Some have challenged its methodology. It is well-known, though, that red blood cells do experience changes when they're kept in storage. Professor Tim Walsh from Edinburgh.

WALSH: We know that blood changes when it's stored in the blood bank, even when it's stored under the optimum conditions. We know the blood cells themselves change shape, they become stiffer, and we know that normally red blood cells have to deform and bend to get through the smallest blood vessels, so it's plausible that the stored cells won't do that as well. Another thing that happens is that the constituents of the cell changes and some of the substances within the cell that we know are very important for picking up oxygen and then delivering it to the tissues either disappear completely or are reduced in concentration and probably take up to a day at least to regenerate in the body, so the cells might not work certainly for the first hours in the body. We also know that substances can accumulate in the bag of blood, which it is biologically plausible could have adverse effects and for which there is some evidence of that in animal experiments and that sort of thing. So there are good theoretical and biologically plausible reasons why it's less good to receive older blood than fresher blood.

CURWEN: In the UK, blood leaving central blood banks to go out to hospitals is already on average more than ten days old. And some estimates put the average age of the blood when it is transfused into the patient at somewhere between fifteen and eighteen days. The hospitals employ strategies to avoid blood going out of date and being wasted. But that might have consequences, according to Professor Mike Murphy, who's a Consultant Haematologist at the John Radcliffe Hospital in Oxford. He says it might mean that, in fact, sicker patients may be given older blood.

MIKE MURPHY: The staff in the hospital blood transfusion laboratories work very hard to make sure that blood is not wasted and so when blood is coming towards its expiry time they will try to allocate that blood to a patient that's definitely going to need it.

CURWEN: What kind of patients will definitely need it?

MIKE MURPHY: So, the sorts of patients that will definitely need blood are haematology patients, patients with leukaemia or bone marrow transplant transplants, critical care patients needing top-up red cell transfusions, patients with massive bleeding, trauma patients, patients with mothers who are having a lot of bleeding after childbirth. So those sorts of patients would be more likely to be allocated this older blood than otherwise fit patients undergoing elective surgery.

CURWEN: So it does sound like sicker patients may, in fact, get blood that is reaching the end of its shelf life?

MIKE MURPHY: It's possible, for the reasons that I have given you, although we have no hard evidence to confirm that, but it's important to emphasise again that we have no evidence to suggest that giving this older blood impacts on clinical outcome at all.

CURWEN: Does this sort of practice make sense, given the concerns being raised? Dr Lorna Williamson is the Medical Director of NHS Blood and Transplant, which runs blood services in England and North Wales.

WILLIAMSON: The staff who run the transfusion laboratories in hospitals go to a great deal of trouble to manage that stock well so that wastage is kept to an absolute minimum. So what they would do would be to make sure that blood, as it's moving through its shelf life, goes to patients who are definitely going to be transfused, but that doesn't for a minute imply that these are the sickest patients most in need of transfusion.

CURWEN: But would a mother, who had perhaps had a lot of bleeding after birth, get the oldest blood, because that's what we've been told?

WILLIAMSON: You make it sound as if this would always be blood, you know, in its last day or two of shelf life and that's not necessarily the case at all. I mean, most blood is used well within its five week shelf life. Not very much of it actually gets out to its last few days. So the chances are that a patient, your example of a woman bleeding after childbirth would get blood that was in extremely good shape, if you like, for the purpose for which it's given, which is to resuscitate someone who's having a life-threatening haemorrhage.

CURWEN: Given the emerging concerns about stored blood, does it make any sense to issue the oldest blood first?

WILLIAMSON: There has been a lot of modelling work done around this. If you issue blood in any other way, I'm afraid you would waste unacceptable amounts of what, after all, is a gift from a donor given with the intention and the belief that it's going to end up inside a patient for that patient's benefit. If we thought at this point that blood in the last few days of its shelf life were dangerous, of course we would not be using it.

CURWEN: But it's not just the age of blood that's caused concern. Nine years ago, a study in Canada raised the first questions about the benefits of transfusing red blood cells. It was a randomised controlled trial which looked at transfusion of intensive care patients. Across the world, different medical guidelines suggest which levels of haemoglobin in a patient should act as a trigger, a red flag for doctors to start giving blood. Professor Paul Hebert investigated whether it was better to allow a patient's blood count to drop to a much lower level before you gave them red blood cells, effectively giving them less blood.

HEBERT: We were, to our shock and amazement, surprised by the results of the study. Most of us, when we went into this study, thought that more blood was better and we were pretty much convinced that giving more blood would increase the amount of oxygen available to injured tissues, whether they're injured through trauma or severe infection, and in doing so would help them heal faster. What we found out instead is that those who got less blood actually did better, or at least tended to do better. And, when we say less blood, it was half the amount of blood – 54% less was given in the group with a low trigger to transfuse. And we thought haemoglobin, if you give more, that it would augment the amount of delivered oxygen, but instead we found exactly the opposite. And I believe what we found is that the transfused blood needs to be directed to the right person, and there are clinical consequences beyond simply giving someone a possible infection.

CURWEN: The suspicion had been raised that the less blood patients got, the better for them. Since then there've been a number of studies using patient records, which suggest that giving blood may carry unexpected risks.

## ACTUALITY IN THEATRE

GAVIN MURPHY: We're just about to start a set of routine coronary artery bypass grafts on a 70 year old gentleman. We're taking an artery from the arm and some veins from the leg and we'll also take an artery from the inside of the chest, and then we'll perform the bypass grafts on the beating heart without the use of the bypass ...

CURWEN: Heart surgeon Gavin Murphy, performing a triple heart bypass operation at the Bristol Royal Infirmary. He and his colleagues analysed the records of more than eight thousand cardiac patients over a number of years, to try to work out whether those who were given blood fared differently from those who weren't. The results of the study, funded by the British Heart Foundation and published in the journal 'Circulation', question the efficacy of transfusing red cells.

GAVIN MURPHY: The widely held belief would be that red cell transfusion should improve the delivery of oxygen to the tissues. Paradoxically we showed that transfusion was associated with a three-fold increase in the incidence of both infectious and ischemic complications – ischemic complications being where organs are not working well because of a lack of oxygen, so heart attacks, strokes and renal failure. And that seems to show that blood transfusion is harmful. We also showed a significant increase in death rates in patients who were transfused. Within the first thirty days the mortality rate increased six-fold in patients that had received a transfusion compared to those that hadn't. The difference in death rates persisted with a three-fold increase in mortality up to one year, but more importantly we showed that the difference actually persisted for up to five years after the procedure.

CURWEN: A lot of members of the public would be really surprised by that, possibly shocked.

GAVIN MURPHY: I think it's important not to scare people. We're giving blood transfusions because someone has made a decision that they think it's in your best interests. The evidence to support that decision isn't perfect, but we have to do the best that we can. Medicine changes all the time. We learn new things and the way we treat people is very different today than it was even ten years ago, when I first qualified. We

GAVIN MURPHY cont:                    become aware of things that we were doing before may not be excellent and we can change, and I think doctors, by and large, are very responsible. I think they do modify their practice in the light of evidence, and it's our duty to provide the evidence.

CURWEN:                                    Medical opinion though is divided about how much reliance should be placed on this type of scientific study, which is similar to the one done in Ohio by Colleen Kook and many others on the risks of transfusion. They're known as retrospective studies, and they look back at patient databases rather than actually recruiting new patients into a randomised controlled trial, which is the gold-standard model of research. Lorna Williamson is the medical director of NHS Blood and Transplant.

WILLIAMSON:                            The problem with studies that look backwards is that if you're comparing patients who've received younger blood or older blood, if you like, you can never be absolutely sure that the two groups of patients are comparable, and so you have to look terribly carefully at the methodology. If you examine the other factors that may have explained the findings, you can actually explain them by another factor, which is that the patients who received the older blood also received far more blood, and we know therefore that they were much sicker patients and therefore not comparable.

CURWEN:                                    What's your reaction to the retrospective study done in cardiac patients in Bristol?

WILLIAMSON:                            Well there are similar limitations, of course, so what's really needed now is a prospective randomised controlled trial comparing blood of younger shelf life with blood of older shelf life, so that you could be sure that the patients in the two groups were absolutely comparable, and such a study has begun in Canada, but it will take some time to report. Now if that study did show a difference between fresher blood and older blood, then we would be taking that extremely seriously, and if we had to we would shorten the shelf life for certain patients, if that's what the study showed we had to do.

CURWEN:                                    But given the lack of evidence for the benefit and increasing worries about the risk, wouldn't it be safer to change your supply policies now?

WILLIAMSON: Well, that sounds like a quick solution, but of course shortening the shelf life of blood may create other problems of supply, and that would be dreadful to change policy on sub-standard evidence, if you like, and waste blood quite unnecessarily.

CURWEN: Gavin Murphy concedes his study cannot prove the red blood cell transfusions actually caused more infections and more heart attacks, but he insists it's important evidence.

GAVIN MURPHY: You can never ignore the fact that the group of patients who received blood transfusion are different from the group of patients who don't receive a blood transfusion, so that we adjusted for what we call confounders, to try and, for example, take into account that patients who receive transfusions are sometimes elderly, sometimes sicker, sometimes undergoing more complicated operations. So even after adjustment for these factors, we found that the risk is increased by a factor of three. Almost every evaluation that's ever been done of blood transfusion has shown it to be harmful in some way, and in fact the difficulty is not finding evidence that blood transfusion is harmful, the difficulty is actually finding evidence showing that blood transfusion is good for you outside of the setting of haemorrhagic shock or life threatening bleeding.

#### ACTUALITY OF CELL SALVAGE

CURWEN: In operating theatres across the UK, some doctors are taking steps to reduce the number of transfusions. They use new drugs to control bleeding, and techniques such as recycling patients' own blood on the operating table. Darren Palmer works with Gavin Murphy in Bristol.

PALMER: Basically, during the surgery, any waste blood that is lost from the patient within the chest can be sucked down into a reservoir, which can then be pumped through into a centrifugal pump where the cells are concentrated. These cells can then be washed with a saline mix to remove any waste products and plasma. The remaining concentrated red cells can then be pumped into a bag which can be transfused back into the patient, and that eliminates the need of using further blood products which can cause transfusion complications with a patient and also can be quite costly for the hospital.

**CURWEN:** For the last five years, the Department of Health has been running a national drive to reduce blood use called 'Better Blood Transfusion'. It has produced audits of blood use, employed doctors and transfusion practitioners to educate their peers about the risks and benefits. The result has been that in England and North Wales, the amount of red blood cells transfused has fallen by 15%. The biggest drop in transfusion rates has been seen among surgical patients. File on 4 has spoken to a number of cardiac units. All show reductions in the proportion of patients being transfused. But there is still wide variation. One gives transfusions to 25% of people undergoing heart surgery, while another still transfuses 60%. Official audits suggest there are still large numbers of cases where patients don't have a low enough blood count to merit a transfusion. Professor Mike Murphy, Haematologist at the John Radcliffe Hospital, who works closely with NHS Blood and Transplant, says some doctors still haven't got the message.

**MIKE MURPHY:** There is large variation in the use of blood between different clinical teams and different hospitals. The reason that the clinicians may not comply with the guidelines – and we know from audits that they don't necessarily comply with the guidelines – is that they're not aware of the guidelines, or they do not accept the recommendations in the guidelines, either because they haven't been drawn up with the involvement of the relevant clinical group or because they're perceived to be based on weak clinical evidence.

**CURWEN:** How many transfusions are there in the UK every year?

**MIKE MURPHY:** In England there are about two million red cell transfusions given every year, which is a considerable number.

**CURWEN:** Do you think it's possible to estimate how many of those red cell transfusions may not be necessary?

**MIKE MURPHY:** Audits of the appropriateness of red cell transfusion show that as many as 20% of red cell transfusions may be given inappropriately at the current time.

CURWEN: 20% of two million transfusions in England and North Wales alone?

MIKE MURPHY: That works out at about 400,000 red cell units out of the two million that may be used inappropriately at the current time.

CURWEN: So that translates to a lot of patients.

MIKE MURPHY: Certainly it's a lot of patients who are potentially being put at risk, at unnecessary risk from having a blood transfusion without getting the clinical benefit, and also it's a considerable cost.

CURWEN: File on 4 has attempted to quantify the cost of that inappropriate use. If you take figures estimated in 2001 for the cost of a unit of blood, including hospital stays and possible complications, the total cost of inappropriate transfusions would be £94 million. It's a conservative estimate. And, if the 20% figure is right, it means 160,000 patients a year are being exposed unnecessarily to the risks of red cell transfusion. But Lorna Williamson, medical director of NHS Blood and Transplant, is sceptical.

WILLIAMSON: It's very difficult to imagine that one in five transfusions is inappropriate, which is really what you're saying. We've invested over £2 million a year in staff to go out and drive better blood transfusion, and hospitals themselves have employed staff to do that. So we've seen a reduction in blood use of around 15% over the last five years, and there is much more awareness of the need to make every transfusion an appropriate one. I think if transfusion were causing patients to have an unexpectedly bad outcome from their underlying disease, I think we would know about it.

#### EXTRACT FROM ADVERT

PRESENTER: Why not give blood? You never know whose life you might save. Do something amazing. Give blood.

CURWEN: The Blood Services have been running high-profile advertising campaigns to attract more donors. That makes the debate over the risks of transfusion very sensitive. Everyone we spoke to in making this programme agrees that the last thing they want is to put people off and risk creating a blood shortage which would affect those whose lives depend on transfusions. But Dr Brian McClelland, strategy director of the Scottish National Blood Service, says that sensitivity should not get in the way of basic questions.

MCCLELLAND: My belief is that, actually those early experiences of transfusion which led us to, led transfusion organisations to promote voluntary blood donation as a fantastically important life-saving contribution to your fellow men, all these things have created a belief in transfusion which actually has removed, if you like, or diluted the pressure that should have been there to actually do the clinical trials to really ask the questions. We question have we lost the plot in putting so much effort into safety and actually, until very recently, so little effort into effectiveness of blood, because without that information it's impossible to make a safe, sensible and ethical choice between the balance of benefit and risk.

CURWEN: But in England, Dr Lorna Williamson, the medical director of NHS Blood and Transplant, insists there's no need for radical change in policy. Has the balance been wrong between spending on screening blood for infections and spending on research which will address the risks and the benefits of blood transfusion?

WILLIAMSON: You have to go back to the days when blood was much less safe than now, and I don't think any of us would want to see infection risks as we saw them twenty or thirty years ago. It's very easy to take a safe blood supply for granted, so we're not suggesting for a minute that we make blood less safe in order to fund clinical studies, but the UK is doing well in clinical research in general and therefore there is scope for good quality studies in transfusion, as in other branches of medicine.

CURWEN: There's not much point in trying to make the blood ever safer if indeed you're putting people at risk by putting it into them.

WILLIAMSON: You have to do both. We're looking at these studies with great interest, but they are not adequate evidence in themselves to change policy.

**CURWEN:** The arguments should be settled once and for all, when gold-standard randomised controlled trials on the effects of stored red blood cells and the safety of transfusion are complete. Some are planned, others are underway, but it may be another five or eight years before the evidence is clear. In the meantime, the questions being raised by some doctors about transfusions may increasingly be asked by patients as well. Professor Mike Murphy, consultant haematologist at the John Radcliffe Hospital in Oxford.

**MIKE MURPHY:** It would be extremely valuable for the public and patients to understand more about the risks and the benefits of blood transfusion, and indeed to be challenging doctors when they're about to prescribe blood and for patients to be asking, 'Do I really need to have this transfusion? Do the benefits that I might get outweigh the risks?'

**SIGNATURE TUNE**