

RISK MANAGEMENT IN TRANSFUSION MEDICINE: *Maximising The Benefits And Minimising The Risks*

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Introduction

Risk/benefit analysis is increasingly important in medical practice. Clinicians desire to achieve the best possible outcomes for their patients in the context of an ever contracting health budget and increasing accountability. Attempts to reduce risk to negligible levels may be associated with progressive loss of benefit, but clinicians must carefully balance and communicate the risk/benefit equation to their individual patients. The dangers of homologous transfusion have always been known, but it was not until the recognition that HIV can be transmitted by homologous blood transfusion that the medical community and the general public gave serious thought to this reality.

It is now accepted that there must be clear reasons for every transfusion of homologous blood in conjunction with a careful appraisal of the potential hazards, informed consent and appropriate administration, monitoring and documentation. Care is taken in identifying a patient's specific haematological defect/s, the appropriate therapies, minimisation of homologous transfusion, improvement in the safety of homologous blood and the use of autologous transfusion techniques, if appropriate. Homologous transfusion should no longer be immediately perceived as the first line of therapy for patients with haematopoietic defects. In many circumstances, it is possible to correct or manage the effects of deficiencies in the haematopoietic system without transfusing homologous blood components. If homologous blood can be avoided, the potential hazards need not be considered. The lawyers are well aware that representing a client who suffers major morbidity or mortality from a transfusion or other therapy which was not clearly indicated is a certain "win".

The decision-making process for blood component therapy is not always easy, and much debate continues in relation to what are the indications for the transfusion of various homologous blood components. In some circumstances the decisions are "black and white", but in others they are more controversial "grey" issues. There are clinical circumstances where homologous transfusion is clearly the only effective and available therapy for a patient, and such therapy should be administered in a timely fashion with the benefits clearly being explained to the patient and/or their relatives. There are other clinical settings where the process of medical decision making may be more complex and a clear identification of the advantages or disadvantages of various available therapeutic options may not be easy. In such circumstances, the clinician should attempt to avoid homologous transfusion. Table 1 outlines the factors to be considered when transfusion therapy is indicated, and Table 2 and Figure 1 the definition of a safe transfusion

Table 1. Factors to consider with transfusion therapy

- Urgency? Elective?

- What is the hematological defect?
- What blood component is indicated?
- Can adverse effects of homologous blood transfusion be avoided or minimised?
- Is there a role for autologous transfusion?
- How is the blood component obtained and how should it be administered and monitored?
- What is a “safe” transfusion?
- What are the risks of the blood component therapy?
- What is the cost of the therapy?
- Is the patient fully informed?
- “Acid test”: If a bad outcome eventuates, would the same decision have been made?

Table 2. What is a safe transfusion?

- There must be a clearly defined indication for the transfusion.
- There must be adequate “dosage” of the functional component/s.
- The administration should not be associated with any ill effects.
- There should be no delayed sequelae from the transfusion, and the transfusion should not transmit disease.
- The safety and efficacy of future transfusion therapy should not be jeopardised.
- The transfusion should be administered with due care and adequate monitoring to ensure that the anticipated aims are achieved and any adverse effects are quickly noted and appropriate action instituted.

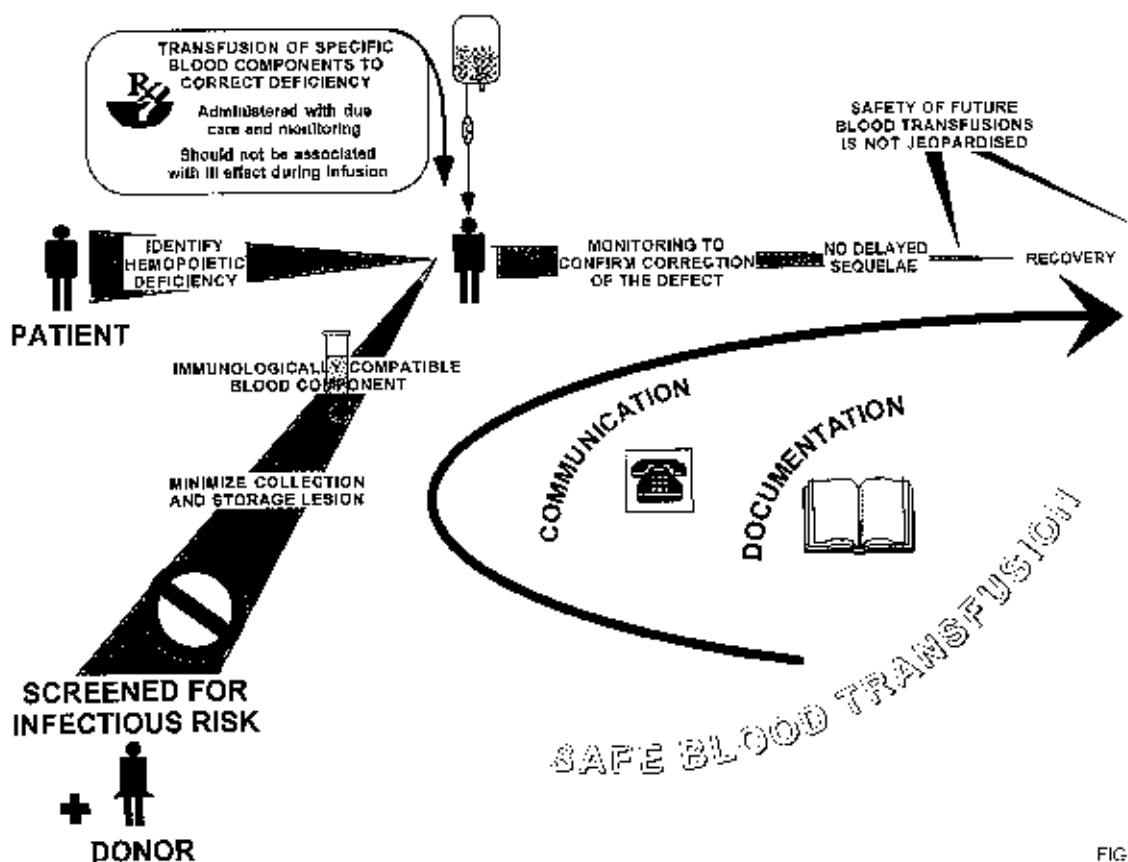


FIG 1

Figure 1. What is a safe transfusion? The figure illustrates the important factors needing attention in the initiation, provision, administration and monitoring of blood transfusion.

It is clearly not possible to satisfy all these criteria, but it is possible to minimise the risks of transfusion and maximise the benefits. Patients must clearly understand that if they avoid a small risk, although it is associated with marked emotional overtones, they may be accepting a more serious risk. Individuals, bureaucracies and governments may all approach risk from different perspectives and with different rules. Utility-oriented approaches purely balance up the pros and cons, and the greater wins. This approach is commonly used by governments and industry when economic factors are paramount, an environment within which we as clinicians have not previously had to work. Rights-based approaches are more familiar to clinicians in that they focus on the individual's freedom and right to make informed choices about their own lives, with the clinician as their adviser and advocate. This approach has in the past been independent of economic considerations.

Medicolegal Responsibilities: Material Risk and Duty to Warn

The obligation to exercise a degree of care, skill and diligence is not limited to the actual performance of medical treatment but also encompasses the obtaining of patient consent prior to the commencement of treatment. Clinicians, as part of informed consent,

have a duty to warn of a material risk of medical therapy. In communicating medical information, there is a scientific versus patient formulation, and legal systems in many countries are moving more towards a patient perspective. Most courts now see little reason to base the standard of skill for communication of professional advice solely on the opinion or practice of a particular profession, since “communication” as a skill is not defined or practised solely by any particular profession. Increasingly, the standard used by courts in regards to the provision of professional advice is that a clinician has a duty to warn a patient of a “material risk”. A risk is regarded as material if a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it; or a doctor is aware or should reasonably be expected to be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.

Acceptable Risk

There are no universally acceptable levels of transfusion risk. This varies with the clinical options, possible adverse consequences and data used in the decision making process. The risk associated with the most acceptable clinical option might be defined as an acceptable risk. However, acceptable risk decisions often appear inconsistent, frequently being based on perception and ignorance rather than a proper risk analysis. Individual and societal choice adds a level of complexity to the determination of acceptable risk, which at times defies logic but highlights the concept that risk management must be viewed in non-linear and “chaotic” terms. The psychosocial and political interactions cannot be ignored.

Risk reduction cannot be view in “linear” terms with a risk “cut-off” point or a zero risk point. Risk reduction should be viewed on an exponential curve which has no beginning and no end, and it can only be said that a risk is greater or less than a particular point. True risk management does not accept the concept of zero risk. If there is zero risk, it is likely that nothing is happening.

Perception of Risk

In day to day life we have only vague criteria for defining risk for most aspects of life’s activities. The greater the benefit, the greater risk that will be accepted. People will accept a much higher risk if the risk is voluntarily accepted. Risks which are familiar to people and well understood are more accepted than risks to which they have never been exposed or with which they are unfamiliar. The closer the temporal relationship of the risk is to the activity in question, the less risk one is likely to accept. Remote risks are perceived as relatively less important, although in reality they may be much worse. It is human nature to underestimate the frequency of common events and overestimate the frequency of uncommon ones, especially if they are high profile. Transfusion-transmitted HIV is now extremely rare in Western countries but has a high “dreadfulness index”.

Principles of Risk Management

The range of adverse effects of homologous transfusion can range on a spectrum from relatively frequent minor mishaps to uncommon major disasters. Management of common minor mishaps is assisted by their relative frequency as it is possible to monitor if performance is improving. This is in contrast to the management of serious adverse outcomes, which is more difficult as they may be too rare to be quantitated and compared with the previous performance. Despite their rarity, adverse outcomes (e.g., HIV), because of their enormity, need to be managed by eliminating the possibility, or at least minimising the possibility. This is the concept of “risk management”.

Risks versus Hazards

In contrast to common usage, “risk” and “hazard” have different connotations in the context of risk management. A hazard is the potential to cause harm whereas risk is the likelihood of occurrence of a defined level of harm. Risk must be expressed in terms of the defined level of harm (e.g., death of one patient) and the likelihood of the event occurring (e.g., probability per transfusion or donor exposure).

The Steps of Risk Management

1. Identify and list the hazards of the blood products and the indications for their use.
2. Summarise possible hazards in a systematic manner, short-listing those requiring full assessment versus those with lower priority. An additional list of low frequency hazards (“frequency score”) for which the consequences for the patient or organisation could be extremely serious (“severity score”). Finally, a score for the probability of failure of a response to the occurrence of the hazard. A “risk score” is calculated by multiplying the severity score, initiation frequency, and the response failure probability.
3. From steps 1 and 2, define the questions that need to be asked and identify the parts of the process or people involved. Some information can be quantified and expressed in numbers, in contrast to other information which cannot. Decisions should not only be made on quantifiable data, as unquantified experience and judgment will be ignored. Assessing risks may require them to be examined and analysed by describing the consequences and likelihood in words alone.
4. Where the questions require a numerical assessment of a risk, the quantified defined risk needs to be identified and/or safety targets set. These are usually expressed as the probability of a defined hazard occurring within a defined time period, such as the risk of death per year (e.g., incorrect patient identification) or the probability of an infected unit of blood per unit being used.
5. For each potential hazard or scenario, assess the likely severity of the consequences, using methods which are appropriate to the type of incident.

6. For each listed potential hazard, assess the probability or frequency of occurrence. Typical approaches are conventional statistical analysis or use of “fault trees”.
- 7.
8. Assess the risk compared to the defined “target” (the exposed patient) by multiplying the severity and the frequency of each hazard and determining the total exposure from all the incidents.
9. Compare the assessed cumulative risk against the criteria or targets, and determine the need for possible risk reduction.
10. By examination of the factors which have made most contribution to the assessed risk, determine the most fruitful areas for risk reduction or risk “transfer” (e.g., insurance) and arrange appropriate investigation and action.
11. There should be awareness and acknowledgment that a fall in operational standards could result in serious and possibly undetected increases in the probability of an adverse occurrence, and hence an increase in risk. It is important to ensure that operational standards remain high and that any deterioration is rapidly detected and appropriate corrective action initiated. There should be a regular monitoring system, for use by those responsible for the process(es), to ensure that the probability of occurrence remains as low as is expected.
12. To accompany the monitoring system for use by those supervisory and managerial staff with a direct line responsibility for the activity, set up a periodic auditing system to check that the appropriate monitoring systems remain in place and reach an adequate standard.

The Transfusion Risk Management Process

Donor Safety

Donor safety has always been a well-controlled and monitored aspect of the blood supply chain and is not addressed in this review.

Infective Risk

The safety of the blood supply from the infective point of view lies predominantly with the central blood supply agencies. Where screening methodology is available, the risks from transfusion are quantifiable and can be communicated to the clinician and the patient in a meaningful way.

The Hospital Transfusion Service

The hospital transfusion service is at the heart of the blood component therapy chain. Its multiple roles include maintaining an inventory of blood components, monitoring their storage conditions and ensuring compatibility when appropriate, as well as being the source of expertise in transfusion medicine and attempting to follow up any adverse consequences of transfusion.

The majority of resources in a hospital transfusion service are centred towards the provision of compatible red cells. Serological compatibility of red cells is taken for granted and rarely does it become an issue in the provision of a safe transfusion, except from the clerical error point of view. The methods for providing serologically compatible red cells are probably as good as they are ever likely to be. Putting more resources into this area of risk management has diminishing returns, and many would feel we have already gone too far and that the costs of current red cell compatibility testing outweigh the benefits (e.g., Should part of or the whole of the crossmatch be eliminated? What is the role of the computer crossmatch?).

The question of serological compatibility of other cellular and plasma components is only beginning to be realistically considered. For example the frustration in providing serologically compatible platelets for the patient refractory to platelet concentrates is one of the current challenges in transfusion medicine.

Blood Storage. The hospital transfusion laboratory has a central role in blood component inventory management. It is recognised that many of the adverse effects of transfusion relate to storage factors. Although there is much more to be learned in this area, particularly studying the clinical significance of storage lesion, there is a substantial amount of information available which should be disseminated and better understood by clinicians.

Allocation, Distribution and Administration of Blood. It can be frustrating for a clinician if a restricted supply of blood products jeopardises patient care. This is probably one of the most difficult areas of transfusion medicine management. With multiple people involved in the blood supply chain, and many clinicians “vying” for blood components, it can be difficult to make appropriate resource allocations. In this context, to minimise risk of patients not receiving appropriate blood products because of supply problems, there must be regular audit of the use of blood products. Priority may be determined by the assertiveness of the requesting clinician rather than patient need. Even worse, one may see the former patient suffer adverse consequences of the therapy at the same time as they observe the latter patient suffering the consequences of not receiving appropriate blood component therapy. When such cases arise, there should be open discussion in the clinical setting and presentations at the departmental transfusion medicine meeting or other educational meetings at the hospital.

Transfusion Surveillance. All hospitals should have a transfusion surveillance system monitoring clinical and laboratory transfusion practices (Table 3).

Table 3. The duties of transfusion surveillance officer.

- Clinical follow-up of transfusion reactions.
- Assistance with post-transfusion infection “look-back” programs.
- In-service education of nursing staff with particular emphasis on blood hanging, blood filtration, transfusion reactions, and updates on viral infection frequencies within the population and amongst donors.

- Counselling patients afraid of homologous transfusion and explaining the benefits and risks involved with the alternatives.
- Retrospective and prospective quality assurance by monitoring the use and misuse of blood products.
- Collection of clinical and laboratory data on transfusions, such that it can be utilised for formulation and updating of Recommended Maximum Blood Order Schedules and Crossmatch /Transfusion ratios.

These activities usually centre around the transfusion committee with input from appropriate participants. There are advantages in having a specific transfusion surveillance officer whose responsibility it is to oversee these activities. In this total quality management era, we are concerned about the safety and efficacy of the transfusion process from the initial collection from donor through to a successful clinical outcome for the patient. If inappropriate or poor outcomes are observed, the breakdowns in the process must be identified. When a poor outcome does occur, it must be carefully analysed as to whether it could have been avoided and what appropriate action should be taken to prevent it in future (Figure 2).

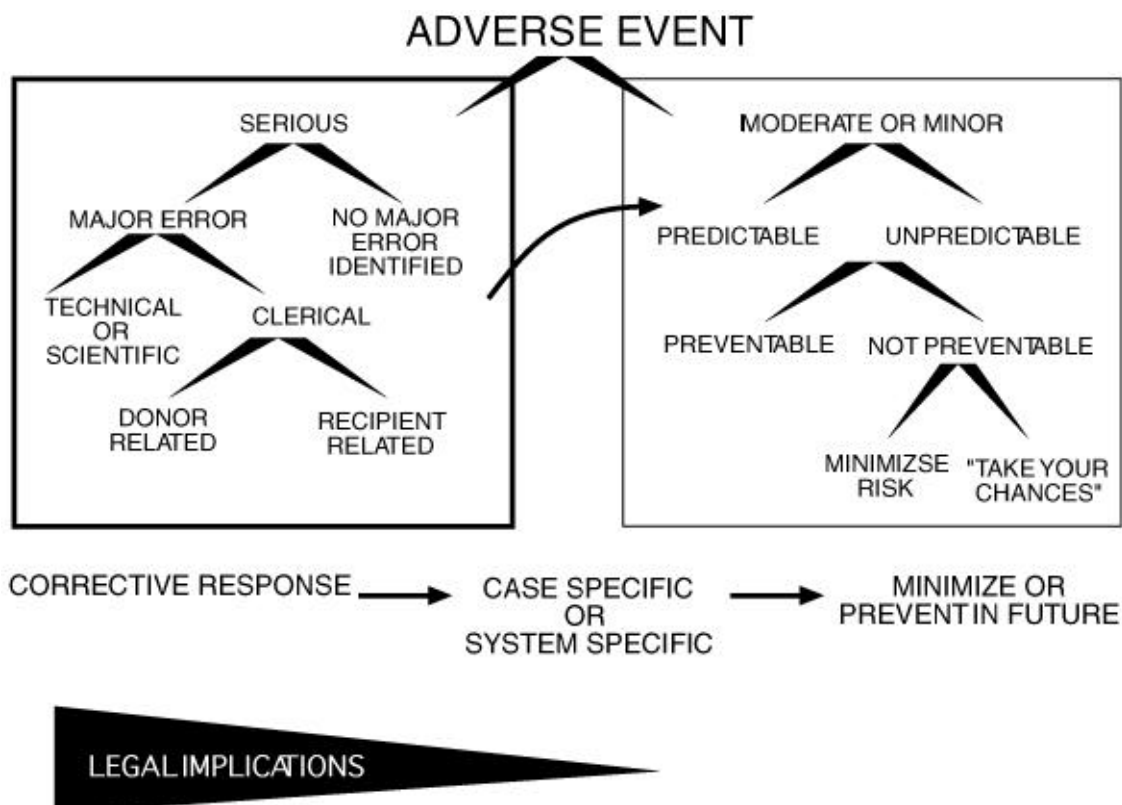


Figure 2. An algorithm approach to assessing a poor outcome of homologous transfusion. The legal implications are greater in cases where there has been a clear breakdown in process(es), in contrast to adverse outcomes where prevention is not possible.

Transfusion Medicine Committee. The primary role of the Transfusion Medicine Committee is to provide a comfortable and active forum within the hospital to nurture, facilitate and actively encourage communication between those directly involved with transfusion in laboratory and clinical areas, with the ultimate purpose of bringing problems to light, resolving them, and channelling back ongoing education. Comprised of senior representatives of the hospital transfusion service (medical, scientific and nursing), together with representatives from the user groups (including medical, surgical, anaesthetic, emergency and intensive care) as well as administration, and thus empowered with regulatory authority, the committee is able to rationally and practically help implement new or altered policies. New information or imbalances observed in the management of the risk/benefit equation can also be highlighted, questioned, and used for educational purposes, and improvements brought about by guideline or policy formulation to assure that the transfusion practice within the hospital is as safe and risk-free as possible.

The Clinician in Risk Management

The clinician usually has a limited role in identifying and minimising risks on the blood component supply side of transfusion medicine; this is usually the responsibility of the blood supply agency and the hospital transfusion service. On the other hand, the clinician has a range of responsibilities in the medical decision-making process, communicating with the patient (Table 4) and recognising adverse effects of transfusion (Figures 3 and 4).

Table 4. Clinician's responsibilities in transfusion risk management.

- Indications and benefits of blood component therapy.
- Patient identification for compatibility testing.
- Identification and communication of information about patients at high risk from specific potential transfusion complications.
- Communication of risk/benefit information to the patient.
- Appropriate handling, administration and monitoring of the blood component therapy.
- Awareness of potential transfusion-related complications, taking steps for early accurate recognition and intervention where necessary (Figure 4).
- Documentation of blood component therapy in the patient's clinical record and communicating relevant information back to the hospital transfusion service.
- Input into quality assurance programmes related to transfusion.

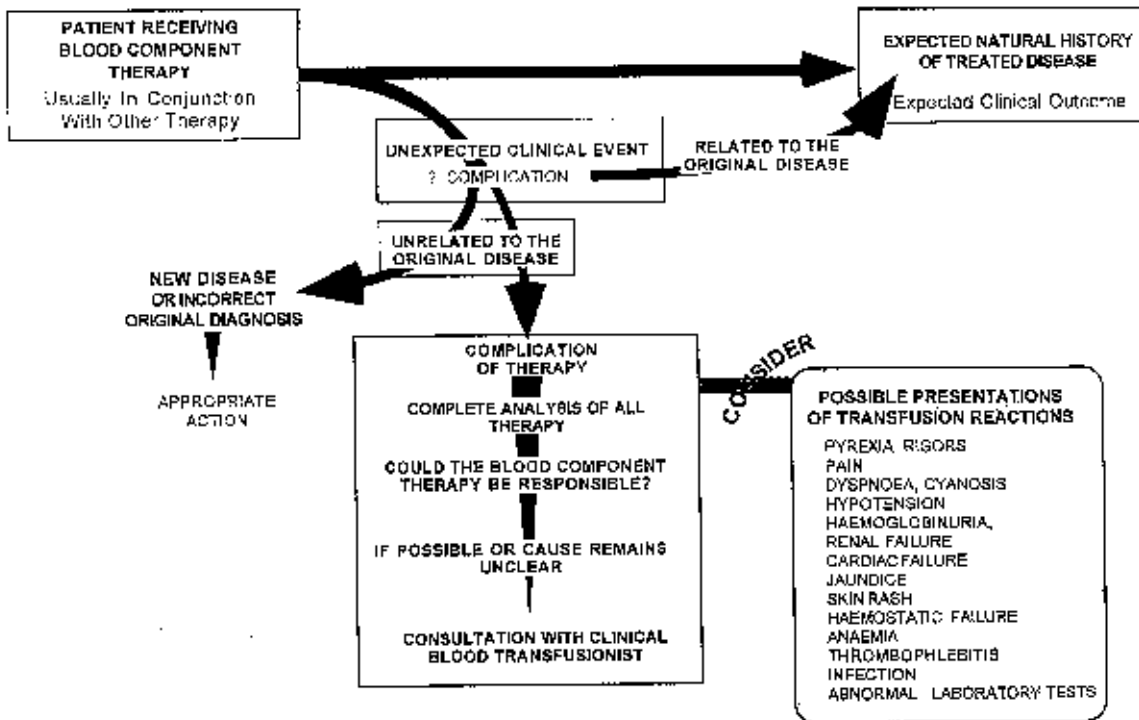


Figure 3. An algorithm approach to assessing unexpected clinical events in a patient's course in which transfusion may be causative or contributory.

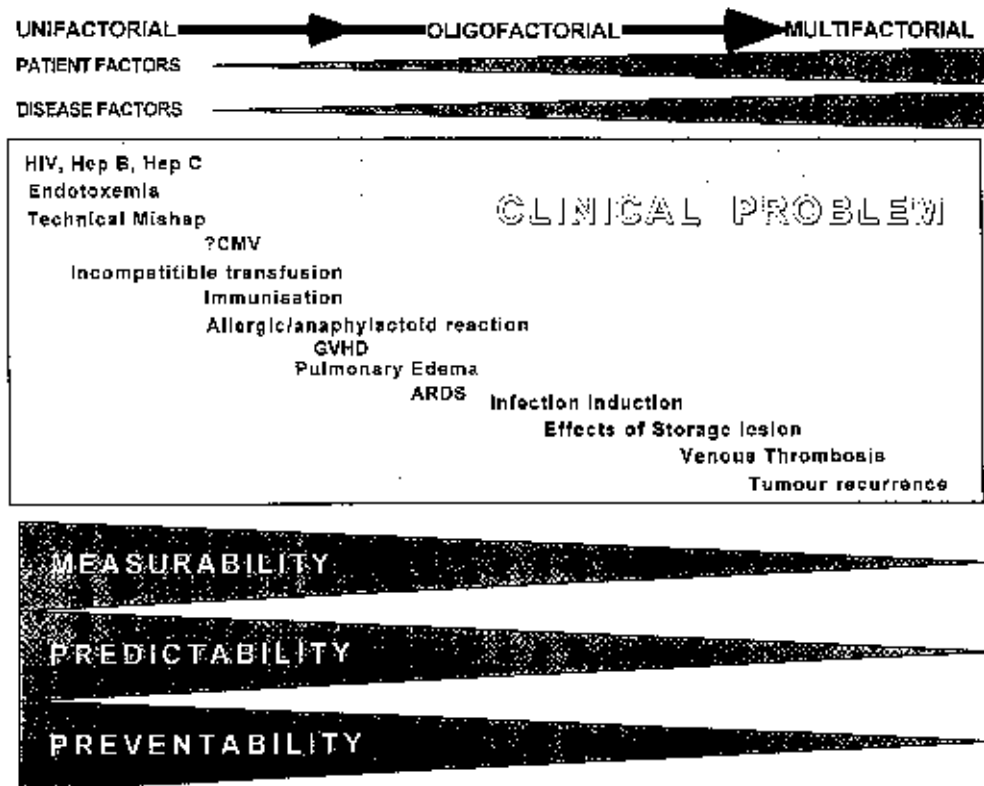


Figure 4. The spectrum for implication of blood transfusion being causative or contributory to a range of clinical syndromes. On the left are the clinical syndromes in

which transfusion is causative and can be proven. Progressing to the right are clinical syndromes in which transfusion is or may be a contributory factor to be considered in conjunction with host and other insult(s) (e.g., trauma, infection, medication) factors. With single causes the measurability, predictability and preventability are high as are the legal implications.

Risk/Benefit Communication

The benefits of therapy, in general, are easier to describe to patients in understandable terms. Table 5 summarises factors to consider in risk communication.

Table 5. Successfully communicating risk/benefit to patients and relatives.

- Understand the patient's current knowledge base.
- Assess the patient's ability to receive and understand information.
- Provide correct and relevant information at the patient's level of understanding. This should take into account the patient's language and cultural, intellectual and educational background.
- Ensuring that the patient understands what they have been told and can make an informed decision. Understanding the concept of uncertainty is crucial.
- Following up and keeping patient and relatives "abreast" of clinical progress, reinforcing the risks and uncertainties.

Conclusions

Since the recognition that HIV can be transmitted by homologous blood transfusion balancing, the risk/benefit equation in relation to blood component therapy has now become a day-to-day issue for blood bankers, transfusion medicine specialists, surgeons and anaesthetists. Blood transfusion has never been as safe a procedure as most patients and clinicians have thought, with a plethora of potential complications and new ones still being recognised.

There is persisting pressure from a society driven by a perceived need to further minimise or abolish the infectious complications of homologous transfusion. The clinician has a clear role in achieving this end by avoiding homologous transfusion whenever possible. Improvement in donor selection or screening will only marginally reduce the risk, at significant financial cost and reduction in the donor pool. Screening tests clearly have their limits of detection as the ultimate level of sensitivity (i.e., detection of a single infectious particle) is unachievable. Methods for inactivation of infectious agents in plasma components continue to improve, but there is little prospect for inactivated cellular products within the next decade.

FURTHER READING

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