

Malaria blood safety policy in five non-endemic countries: a retrospective comparison through the lens of the ABO risk-based decision-making framework

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Background. In non-endemic countries, malaria risk is addressed by selectively testing or deferring at-risk donors. These policy decisions were made using a variety of decision-making frameworks prior to the development of the Alliance of Blood Operators Risk Based Decision-Making Framework. It is unclear whether the range of items assessed in the decision-making process would be increased if the Framework were used. We compared assessments considered in France, England and Australia for decisions to implement selective testing, plus donor selection criteria (Canada and the USA included) with those recommended by the Framework.

Materials and methods. Elements of the Framework were identified: the intervention, safety threat, availability threat, donor impact, financial implications, risk communication, stakeholder and regulatory aspects. Decisions about selective testing and donor selection criteria were analysed separately. Assessments were compared against elements of the Framework and the level of concern for considerations rated.

Results. Sufficiency of the blood supply (plus safety in France) were the drivers for selective testing; main trade-offs were high operational impact and cost. In three donor criteria examples, transfusion-transmitted malaria cases prompted the change. Social concerns were high in France and Australia, political/regulatory concerns influenced decisions in France, Australia and Canada, while sufficiency was a consideration in Canada and the USA. Decision trade-offs involved moderate operational impact.

Discussion. The assessments considered in each country were generally consistent with the assessments recommended by the Framework. When data supported quantified risk assessment, safety and operational feasibility had the greatest weight. When risk was not well defined, contextual factors such as social and political concern had greater weight.

Keywords: malaria, policy decisions, selective testing, deferral.

Introduction

Malaria is a mosquito-borne apicomplexan parasitic infection causing cyclic fever. There are about 216 million cases per year (445,000 fatal); more than 80% occur in Africa¹. Of the five species of *Plasmodium* which can infect humans, the most frequent and most serious is *P. falciparum*; the next most common is *P. vivax*. Malaria can also be transmitted by blood

transfusion. In non-endemic countries, transfusion risk has two distinct sources: 1) blood donors who travel to endemic areas; and 2) former residents of endemic countries. Most infected travellers develop symptoms shortly after returning home. Semi-immune former residents of endemic countries can remain infected but asymptomatic for years, thus posing a greater risk.

Following a 2010 International Consensus

Conference on Risk-Based Decision Making for Blood Safety², the Alliance of Blood Operators reviewed decision-making frameworks that were in current use. From this base, the Risk Based Decision-Making Framework (the Framework)³ to optimise blood safety was developed. It involves a multi-disciplinary approach to assessment of a range of potential risks and advocates proportional allocation of finite resources to mitigate the most serious risks. It considers a range of contextual factors that affect decision making such as social, economic and ethical perspectives⁴. While evidence-

based decision making is generally advocated, uptake of the Framework into routine decision making has been slow, and its tangible impact beyond frameworks already in use is unclear. Specifically, it is unclear whether the range of items assessed in the decision-making process would be increased if the Framework were used. To our knowledge, there have been no publications to date comparing prior items considered in decision-making processes with those recommended by the Framework.

We have previously described policies addressing imported malaria in five non-endemic countries^{5,6}. Three

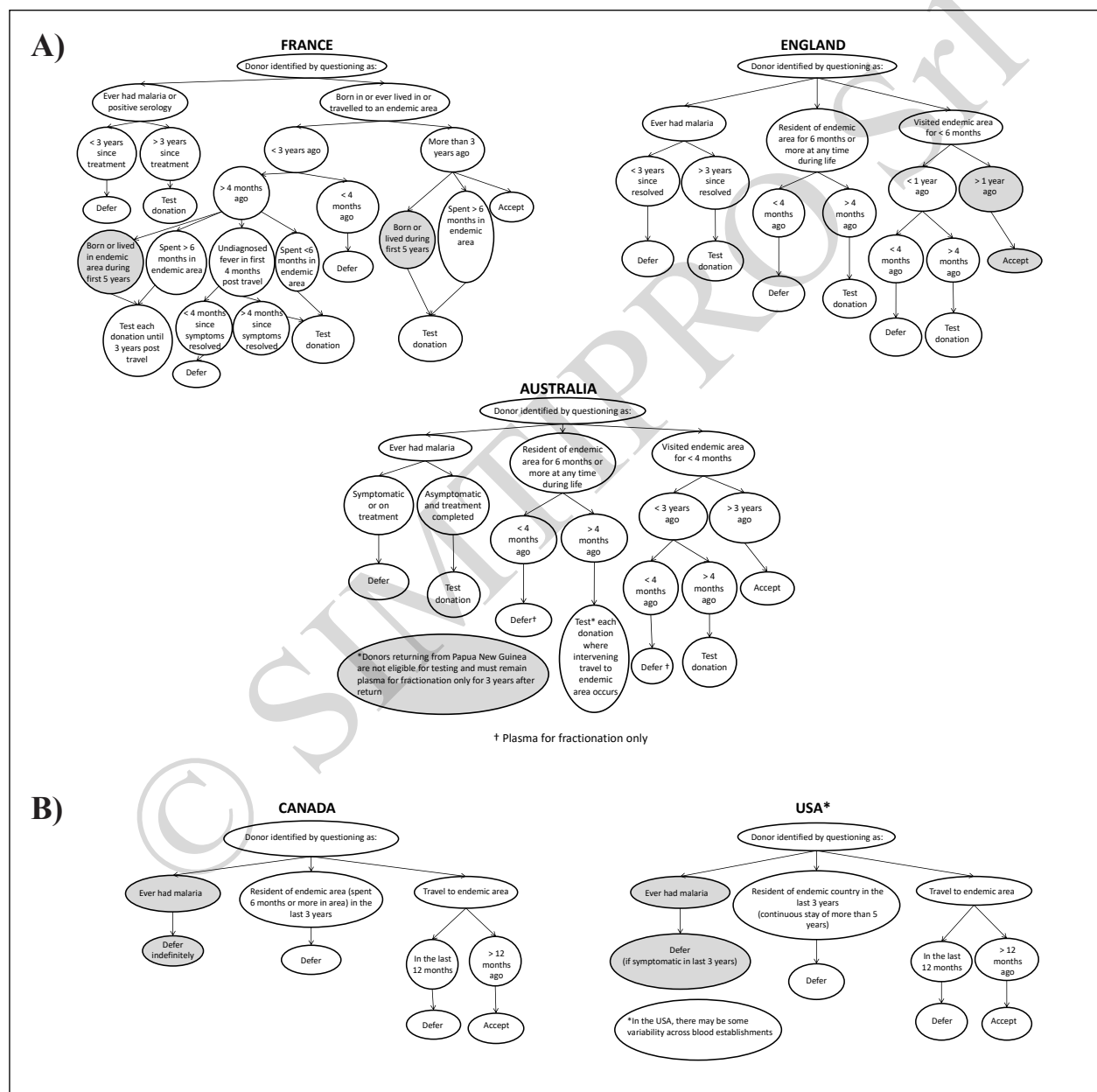


Figure 1 - Donor selection policies in: A) three countries with selective testing policies; and B) two countries with deferral policies.

Policy changes selected for analysis are shown in grey.

Table I - Donor criteria chosen for analysis of policy decision.

France	Testing if born in or lived in an endemic country during first 5 years of life.
England	Accepting donors if they returned from travel more than 12 months ago. (In France and Australia these donors would be tested if travel was within the last 3 years.)
Australia	The 3-year deferral for donors with travel to Papua New Guinea. (Eligible for plasma for fractionation donation.)
Canada	Permanent deferral of donors with a history of malaria.
United States of America	The 3-year deferral for donors with a history of malaria.

of these (France, England and Australia) have selective testing policies in which at-risk donors are identified through screening questions and tested for antibodies to *Plasmodium* species. The other two (the USA and Canada) have deferral policies (no testing) with longer, sometimes indefinite, deferral periods. Each country has somewhat different donor eligibility criteria. Here we aim to compare the types of assessments and information to formulate these policies using pre-existing decision-making frameworks with those recommended by the Framework.

Materials and methods

The relevant elements (topics of assessment) of the Framework for malaria risk mitigation were identified. These were: intervention, threat to safety, threat to availability, impact on donors, financial implications, risk communication, stakeholder relations, and regulatory aspects. Assessments are defined as the data and analysis put forward for consideration of policy formulation or change for each of these elements. Decisions are defined as the resolution after considering all of the assessments. Decisions for selective testing and donor criteria were analysed separately. The decision to implement selective testing was considered for the three countries that use it. The donor criteria for each country are shown in Figure 1². Table I shows the donor selection criteria decisions chosen for analysis to provide a range of decisions. Based on our previous publication, and additional input from the investigators, details of assessments were collated in a spreadsheet. These were compared against elements of the Framework, and the level of concern for considerations of the Framework were rated. The level of concern rating was based on two tools from the Framework: 1) the risk tolerability evaluation tree; and 2) worksheet 5 of the risk matrix. Application of these tools required the judgement and consensus of the investigators.

Results

Testing decisions

Three countries implemented selective testing strategies: France in 1986, England in 2001, and Australia in 2005⁵. In Canada and the USA, a licensed assay was not (and is still not) available. Table II summarises information relating to the selective testing implementation decisions in France, England and Australia.

France

After the emergence of HIV in the 1980s, social concern for risks of infection grew. Transfusion-transmitted malaria (TTM) was becoming more frequent in France: 24 cases reported in the 1960s vs 79 cases in the 1970s⁷. In the same time period, the proportion of post-transfusion malaria infections caused by *P. falciparum* rose from 15.4 to 84%. The recrudescence of cases was explained by: 1) high immigration from former French colonies in western and central Africa (where the predominant species was *P. falciparum*); 2) increasing tourism or business travel to endemic areas; and 3) changes in transfusion practice.

Since the 1950s, individuals who had malaria were deferred for five years following the last clinical manifestation⁸. In the 1970s, the availability of an indirect immunofluorescent assay test (IFAT) for *Plasmodium* antibodies prompted evaluation and a proposal for alternative strategies. There was also an increasing need for red cell phenotypes corresponding to sub-Saharan origin populations, especially for sickle cell disease treatment. Based on the IFAT performance, operational feasibility, cost and risk assessments, several studies indicated that testing at-risk donors was more efficient and safer⁹⁻¹¹ than deferral. This was because the donor criteria for selective testing could be broader than was practical for deferral. Screening of exposed donors using IFAT was recommended in February 1981 by the French National Society for Transfusion, and in 1986 serological testing became mandatory for at-risk donors.

Because fatal cases of TTM were mostly caused by *P. falciparum*, an immunofluorescent (IF) assay based on *P. falciparum* antigens was developed with other species detected *via* cross reactivity. To allow sufficient time for antibodies to develop, there was a deferral period of four months after return from a malaria risk area. During the pre-donation questioning, all donors were asked about risk factors and dates of exposure. If considered at risk, the physician would require testing be performed. The IF assay was fully manual requiring two independent operators for reading and interpreting the results. For this reason, and because the number of tests was increasing over time, in 2005, an ELISA assay was implemented. This mitigated operator error

risk and increased both throughput and reproducibility of the assay. After a large-scale study supporting these mitigation efforts¹², no further formal assessment was conducted at that time. This decision was based on comparison of the performance between the ELISA and IF assays, sensitivity for the detection of well characterised clinical sample panels, and review of international literature. Cost was not a main driver.

As shown in Table II, the concern level was high for safety, sufficiency, political influence, and social concern, thus these were the key factors in decision making.

England

In the late 1990s, low risk of HIV was established. Public attention was focused on the variant Creutzfeldt-Jakob disease (vCJD) epidemic in the food chain. With deferral in place for travellers to and residents from malaria risk areas, risk to the blood supply was addressed, as evidenced by the absence of TTM cases. Thus, both social and safety concerns were low. In England, immigration from malaria risk areas is primarily from Africa and the Indian sub-continent where *P. falciparum* and *P. vivax* are the main potential infections. Deferral of safe donors was considered inappropriate and unnecessary given that an alternative was available, and there was pressure from

both donor and recipient groups to extend eligibility. Sufficiency of rare red cell phenotypes corresponding to ethnic groups likely to be deferred was also a concern. This, together with sufficiency in general across a range of ethnicities associated with nationals of endemic countries living in England, drove the decision-making process. Options were to maintain the *status quo* or implement selective testing. The expected donation gain with selective testing was estimated from donor deferral data. In the late 1990s, an in-house immunofluorescence assay specific to *P. falciparum* was piloted¹³. Later, a high-throughput EIA assay was implemented, deemed necessary to manage the volume of testing. The sensitivity of the assay across species and operational feasibility of testing were taken into consideration. Budget impact was assessed, although cost was not a main driver. Table II shows sufficiency and operational issues had the highest concern. Sufficiency, particularly for rare phenotypes, was the main decision driver.

Australia

By the beginning of the 21st century, TTM-risk was acceptably managed by deferral as evidenced by the absence of TTM cases¹⁴, thus safety concerns were low. However, travel to malaria risk areas, particularly

Table II - Information relating to selective testing decisions in France, England and Australia.

	France	England	Australia
Risk presented	5 TTMs per year despite deferral. High immigration from malaria areas. Increased donor travel to endemic areas.	Travel to endemic areas. Immigration from malaria areas. No TTM with deferral.	Increased donor travel to malaria risk areas (approximately 5% of whole blood donations). No TTM with deferral.
RBDM considerations	Level of concern	Level of concern	Level of concern
Safety	High	Moderate	Moderate
Social concern	Moderate to High	Low	Low
Political / regulatory influence	High	Low	Low
Operational impact	Moderate concern	High	High
Cost	Moderate	Moderate	Moderate
Donor impact	Moderate	Moderate	Moderate
Sufficiency of supply	High (rare phenotypes)	High (rare phenotypes)	High
Ethical considerations	Moderate (deferral of safe donors)	Moderate (deferral of safe donors)	Moderate (red cells from safe donors are discarded)
Decision	Selective testing	Selective testing	Selective testing
Key factors in decision making	Safety. Sufficiency (rare phenotypes and overall). Social concern. Political influence.	Sufficiency (rare phenotypes). Inclusion of wider range of nationalities migrating to and living in England.	Sufficiency. Donor impact.
Decision trade-offs	Accepted high operational impact. Accepted cost.	Accepted high operational impact. Accepted cost.	Accepted high operational impact. Accepted cost.
Absent	Stakeholder consultation.	Stakeholder consultation (some input was obtained indirectly).	Donors not consulted. Positive impact was reported for testing including additional use of blood donation from donor, and health benefit of malaria testing for undiagnosed disease.

RBDM: risk-based decision making; TTM: transfusion-transmitted malaria.

to Asia, was expanding rapidly, impacting up to 5% of presenting donors. Given that travel to risk areas was expected to continue increasing, the existing strategy of restricting "at-risk" donors to source plasma for up to three years was considered sub-optimal. Selective testing was validated as a suitable alternative, and since this was largely an operational issue, social concern was low and stakeholder consultation beyond donors, funders and the blood regulator was not deemed to be required. A specific communication for malaria-restricted donors notifying them of the intent to test, the rationale and personal implications, including management of positive results was provided at their first donation after implementation of testing. In Australia, Council of Europe guidelines are mandated which permit selective testing with a suitably sensitive licensed assay. The decision to implement selective testing considered the sensitivity of the assay across the predominant imported species and the operational feasibility. A limited cost effectiveness analysis was also conducted which strongly supported testing efficiency. Operational impact and sufficiency were the highest concerns and were the main decision drivers.

Donor criteria decisions

Information relating to decisions about donor selection criteria are shown in Table III.

France

After implementing testing, cases of TTM were very rare¹⁵. However, in 2002, a TTM case occurred resulting in recipient death. The donor from West Africa had lived in France for more than four years without symptoms, unaware she had ever had malaria. Under the criteria at the time (no testing required three years post exposure) she was eligible to donate. On follow up, she had low level parasitaemia and detectable antibodies. Safety concerns prompted a review of the criteria.

The main decision driver was to reduce risk from donors unaware of childhood malaria, but risk to the blood service's reputation and public confidence were also important. A quantitative risk assessment was not possible. Screening questions were changed to stipulate testing for donors born in or living in an endemic area before the age of five years, no matter how long that donor had resided in mainland France. In addition, testing was required for all former residents at each

Table III - Information relating to donor selection criteria decisions in France, England, Australia, Canada and the USA.

	France	England	Australia	Canada	United States
Change in criteria	Born in or lived in France during first 5 years of life	Accept 12 months after travel	Deferral for 3 years after travel to Papua New Guinea (source plasma donation accepted)	Permanent deferral for history of malaria	3-year deferral for history of malaria
Risk presented	1 TTM case: donor unaware of childhood malaria	Other countries test for a longer period than current UK practice	2 donors diagnosed post donation with relapsing <i>P. vivax</i> malaria	2 TTM cases: donors eligible to donate	1 TTM case every 1-2 years
RBDM considerations	Level of concern	Level of concern	Level of concern	Level of concern	Level of concern
Safety	High	Low	High	High	High
Social concern	High	Low	High	Low	Low
Political/regulatory influence	High	Low	High	High	Moderate
Operational impact	Moderate	Low	Moderate	High	High
Cost	Moderate	Low	Low	Moderate	High
Donor impact	Low	Low	Low	Moderate	High
Sufficiency of supply	Low	Low	Low	Moderate	High
Ethical considerations	High	Low	Moderate	Moderate	Moderate
Key factors in decision making	- Safety. - Social concern. - Political concern.	- Safety. - Sufficiency. - Broad donor pool.	- Social concern. - Political/regulatory concern.	- Political/regulatory concern.	- Donor impact. - Sufficiency of supply. - Operational impact.
Decision trade-offs	- Accepted moderate operational impact. - Accepted moderate cost impact.	- Accepted moderate operational impact. - Accepted moderate cost impact.	- Accepted moderate impact on donors and operations. - Accepted increased cost.	- Accepted moderate operational impact. - Accepted moderate cost impact.	- Safety. - Political/regulatory concern. - Ethical considerations.

RBDM: risk-based decision making; TTM: transfusion-transmitted malaria; *P. vivax*: *Plasmodium vivax*.

donation for three years after returning to France. The greatest concerns related to safety, social concern and political/regulatory influence (see Table III). Since implementing this change, no TTM case has precipitated policy modification. The most recent case of TTM was a blood donor originating from Africa with very low levels of both antibodies and parasites¹⁶. Other serological tests had discrepant results; the negative result of the ELISA test used for screening was likely due to the limit of detection for this assay. The donor was classified as an immune-silent individual, and as this profile is probably very rare, it was considered an exceptional event that did not require strategy modification.

England

Prior to selective testing, donations were accepted from travellers to risk areas 12 months after returning to England. When selective testing was implemented, these donors were tested after a shorter deferral period (originally six months; more recently four months) and no testing required after 12 months, consistent with the EU directive. However, in France and Australia, testing for an additional period was included. This decision was taken in order to address Council of Europe requirements to otherwise ask about and defer in case of fever in the last six months (potentially consistent with malaria symptoms). In England, this risk is addressed by testing or deferring donors with fever consistent with malaria and travel-risk history. The level of concern for all considerations was low (see Table III). Post-implementation monitoring has not identified any TTM cases¹⁷.

Australia

In 2008, two "near misses" involving post-donation malaria were reported^{5,18}. Both donors had hiked the Kokoda trail in Papua New Guinea (PNG) where risk is high, but complied with prophylaxis; one donated four months after returning to Australia, the other four times in the period 5-15 months after returning. Both were diagnosed with relapsing *P. vivax* one-two months post donation. Their donations were negative for malaria antibodies, unlikely to be parasitemic at the time, and no blood components were transfused. The revelation that the antibody assay could not predict potential for relapse with this PNG variant of *P. vivax* was a safety concern that prompted a revision of policy. Although it was not initially possible to accurately quantify the risk, that 2 "near misses" had occurred in close succession suggested that more could occur. Ethical issues and due diligence were considered. A risk and impact assessment based on the country of acquisition of *P. vivax* relapse cases reported in Australia was undertaken. This identified "higher risk" countries, with PNG contributing more than eight times the number of cases

than any other country. Based on available donor travel data, a sufficiency assessment with predicted donor loss was conducted. The regulator's expectation was that this process failure be appropriately investigated and any ongoing risk be mitigated within agreed risk tolerance. The driver was to address risk from such donors, but also social concerns and risk to reputation and public trust (see Table III). As no change in testing strategy could address this, the possible courses of action were to maintain present criteria or implement testing restrictions for PNG travel. Although the risk was presumed to be very small, the expected impact on blood product sufficiency was also small given the low incidence of travel to PNG. It was decided to exclude donors from testing for three years following their return from PNG (effectively restricting them to plasma for fractionation) with ongoing monitoring for further cases and possible revision at a later date.

Canada

In 1995, two cases of TTM had been reported (in 1994 and 1995)^{5,19} in which the donors had a malaria history, but had not lived in a malarious area within three years (thus satisfying eligibility criteria). Risk could not be quantified, but as two cases had occurred in relatively close succession, future cases could not be ruled out. These cases occurred during the transition of the blood programme from the Canadian Red Cross Blood Transfusion Society to two new blood services: Canadian Blood Services and Héma-Québec. The review of policy was initiated by the regulator. The Krever Commission of Inquiry into human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infection (1997) in the blood supply was in progress, attracting intense public scrutiny of blood safety (not specifically TTM), thus leading to high political and regulatory influence. As shown in Table III, political/regulatory concern was the main decision driver. The number of donors deferred for malaria residence (3-year deferral) was considered, presuming fewer would have a known history of malaria. Although social concern specific to TTM was low, public expectations and ethical concerns were considered. A licensed assay was not available; therefore the options were either no action or additional deferral for malaria history. Because there was a risk not fully addressed by the policy, although likely very small, and the impact on supply was anticipated to be modest, a permanent deferral was implemented. There has been one further case of TTM in 1997 from a donor who met the new criteria.

United States of America

Since 1994, USA blood collectors have followed the USA Food and Drug Administration (FDA)

recommended donor deferral algorithm: 12-month deferral for travel to a risk area, 3-year deferral for prior residence in a malarious area and for malaria history. About half the cases of TTM in the USA had a malaria history, thus some blood collectors implemented a permanent deferral for malaria history (not required by the FDA). Donor loss due to travel deferrals was high, but no associated TTM cases were reported, prompting malaria policy to be reviewed several times since 2006 (included testing options in 2006 and 2008) by the FDA's Blood Products Advisory Committee (BPAC). The testing option was not pursued after risk assessment data were presented. In 2008, two USA blood organisations also presented data indicating that over 40% of travel deferrals were due to travel to Mexico. It was decided to focus additional risk analysis on the potential to modify criteria for these low-risk Mexican travel deferrals plus further work on testing. In 2009, the FDA sought guidance from the BPAC specifically on a strategy of minimising donor loss from Mexico travel deferrals. Since research studies and FDA risk assessments showed that most Mexico travel was to the lowest risk areas, and that many donors could be regained simply by eliminating the deferral for two Mexican states²⁰⁻²². These recommendations were implemented following the June 2012 FDA Guidance²³. As shown in Table III, the main decision drivers were the impact on donors/sufficiency of the blood supply and operational impact.

Discussion

The Framework applies to a broad range of transfusion policy decisions in different situations³. In this report, we describe decisions of five countries relating to different malaria policies which all pre-date the Framework. Because both drivers and the year of the decision differ, these decision processes are not directly comparable. However, it is possible to determine the extent to which the assessments included those recommended by the Framework.

Both deferral and testing policies rely on obtaining correct answers from donors. Ethical issues relating to unnecessary deferral of safe donors supported the decision to test. Feasibility of testing includes obtaining/sorting samples and fast turnaround of results, although the operational issues varied in the three countries where testing occurs. In France, it could initially be managed as a separate process with a non-automated assay. But as testing volume increased, full integration with the routine process was necessary, similar to England and Australia. Deferral impacts negatively on sufficiency of the blood supply and requires additional donor recruitment. The negative impacts of deferral but high operational feasibility and safety of selective testing had considerable weight on the decisions to be implemented.

The infectious risk of selective testing vs deferral is fundamentally the risk of a false negative result. In France, most infections were known to be *P. falciparum*. By the time England was considering selective testing, there had been many years' experience with the French *P. falciparum*-based assay and there had been no reports of false negatives from any species. When Australia implemented testing, a commercial assay (then Newmarket malaria antibody EIA, now Trinity Biotech Captia™ Total Malaria Antibody EIA) based on both *P. falciparum* and *P. vivax* antigens was available and being used in England. In all three countries, risk assessment was key to the decision.

The Framework would require that safety, operational feasibility and budget impact be considered for the selective testing decision, and all three countries did so. Trade-offs were to accept high operational impact and cost. As suggested by the Framework, donor loss with the deferral-only option was formally assessed and cost comparison of deferral vs testing considered. The Framework also recommends that contextual factors such as social concern and political/regulatory concern be assessed. These were adequately recognised at the time, and did not exert a strong influence on the ultimate decision. The blood operators determined that the availability of rare red cell phenotypes and reduction in travel-based red cell losses (plus increased safety in France) justified the cost. The decision-making processes, therefore, included the assessments recommended by the Framework.

Evaluation of donor criteria decisions shows that decisions were often prompted by a TTM case (or "near miss") as seen in the examples from France, Canada, Australia⁵, and also in England²⁴. With rather limited tolerance for risk, delaying action to assess the frequency of TTM is generally unacceptable. Because there are ethical concerns and public expectation to act in the face of risk, a clear and timely decision is required. Due to both the rarity of such TTM cases and insufficient public health data, invariably risk cannot be accurately quantified, requiring a subjective assessment as to whether more cases would be seen without a policy change. The occurrence of a TTM case shifts thinking from a theoretical risk to an actual risk, and the lack of clarity as to the true risk gives contextual factors such as social and political concerns greater weight. The concern of reputational risk on recipients' sense of safety is recognised as a legitimate concern in the Framework, and this to some degree influenced many decisions described in this report. Stakeholder consultation is recommended by the Framework and is an ideal way to assess social concerns, although it is unclear if greater attention to these would have had any impact. Relationships and channels of communication built over time can create

a forum for effective engagement and risk communication even on complex operational and scientific issues, and can sometimes modify stakeholder expectations.

The Framework acknowledges that different operating environments can result in different assessment outcomes on the same topic. In Australia, two "near misses" in close succession identified a previously unknown *P. vivax* risk. Geographic proximity of PNG, public awareness of travel options, as well as reputational concern were important considerations. This prompted a 3-year testing exclusion period for PNG travel. A similar case in England in 2011 (*P. vivax* acquired through travel to India) prompted no policy change. In the USA, the decision by the FDA not to require permanent deferral of donors with a history of malaria sets it apart from the other countries in this report. The deferral would be expected to prevent one TTM case every 2-3 years. However, the policy review was in the context of reducing deferral of safe donors for travel to Mexico. Donor gains from a less restrictive travel policy would be counteracted by permanent deferral for history of malaria. Because the FDA sets minimum deferral criteria, this does not necessarily imply that a permanent deferral was determined unbeneficial. Blood centres in the USA can exceed the criteria in the Guidance for Industry, and some USA centres have elected to do so.

The Framework requires some form of health economic assessment to be considered. This would take into account, for example, the costs of implementing assays with the benefits of reduced donor deferral. Following the recognition that HIV was being transfusion-transmitted, the predominant view was that any intervention that improved safety slightly, even if only in theory, should be implemented^{25,26}. An extended period of safe blood, declining red cell demand, and an overall squeeze on health care expenditure has encouraged the allocation of resources proportional to risk. Cost was not a main driver in decisions in this report, but was considered where appropriate. Health economics may be a more influential driver now and in the future.

Our analysis has several limitations. Our rating of levels of concern was based on tools from the Framework, but nevertheless some subjectivity was required. Because this was a retrospective analysis, it is possible that some assessments and information considered in the decisions were not identified, although for the most part, an investigator from the country was present at the time of the decision. Finally, it was not possible for investigators to provide copies of the assessments considered in their country; therefore, we could not compare the content of the assessments.

Conclusions

Information and assessments in the decisions analysed in this report were largely consistent with those recommended by the Framework. When data supported quantified risk assessment, safety and operational feasibility tended to have the greatest weight in decisions. When risk is not well defined, contextual factors such as social and political concern have greater weight. Elements of the Framework that were of lesser importance include health economics assessment and stakeholder consultation. However, current public expectation of openness and accountability make these increasingly a requirement in blood safety decisions. By providing a common reference that ensures that each element will be considered for each decision, the ABO Risk Based Decision-Making Framework is a consistent pathway to navigate complex policy decisions. It appears that in recent years many countries are making decisions that strive less for zero risk and more for a reasonable balance of operational feasibility, cost, social responsibility, and risk mitigation. For example, the deferral for men who have sex with men has been reduced to 12 months or less in a number of countries²⁷, and some countries are (or are considering) testing only first-time donors for human T-cell leukaemia-lymphoma virus rather than all donors²⁸. Our retrospective analysis of malaria risk mitigation decisions suggests that the change in policy is not due to lack of a reasoned approach or framework for decision making in the past. It is likely more a reflection of changing operating environments in which efficiency and changing societal expectations are drivers.

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Authorship contributions

All Authors have contributed to the design, acquisition or analysis, and all contributed to interpretation of data. SFO'B was study leader. SW provided expertise on the Framework and analysis. GL and DAL assisted with the design and data from Canada and the USA, respectively. Data were provided by CF, PG and JP from France, by ADK and KD from England, by CRS from Australia, and by WRS from the USA. SFO'B drafted the manuscript and all Authors revised it critically. All Authors approved the submitted version.

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