Editorial Commentary

Changing donor policy for men who have sex with men: it's all about the data

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Comment on: Pillonel J, Pilat C, Tiberghien P, *et al.* The evolving blood donor deferral policy for men who have sex with men: impact on the risk of HIV transmission by transfusion in France. Transfusion 2020;60:525-34.

Received: 13 March 2020; Accepted: 30 March 2020; Published: 30 June 2020.

doi: 10.21037/aob.2020.03.03

View this article at: http://dx.doi.org/10.21037/aob.2020.03.03

In the 1980's most blood services implemented a deferral for men who have sex with men (MSM) to reduce the risk of HIV infection to recipients. Most kept this as a permanent deferral until fairly recently. In 2000 Australia consolidated regional blood centres with variable MSM deferral periods into one blood service, and standardized their criteria to a national 1 year deferral (1). A number of years later, numerous other countries re-assessed their deferral and shortened to 1 year. Further to that a few have reduced their deferral period further. For example, England and Canada now have a 3-month deferral, the Netherlands and France have 4 months.

Why the change? Many factors have contributed (2). HIV testing has improved with the implementation of nucleic acid testing (NAT), greatly reducing the window period of infection. Advanced computer systems have reduced the risk of erroneously releasing a positive unit into inventory. Societal expectations lean towards a more inclusive sentiment and sensitivity to discrimination. Younger generations have no memory the early 1980's when there was fear of certain death from AIDS/HIV and know HIV as an infection that can be managed with medication. Gay rights activists have been vocal about perceived injustice. Court challenges to the deferral have occurred. Politicians have advocated for abolishing the deferral altogether or replacing it with other, more specific questions. Many blood services have engaged with recipients and improved trust in the safety of the blood system.

But let us not forget that trust must be earned. Safety of the blood system is paramount. HIV infection is still disproportionately high in MSM in most western countries (3). Much as blood services should not be unnecessarily restrictive, donor criteria should be based on clear evidence that recipients will receive the safest blood possible (4). Paradoxically, the existence of a permanent deferral for MSM has hampered such evidence because there were no MSM donors for whom HIV prevalence and incidence statistics could be gathered. These data are essential for estimating residual risk. One might think that with over 40 years since the emergence of AIDS/HIV suitable data would be plentiful. However, public health data on community cases collect broad categories of risk factors such as MSM, which lumps all MSM into one high risk category. Blood donors are a low risk subset of the population having met numerous screening criteria. They are community minded individuals who believe their blood is safe for a recipient. Most community studies in gay and bisexual men's health focus on populations at higher risk of HIV. Thus data on HIV incidence in men without any obvious risk behavior other than a male partner is remarkably limited. Models for the residual risk of HIV have traditionally overestimated the risk (5). This is mainly because assumptions had to be made based on these data about incidence among MSM who would donate.

Although criticized for not moving fast enough, incremental reductions in deferral period have generated the most convincing evidence to assess safety. In Australia, Seed *et al.* (1) reported that HIV rates were unchanged after

implementing a 1-year deferral. Similarly when England switched to a 1-year deferral no change was observed, nor when a 3-month deferral was implemented (6). In Canada, no change has been observed when switching to a 5-year, then a 1-year deferral (7). Accumulating data also suggest no change after a 3-month deferral. Importantly, many countries shortening their deferral periods have also carried out anonymous donor surveys to measure non-compliance with the criteria after the change (7-9). These indicate that MSM donating while ineligible is quite rare, thus dispelling initial concerns that more MSM would donate while ineligible if the deferral period were shorter.

For the past 5 years, a team of risk modelers associated with the International Society for Blood Transfusion (ISBT) Transfusion-Transmitted Infectious Diseases Working Party have met. The goal was initially to develop an optimized model for estimating residual risk with time deferrals (10). It was then applied to estimate risk of reducing from 12- to 3-month deferral in Canada (11). Data necessary for the model such as HIV incidence in MSM donors and numbers of MSM donating by time since last male sexual contact were generated from blood donor surveillance and donor surveys post-implementation of reduced deferral periods. These data were applied to scenario based models indicating very low risk from shortening to a 3-month deferral.

There is now interest in moving away from a time deferral to permit low risk MSM to donate blood (12). This is currently done in Italy and Spain although not directly applicable to other jurisdictions due to differences in HIV epidemiology and screening practices. In Canada, in 2017 the government funded an ambitious research program to gather data necessary to consider a change on policy (13,14). More than 15 studies were funded, many involving existing community MSM studies that would recruit participants more representative of donors. In the United Kingdom the FAIR (For the Assessment of Individualized Risk) Steering Group was initiated to explore if a more individualized approach to blood donor selection policy can be safely and practically introduced (15). France has become a country to watch. Theirs was the first national blood program to permit MSM to donate apheresis plasma for transfusion without a time deferral. Data will be forthcoming. There is now a similar program in Israel (16). In France a quarantine step was already in place for apheresis plasma. Products were not released until the donor had returned after the window period and was re-tested, providing an extra safeguard. There is also a criterion for all donors (whole blood and apheresis) to not have more than one sexual partner in the last 4 months.

To consider ways to make whole blood donation open for more MSM in France, Pillonel and colleagues recently applied mathematical models to estimate the baseline residual risk of HIV and compare it with two potential policies: reduction of the MSM deferral from 12 to 4 months, and removal of the deferral altogether (17). Two things make this risk assessment stand out: the enhancements to methodology and the data. Risk was estimated using the incidence-window period model. They built on the work of UK modelers (18) and the ISBT modelling group (10) by estimating the residual risk for non-MSM and MSM as separate parts of the model. Uncertainty around the point estimate was estimated using a Bayesian network with a Monte Carlo simulation approach to consider multiple uncertainties.

They were able to utilize data that likely come close to the true input parameters in the model. France has an excellent blood surveillance program in which the blood transfusion service is integrated with the national reference laboratories. HIV incidence was based on an enzyme immunoassay that discriminates between infections of less than 180 days and longer standing infections. This includes first time donors. The numbers of additional MSM for the two scenarios were derived from a donor compliance survey, Complidon, completed after the 12-month deferral was implemented, as well as two MSM community surveys. Incidence among new MSM donors with the 4 months deferral scenario was derived from HIV incidence in MSM with the 12-month deferral (blood donor surveillance data) and the number of new MSM donors. The incidence for MSM with only 1 sexual partner was derived from a community MSM survey. In order to be more reflective of MSM who would donate, the estimated HIV incidence among additional MSM donors expected to donate with no deferral was derived from the ratio of HIV incidence among single partner MSM and all MSM from the survey applied to the overall incidence among MSM in France.

The results indicate very low risk with a 4-month deferral. Although the rate of non-compliance tends to be slightly higher in France compared with other countries such as Australia, Canada and the United Kingdom (7-9), the non-compliance rate does not seem to change with shortening of deferral periods, thus the non-compliant incidence rate is already captured in the baseline residual risk. As 4 months would easily capture any window period infections, and previous shortening of the deferral had

no impact on residual risk the low estimated risk of a 4-month deferral is quite plausible. Further to this, the risk of removing the deferral altogether was also estimated to be very low. Not taken into account is the as yet unclear risk of delayed detection of HIV from donors taking pre-exposure prophylaxis medication (19). Ultimately, the decision was to implement a 4-month deferral with active post-implementation monitoring, after which removal of the deferral will be re-considered. This reflects continued caution in changing this deferral, and that incremental reduction in stringency of deferral permits accrual of new data and accurate risk estimation. And decisions based on the best evidence possible are what patients deserve.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Annals of Blood*. The article did not undergo external peer review.

Conflicts of Interest: The author has completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/aob.2020.03.03). The author has no conflicts of interest to declare.

Ethical Statement: The author is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/aob.2020.03.03
Cite this article as: O'Brien SF. Changing donor policy for men who have sex with men: it's all about the data. Ann Blood 2020;5:16.

