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TITLE: Blood donation among people who inject drugs in Australia: Research supporting policy change

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ABSTRACT

Background and Objectives: Until recently, people in Australia with a history of injection drug use (IDU) were deferred indefinitely from donating blood. Knowledge gaps regarding policy non-compliance and the prevalence of blood donation practices among people who inject drugs (PWID) precluded changes to this policy. We sought to address these gaps and to estimate the additional risk to Australia's blood supply associated with changing the indefinite deferral policy to one or five years since last injecting episode.

Materials and methods: Data on blood donation among PWID were collected from 1,853 interviews across two Australian studies of PWID conducted during 2015/16. Mathematical modelling was used to estimate the additional risk of hepatitis C (HCV)-infected window period collections as a result of changing the deferral policy.

Results: Very few (2-4%) study participants reported ever donating blood after ≥1 IDU episode. Changing the deferral policy from indefinite to one or five years was estimated to result in an additional 0.00000070 (95%CI: 0.00000033-0.00000165) or 0.00000020 (95%CI: 0.00000008-0.00000041) HCV-positive window period collections per year, respectively.

Conclusion: Changing Australia's indefinite deferral period to one or five years since last injecting episode poses a negligible increase in the risk of HCV-infected window period collections from blood donors with a history of IDU. Our results informed a successful submission to the Australian regulator to change the deferral period from indefinite to five years since last injecting episode, a policy which came into effect in September, 2018.

Keywords: blood donation; transfusion-transmissible infections; injecting drug use; non-compliance; mathematical modelling

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INTRODUCTION

To reduce the risk of infectious disease transmission, the Australian Red Cross Lifeblood (formerly the Australian Red Cross Blood Service; hereafter: 'Lifeblood') maintains a policy of 'deferral' of potential blood donors on the basis of 'group' risk. In this context, and consistent with standard practice worldwide, potential Australian blood donors were, until September 2018, deferred indefinitely if they reported a history of IDU. The rationale for deferral for injection drug use (IDU) is that it is a key transmission route of some transfusion-transmissible infections (TTIs), particularly hepatitis C virus (HCV) [1]. Further, because TTIs can be sexually transmitted [2], potential donors are deferred for 12 months if they report having engaged in recent (past-year) sexual activity with someone who may have injected drugs.

The indefinite exclusion policy for IDU in Australia had been unchanged since its inception in the early 1980s in compliance with the requirements of the Council of Europe (CoE) Guide to the Preparation, Use and Quality Assurance of Blood Components. In addition to the CoE Guide, Lifeblood is required to comply with the Therapeutic Goods Order No. 88 (TGO88) – Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products. This standard states that a donor who has ever injected, or been injected with, any drug for a non-medical reason is ineligible to donate for a minimum of five years from last injection.

Donors who meet the eligibility criteria and satisfactorily complete and sign a comprehensive donor questionnaire form are tested for the following TTIs: HIV, HCV, hepatitis B virus (HBV), human T-lymphotropic virus (HTLV), and syphilis [3]. Despite using a combination of serological (antigen/antibody) screening and nucleic acid testing (NAT) for HIV, HCV and HBV to optimise detection sensitivity [4, 5], there remains a 'window period' during which infections are too recent to be detected. For example, the current window period estimate for detecting HCV by individual donation NAT is approximately three days, compared to six days for HIV and 16 days for HBV [6]. Lifeblood uses these window period estimates to model the 'residual risk' of viral transmission to patients, with the current risk for HIV, HCV, HTLV and HBV all considered 'negligible'; i.e., less than one in one million per unit transfused [6].

To be effective, donors must correctly interpret the deferral screening questions on the donor questionnaire form and provide considered and honest answers [7]. Failure to disclose information at the time of a donation that would have resulted in deferral is termed 'non-compliance'; this poses a TTI transmission risk because of the possibility a non-compliant donor is in the testing window

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period at the time of donation and therefore evades detection. While non-compliance to the IDU deferral has not been widely studied, an online Blood Service survey conducted in 2012/2013 of 30,274 TTI-test negative donors who donated within the prior six weeks identified 0.36% of respondents who reported lifetime IDU (i.e., were non-compliant). This finding is mid-range compared to non-compliance rates reported for Canada (0.15%) [8] and the United States (0.51%) [9]. A slightly larger percentage (0.54%) reported engaging in sexual activity with someone who had ever injected drugs during the 12 months pre-donation [10].

In 2014, Lifeblood commissioned an independent review of the ongoing appropriateness of excluding potential donors who had ever engaged in IDU or in recent sexual activity with PWID. The goal was to recommend how exclusions or deferrals from donation should be structured going forward based on currently available evidence [11]. Considering the epidemiology of IDU in Australia and the sensitivity of tests used by Lifeblood to detect TTIs, the Expert Review Committee (henceforth: 'the Committee') noted that the current deferral policy of indefinite exclusion was probably excessive. Whilst the Committee considered it was reasonable to reduce the deferral period to five years since last injecting episode, they were ultimately unable to provide such a recommendation due to key knowledge gaps, including a lack of information about the prevalence of blood donation practices among PWID.

A series of projects were undertaken to address these knowledge gaps. First, data were collected to estimate the prevalence of lifetime blood donation practices among Australian PWID, including the temporal proximity of most recent injecting occasion to last blood donation. Second, mathematical modelling estimated the additional risk to Australia's blood supply associated with changing Lifeblood's IDU-related deferral period from indefinite to either one or five years since last injecting episode. In consideration of the high prevalence of HCV among Australian PWID, and given that IDU is the most common mode of HCV exposure nationwide [12], the modelling focused on the additional risk associated with HCV-infected window period collections from this population.

METHOD

This study was commissioned to generate evidence to inform the Committee's consideration of Lifeblood's donor criteria relating to IDU. A corresponding systematic literature review was also undertaken, exploring interventions used to increase blood donor compliance with deferral criteria (unpublished).

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During 2015 and 2016, data on blood donation practices among PWID were collected from two ongoing Australian studies:

1. The Illicit Drug Reporting System (IDRS); an annual, national, serial cross-sectional survey of PWID (N≈900/year) conducted in the capital city of every Australian jurisdiction [13, 14].
2. The Melbourne Injecting Drug User Cohort Study (formerly 'MIX', currently 'SuperMIX') [15]. SuperMIX is the largest community-based prospective cohort study of PWID in Australia (N>700). Recruitment commenced in 2008.

Both studies' methodologies and findings have been described in detail elsewhere [13, 15].

Sample

IDRS: Eligible IDRS participants were aged ≥16 years in all cities other than Melbourne where participants were aged ≥18 years, had injected at least monthly during the six months preceding interview, and resided in the capital city in which they were recruited/interviewed for at least 12 months. Recruitment generally occurs mid-year via targeted measures [e.g., through treatment agencies and needle and syringe programs (NSPs)]. The IDRS sample sizes in each jurisdiction reflect predetermined quotas.

SuperMIX: Eligible participants for MIX were Melbourne residents who had injected methamphetamine or heroin at least monthly during the past six months, were able and willing to provide a valid Medicare (Australia's universal healthcare system) card number to be used for data linkage, and were aged between 18 and 30 years (the age restriction was relaxed following slower-than-expected recruitment, resulting in a baseline sample comprising 38 participants over the age of 31 years [15]).

Participants in both studies were reimbursed $40 for their time and out-of-pocket expenses. Voluntary informed consent was obtained from all participants prior to data collection.

Questionnaire design and administration

Data were collected for both the IDRS and SuperMIX studies via structured, interviewer-administered surveys conducted face-to-face. Questionnaire data are collected and managed electronically using hand-held electronic tablets programmed with Research Electronic Data Capture (REDCap) software; a secure web-based application designed to support data capture for research studies [16].

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The IDRS and SuperMIX surveys comprise tailored questions and validated items that cover multiple domains, including: key sociodemographics; current/recent drug use and drug use history; drug-related health problems; and, law enforcement-related issues associated with drug use. Both surveys take approximately 30-60 minutes to complete.

Measures

In addition to the standard items specific to IDRS and SuperMIX surveys, brief questions regarding blood donation practices were added to each study's data collection instruments in 2015 and 2016. Participants were required to provide separate consent to complete this subset of questions. Following the provision of consent, participants were asked if they had, 'ever donated blood or been a blood donor?' Those who responded 'yes' to this question were then asked, 'Before you ever donated blood, had you ever injected (drugs)?' Participants who reported having done so were then asked to estimate the amount of time between their most recent injecting episode and subsequent blood donation. If the participant was injecting regularly around the same time as their last blood donation, this period was coded as zero days.

Design and statistical analysis

Aim 1: Blood donation among Australian PWID

Descriptive statistics were calculated to characterise the study samples and investigate outcomes of interest. With respect to NAT window periods for key TTIs (e.g., HBV, HCV and HIV) [6], the percentages of participants who reported donating blood after injecting a drug in $\leq$30 days prior were also ascertained. Given the small numbers of study participants who reported the key outcome of interest (lifetime blood donation post-IDU), and given only minimal significant differences between groups in bivariate analyses (not presented here), multivariable logistic regression analyses were not undertaken to identify factors independently associated with ever donating blood following IDU. All data analyses were conducted using Stata Version 13 (Statacorp LP, Texas, USA), with a significance level of $p<0.05$. All reported percentages are rounded to the nearest whole number.

Aim 2: Mathematical modelling

Lifeblood's estimate for the risk of HCV transmission by transfusion (residual risk) was derived from the median value of three published models [17]. Based on combined 2013 and 2014 calendar year donation HCV testing data, Lifeblood's estimated HCV residual risk was 1 in 11,524,000 per unit transfused (1 in 2,883,000 – 1 in 17,180,000) (Blood Service, unpublished).

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The potential additional risk of HCV-infected blood being donated if Lifeblood changed its deferral period from indefinite exclusion of anyone who has ever injected drugs, to a period of one year or five years since last injecting episode was calculated taking into account the current tolerated residual risk. It was assumed the additional risk, as opposed to existing risk (since non-disclosure is already possible), would be a result of PWID who (1) stopped injecting consistent with the one- or five-year policy (the amended deferral period), (2) donated blood (allowed as a consequence of the new policy); and (3) then relapsed to IDU but continued to donate blood (i.e., were non-compliant with the new deferral policy). As well, for this behaviour to result in HCV-infected blood being donated, this subgroup of individuals would have to become infected with HCV and donate blood within the following 2.6 days (the window period for HCV). This additional risk was calculated via the deterministic model:

Additional risk = estimated number of active PWID who do not currently have HCV
× probability of one- or five-year cessation
× uptake of blood donation among general population
× probability of relapse after one or five years
× non-compliance with deferral policy
× Australian blood donor average number of yearly donations
× yearly probability of PWID becoming infected with HCV
× HCV window period
× yearly risk of a PWID donating during the window period.

Parameters and sources are provided in Table 1.

Additional modelling assessed the impact of uncertainty in some of the parameters. Specifically, the Committee acknowledged that if the deferral period were to change to one or five years post-last injecting episode, the potential uptake of blood donation among newly eligible prospective donors would be unknown, but likely higher than the 0.57% rate of blood donation uptake among the general population (Table 1). There was also inherent uncertainty in the non-compliance rate used. Consequently, a 'worst case' pessimistic scenario was modelled to generate the more conservative estimate of the risk associated with the proposed changes to the deferral period. This approach estimated that the uptake of blood donation among newly eligible prospective donors was 15% – a conservative figure of approximately 3x the baseline age-eligible Australian donation rate [18] –

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and the non-compliance rate was 4.7% (the upper limit of the weighted non-compliance estimate from Aim 1 of the current study).

Ethical approval

MIX (now SuperMIX) was initially approved by the Victorian Department of Human Services (now Department of Health and Human Services) and Monash University Human Research Ethics Committees. The organisations responsible for IDRS data collection obtained approval to conduct the study from their applicable jurisdictional Ethics Committees.

[Table 1 about here]

RESULTS

Sample characteristics

Seven hundred and forty-three (84%) of 888 participants in the 2015 IDRS responded to the blood donation questions (Table 2). A similar number of participants (n=756; 86%) responded to the blood donation questions for the 2016 IDRS (N=877). Three hundred and fifty-four (99.72%) SuperMIX participants responded to the blood donation questions during the 2015/16 study recruitment period.

Briefly regarding the key sociodemographic characteristics of the study participants, each sample included only a minority of participants who identified as female (31-38%) or Indigenous Australian (5-19%), or who were employed at the time of interview (10-24%) (Table 2). IDRS participants were typically older than their SuperMIX counterparts (consistent with the latter study's sampling of younger PWID). Less than half (43-45%) of each IDRS sample reported currently being prescribed opioid substitution therapy (e.g., methadone, Suboxone®), compared to 57% of SuperMIX participants.

[Table 2 about here]

Blood donation practices

As listed in Table 2, a minority of each sample (9-15%) reported having ever donated blood. An even smaller percentage of participants (2-4%) reported having ever donated blood following at least one episode of IDU. Given the total number of participants from each study who reported pre-donation IDU (n=69), and the overall total sample size for the three studies combined (N=1,853),

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the probability of non-disclosure of engaging in IDU prior to blood donation was calculated to be 3.7% (95% Cl: 2.92 - 4.68%).

The minimum amount of time SuperMIX participants (n=6) reported donating blood after their most recent injecting occasion was seven days, with a median time of 540 days. In comparison, among IDRS participants who reported at least one episode pre-blood donation in 2015 (n=31) and 2016 (n=32), the median number of days between IDU and blood donation was 10.5 and 30 days, respectively. As noted previously, reporting a period of zero days indicated that participants (n=6 IDRS participants in 2015 and n=4 in 2016) were injecting regularly around the time they last donated blood. Overall, most participants reported donating more than a month following their most recent injecting episode, which is longer than the NAT window periods for key TTIs such as HBV, HCV and HIV (15, 2.6 and 5.9 days, respectively).

Mathematical modelling

Additional estimated risk from changing to a one- or five-year deferral period

The mathematical modelling results are presented in Table 3. If the deferral policy was changed from indefinite to one year, the additional number of HCV window period collections was estimated to be 0.00000070 per year (95% CI: 0.00000033 – 0.00000165), or one infection every 1.4 million years. If the deferral policy was changed from indefinite to five years, the additional number of window period collections was estimated to be 0.00000020 per year (95% CI: 0.00000008 – 0.00000041), or one infection every 5.6 million years. The additional risk presented by a one-year deferral period is 100,000 times smaller than the current tolerated risk. The additional risk of a five-year deferral period is even lower; about one million times smaller than the current tolerated risk. Confidence intervals were calculated by uniformly sampling the uncertainty ranges of each of the parameters shown in Table 1. The first and final 2.5% of samples were removed from the range to give 95% confidence intervals. Donation uptake and donation yearly average were considered as constants as these parameters came directly from the Australian Blood Bank and were exact figures.

Pessimistic scenario

The additional, more conservative modelling estimated that the increase in the number of HCV-infected window period collections from a PWID blood donor was 0.0000409 per year. This corresponds to one additional HCV infected donation every 43,945 years.

[Table 3 about here]

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DISCUSSION

We used data from two serial cross-sectional samples and one prospective cohort involving PWID in Australia to inform a mathematical model of the impact of changing the deferral period for blood donation in PWID from indefinite to one or five years. To the best of our knowledge, our study uniquely investigates lifetime experience of blood donation among active PWID, including the prevalence of lifetime blood donation practices and IDU prior to blood donations, and the risk this might pose to a country's blood supply with regard to TTIs.

Only a minority of PWID in the studies reported ever donating blood (range: 9-15%). To provide some context, a recent study examining data from the Sax Institute's '45 and Up Study' found that, among a sample of older (>44 years) residents of New South Wales (Australia's most populous State), around 48% of 142,503 participants reported ever donating blood [19].

Our modelling, informed by the above data, suggests there is negligible potential additional risk to the blood supply if the IDU-related deferral period was changed from an indefinite exclusion to one or five years post-last injecting occasion. The additional risk would be approximately one HCV-infected blood donation every 1.4 million years or 5.6 million years respectively. Even in the pessimistic model – the most conservative estimate –the additional risk was estimated to be one HCV-infected blood donation every 43,945 years. It is reasonable to view these risks as negligible, since they are less than 100,000 times lower that the risk currently tolerated by Lifeblood.

It is possible that our modelling has overestimated the additional risk as a result of the effective scale up of HCV direct-acting antiviral therapies in Australia. As more Australian PWID are treated, the population incidence of HCV is predicted to decrease due to a declining viremic pool [20, 21]. As blood donors are drawn from the general population and the HCV residual risk directly correlates with HCV incidence, any decline in incidence would further reduce HCV residual risk.

Importantly, a change in deferral duration for PWID to one or five years since last injecting episode is expected to expand the eligible donor base, resulting in a positive impact on blood product sufficiency. The exact impact of such a change in terms of newly-eligible donors attending is difficult to quantify because the number of currently ineligible PWID who appropriately self-defer is unknown. However, we generated a rough estimate of the number of newly eligible donors as a result of the implementation of a one-year deferral since last injecting episode in consideration of the following points:

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- Only a small minority of the Australian community inject drugs; findings from the 2016 National Drug Strategy Household Survey indicated that an estimated ~1.5% of the general population had ever injected drugs, with 0.3% engaging in recent (past-year) use (a figure that has remained stable-to-decreasing over the last two decades) [22];
- Australia's Estimated Resident Population aged 18-80 years (as per Blood Service eligibility criteria) was 18,548,083 in June, 2018 [23];
- Of this total, around 1.2% would be newly eligible with a change to the IDU-related deferral criteria (1.5% with lifetime history minus 0.3% who had injected in the past year), equating to approximately 222,577 people;
- Assuming that 25% of this group is ineligible to donate for other reasons, around 166,933 Australians with a history of IDU would become eligible to donate blood or blood products if the IDU-related deferral period changed from indefinite to 12 months since last injecting episode.

Translation to policy

Overall, our findings suggest that changing from an indefinite to either a one- or five-year deferral since last injecting episode poses a negligible increase in the risk of HCV-infected window period blood donations. While the Committee recognised that a one-year deferral was scientifically reasonable, they decided to recommend a five-year deferral policy for a combination of reasons: a) the absence of an immediate blood inventory supply risk; b) that a five-year deferral would meet the requirements of TGO88; and, c) that a five-year deferral would enable Lifeblood to evaluate any operational impact arising from an increase in undiagnosed prevalent HCV infections in blood donors as a consequence of the policy change. The Committee also recommended that Lifeblood conduct post-implementation monitoring to assess any impact of the change on the rate of window period infections. The outcome of such monitoring may indicate that a further reduction in the deferral period from five years to one year is warranted. This recommendation was documented in a formal report subsequently provided to Lifeblood. After due consideration and being satisfied that the recommended minimum five-year deferral provided an appropriate safety margin, Lifeblood sought (and subsequently received) an exemption to the CoE standard requiring indefinite deferral, and the five-year deferral for IDU was implemented by Lifeblood effective September, 2018. To our knowledge, only one other country (Japan) currently has a temporary deferral (six months since last injecting episode), while the UK Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) have recommended a change to a one-year deferral, with implementation pending legal changes [24].

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Limitations

The Expert Review Committee, when deliberating the evidence, also considered the potential limitations of the available data. The self-report nature of data collection for IDRS and SuperMIX meant that the findings were subject to recall and social desirability biases; for example, donors may not have accurately remembered the period between their most recent injecting episode and subsequent blood donation. The reliance on service-based (i.e., targeted) sampling for the IDRS, and a focus on younger (≤30 years) PWID for SuperMIX, means these samples were likely not representative of Australia's broader injecting population, particularly PWID residing/ staying in non-metropolitan areas. Given that data for this study were collected during SuperMIX's follow-up period, the characteristics of this study's participants (i.e., those retained in SuperMIX) differed to those of the broader SuperMIX sample in some instances (e.g., 34% of the sample were currently prescribed opioid substitution at baseline, compared to 57% of participants in our study). Further, both studies recruited active PWID and were therefore possibly not representative of former PWID.

There is also the possibility that some individuals participated in more than one of the studies during 2015/16 and therefore answered the blood donation questions multiple times. This could result in uncertainty in the prevalence estimate of lifetime blood donation practices among study participants. Additionally, the model applied the non-compliance rate of 'ever' donating blood to a yearly risk, which conservatively extrapolates the non-compliance risk. The model assumes that PWID who become eligible following cessation of IDU will donate at the same rate as the general population – this may be an overestimate. Finally, a fundamental assumption of modelling the impact of a policy change is a 'steady state'; i.e., there are no significant changes in the key input parameters unrelated to the policy change. Overall, the methodology and resultant parameters used in the model are expected to overestimate the calculated risk.

CONCLUSION

Data from two serial cross-sectional samples and a prospective cohort study suggest that only a small minority of Australian PWID have ever donated blood following IDU. Mathematical modelling conservatively leveraging this data indicated that changing the IDU deferral period from lifetime to either one or five years since last injecting episode poses a negligible increase in the risk of HCV-infected window period collections from PWID blood donors. These data were pivotal for a subsequent successful Blood Service submission to the Australian blood regulator (Therapeutic Goods Administration) to change the indefinite deferral period to five years since last injecting episode. The policy change is predicted to lead to a positive impact on the Australian donor base. Post-implementation evaluation on the residual risk and operational impact, including if a

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significant increase in prevalent HCV infections in first-time blood donors occurs, will determine if the deferral period should be further reduced. Based on our calculated risk, a one-year deferral is an acceptable deferral period.

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Each author's individual contributions to the work described in the manuscript are listed below:

- BQ was involved in the overall study conception and design, data collection and analysis, and in preparing, revising and submitting the manuscript.
- RP was involved in the overall study conception and design, data analysis, and in preparing and revising the manuscript.
- JC was involved in the overall study conception and design, and in preparing and revising the manuscript.
- CS was involved in the overall study conception and design, and in preparing and revising the manuscript.
- NS was involved in the overall study conception and design, data analysis, and in preparing and revising the manuscript
- VH was involved in the overall study conception and design, and in preparing and revising the manuscript.
- PD was involved in the overall study conception and design, data collection and analysis, and in preparing and revising the manuscript
- DW was involved in the overall study conception and design, data analysis, and in preparing and revising the manuscript.
- LM, AT, MF, MHa, SC, JP, GK and MHe were involved in the overall study conception and design, and in preparing and revising the manuscript.

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Table 1: Mathematical models: Data used

Parameter	Best estimate	Reference/source
Annual incidence of HCV among PWID	Scenario 1: 11.2 per 100 person years [95% Confidence Interval (CI): 8.9-14.0)]	[25]
Probability of non-disclosure of IDU	3.7% (95% CI: 2.92-4.68%)	Current study; Percentage of IDRS and SuperMIX respondents who reported having ever donated blood after injecting drugs at least once
Window period for HCV testing	2.6 days (95% CI:2.4-2.9 days)	[26, 27]
Estimated current PWID in Australia	93,000 (95% CI: 68,000-118,000)	[28]
Estimated prevalence of HCV among Australian PWID	50% (95% CI: 40-60%)	[25]
Yearly risk of a PWID donating blood in the window period	24.6% (95% CI: 14.0-40.2%)	Current study; Proportion of non-compliant donors who donated during the HCV window period following most recent drug injecting occasion
Probability of one-year cessation	5.4% (95% CI:4.3-6.7%) per year	[29]
Probability of five-year cessation	4.4% (95% CI: 4.0-5.1%) per year	[30]
Probability of relapse in one year	0.4% (95% CI; 0.3-0.4%)	An estimate for this was unavailable; a proxy was generated based on the five-year probability, assuming that the annual risk of relapse applied independently to each year. Specifically: $1 - p = (1 - p_{annual})^5$ where p is probability of relapse in five years

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Parameter	Best estimate	Reference/source
		(below) and p_{annual} is the annual probability (to be determined).
Probability of relapse in five years	0.6% (95% CI0.5-0.6%)	[31]
Uptake of blood donation among general population	0.57% (89,738/15,730,000) 89,738 new donors in 2015 15,730,000 people aged 15-64 years	[32, 33]
Average yearly number of whole blood donations among Australian blood donors	1.8	Dr Veronica Hoad, Australian Red Cross Blood Service (unpublished)
Estimated residual risk of HCV	1 in 11,524,000 per unit transfused (1 in 2,883,000 – 1 in 17,180,000)	Blood Service, unpublished

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Table 2: Sociodemographic characteristics and self-reported blood donation practices among IDRS and SuperMIX study participants, 2015/16, n (%)

Sociodemographic characteristics	IDRS 2015 N=743	IDRS 2016 N=756	SuperMIX 2015/16 N=354
Female	250 (34)	236 (31)	135 (38)
Age in years, median (range)	43 (17-71)	43 (19-72)	34 (23-55)
Aboriginal and/or Torres Strait Islander	140 (19)	132 (17)	17 (5)
Main language: English	732 (99)	742 (98)	304 (86)
Employed	89 (12)[a]	75 (10)	109 (24)
Currently on opioid substitution therapy	319 (43)	342 (45)	200 (57)
Ever incarcerated	406 (55)	411 (54)	207 (58)
Blood donation variables			
Ever donated blood (Yes)	112 (15)	94 (12)	24 (9)
Ever donated blood post-IDU (Y)	31 (4)	32 (4)	6 (2)
Num. days donated after most recent injection, median (range)	10.5 (0-1,825)	30 (0-2,190)	540 (7-2,920)
Donated $\leq$30 days since most recent IDU occasion (Y)[b]	16 (2)[c]	16 (2)[c]	1 (<1)

[a]Missing data for 13 respondents

[b]With respect to current NAT window periods for HBV (15.1 days), HCV (2.6 days) and HIV (5.9 days)

[c]Missing data for four respondents

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Table 3: Mathematical modelling results*: Additional potential risk attributable to proposed changes to the Blood Service's IDU*-related deferral criteria

	One-year deferral	**Five-year deferral**
Additional annual number of window period HCV-infected collections from a blood donor with IDU history	0.00000070 (95% CI: 0.00000033 – 0.00000165)	0.00000020 (95% CI: 0.00000008 – 0.00000041)
Total residual risk (per unit transferred)	1 in 11,523,929	1 in 11,523,981
% increase in risk	0.000006	0.000002

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