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Successful Implementation of an Increased Viral Risk Donor Waiting List for Preconsented Kidney Transplant Candidates in Victoria, Australia

Darren Lee, PhD,[1,2] Indra Gramnea, MN,[3] Nina Seng, MN,[3] Meaghan Bruns, PGDipNP,[3] Fiona Hudson, BAppSci,[4] Rohit D'Costa, MBBS,[3,5] Leanne McEvoy, GradDip,[3] Joe Sasadeusz, PhD,[6] Michael J. O'Leary, MD,[7] Gopal Basu, DM,[8] Joshua Y. Kausman, PhD,[9,10,11] Rosemary Masterson, PhD,[12,13] Kathy Paizis, PhD,[2] John Kanellis, PhD,[14,15] Peter D. Hughes, PhD,[12,13] David J. Goodman, PhD,[16] and John B. Whitlam, PhD[2,13]

Background. Increased viral risk donors (IVRDs) with increased risk behaviors for blood-borne virus infection and negative nucleic acid testing have a low absolute risk of "window period" infection. Utilization and allocation of IVRD organs differ between jurisdictions. **Methods.** We examined the characteristics and utilization of deceased donor IVRD kidneys and recipient outcomes within a 2-y period (July 31, 2018–July 31, 2020) postimplementation of a new opt-in allocation pathway for preconsented recipients in Victoria, Australia. **Results.** Fifty-six kidneys from 31 IVRDs were utilized, comprising 13% of donors. Preconsent rate to accept IVRD kidneys increased to 41% of the waitlist in the 2 y postimplementation, and IVRDs having no kidneys utilized reduced to 0%. Compared with non-IVRD kidneys, kidney offer declines >10 per donor were less likely from IVRDs (3% vs 19%; $P < 0.05$). IVRDs were younger (median age 36 [IQR 30–44] vs 51 [35–60] y; $P < 0.0001$), with lower kidney donor profile index (25% [13–40%] vs 57% [29–75%]; $P < 0.0001$), and less hypertension (0% vs 22%; $P < 0.01$). Estimated glomerular filtration rate 3 mo post-transplant was superior ($P < 0.01$). Injecting drug use (61%) was the most common increased risk behavior. 29% of IVRDs were hepatitis C antibody positive but nucleic acid testing negative. No active infection was detected in any recipient post-transplant. **Conclusions.** The described opt-in system permits efficient allocation and utilization of kidneys from IVRDs, with superior quality and graft function. Education is crucial to facilitate informed consent and equity of access to this donor pool.

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The number of people awaiting deceased donor kidney transplantation continues to exceed the availability of kidneys worldwide. Organs from increased viral risk donors (IVRDs) with increased risk behaviors for blood-borne virus (BBV) infection have historically been under-utilized. With the introduction of universal prospective nucleic acid testing (NAT) for IVRDs, the risk of "window period" infection

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[1] Department of Renal Medicine, Eastern Health Clinical School, Monash University, Box Hill, Australia.

[2] Department of Nephrology, Austin Health, Heidelberg, Australia.

[3] DonateLife Victoria, Carlton, Australia.

[4] Victorian Transplantation and Immunogenetics Service, Australian Red Cross Lifeblood, West Melbourne, Australia.

[5] Intensive Care Unit, Royal Melbourne Hospital, Parkville, Australia.

[6] Department of Infectious Diseases, Royal Melbourne Hospital, Parkville, Australia.

[7] New South Wales Organ & Tissue Donation Service, Sydney, Australia.

[8] Department of Renal Medicine, The Alfred Hospital, Monash University, Melbourne, Australia.

[9] Department of Nephrology, Royal Children's Hospital, Melbourne, Australia.

[10] Murdoch Children's Research Institute, Royal Children's Hospital, Melbourne Australia.

[11] Department of Paediatrics, University of Melbourne, Parkville, Australia.

[12] Department of Nephrology, Royal Melbourne Hospital, Parkville, Australia.

[13] Department of Medicine, University of Melbourne, Parkville, Australia.

[14] Department of Nephrology, Monash Health, Clayton, Australia.

[15] Department of Medicine, Centre for Inflammatory Diseases, Monash University, Clayton, Australia.

[16] Department of Nephrology, St Vincent's Hospital Melbourne, Fitzroy, Australia.

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Correspondence: Darren Lee, MBBS (Hons), PhD, Department of Renal Medicine, Eastern Health, Level 2, 5 Arnold St, Box Hill, VIC 3128, Australia. (Darren.Lee@easternhealth.org.au).

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and donor transmission is low based on prevalence and modeling of at-risk nonorgan donor groups[1-3] and reported cases of transmission from IVRDs.[4-11] This has led to kidneys from IVRDs being increasingly utilized in countries including the United States of America (USA), where IVRDs have risen to 27.1% of deceased donors in 2018.[12,13] At the time of writing, the last reported cases of HIV transmission from deceased[14] or living[15] donors in the USA was in 2007 and 2009, respectively. The availability of hepatitis B virus (HBV) vaccination and antiviral agents, and the highly effective and well-tolerated direct-acting antivirals for hepatitis C virus (HCV), also substantially reduce the consequences of potential disease transmission.

IVRDs are often younger,[6] with a lower kidney donor profile index (KDPI).[4] Furthermore, accepting an IVRD kidney provides a survival benefit in the USA, compared to remaining on the waitlist for a non-IVRD kidney.[16] Despite a favorable risk-benefit profile for IVRD kidneys, the nonutilization rate remains surprisingly high,[17,18] especially when compared with matched younger non-IVRD subgroups with similar KDPI, suggesting a labeling effect.[4,16]

Before 2018, the state of Victoria in Australia had no formal structure for the identification or allocation of IVRDs. IVRD kidneys were offered to the standard transplant waiting list, where consent was obtained at the time of the offer. All donors (IVRDs and non-IVRDs) for kidney allocation had prospective NAT donor screening performed. An opt-in process was introduced in 2018 wherein kidney transplant recipient (KTR) candidates who had undergone education and provided specific written informed consent (**Table S1, SDC,** http://links.lww.com/TXD/A355) were placed on an additional waiting list for IVRD kidneys. These KTR candidates preconsented to the highest modeled Australian BBV transmission risks,[2] with the expectation that no further risk stratification would be performed at the time of offer. Preconsented KTR has the opportunity to decline an IVRD kidney when the offer is made. KTR candidates who had not given consent to receive an IVRD kidney were not offered these organs.

In this study, we aimed to compare the utilization and allocation efficiency of IVRD kidneys via this new Victorian IVRD program with non-IVRD kidneys during the same 2-y period. Additionally, we compared the characteristics of IVRD and the associated KTR outcomes with non-IVRD kidneys from the same era. We also compared our findings to those from New South Wales, an Australian state with a similar number of kidney transplant centers and volume to Victoria but without a formal opt-in IVRD kidney allocation system (similar to Victoria before IVRD waiting list implementation).

MATERIALS AND METHODS

Definition of IVRD in Victoria

IVRDs were defined as donors meeting the following criteria: (1) increased risk behaviors in the preceding 12 mo, (2) time from hospital admission to donation within NAT window period (22 d to incorporate HBV),[19] and (3) no evidence of active BBV infection (negative prospective NAT for HBV, HCV, and HIV, negative hepatitis B surface antigen [HBsAg], and negative HIV antigen/antibody). The criteria for increased risk behaviors were based on the US Public Health Service 2013 guideline.[20] These included (1) people injecting drugs for nonmedical reasons, (2) men who have sex with men, (3) sex workers, (4) people in prison for more than 72 consecutive hours, (5) people with sexually transmitted infections, and (6) when risk factors cannot be determined. People who have had sex with those in the increased risk behavior groups (1)–(3) as specified above, or known or suspected HBV, HCV, or HIV infection, were also defined as IVRD. Kidneys from (i) HCV antibody (Ab) positive NAT negative (HCV Ab+/NAT–) donors or (ii) hepatitis B core antibody (HBcAb) positive, HBsAg negative, NAT negative donors without increased risk behaviors were allocated as non-IVRD kidneys to the standard waiting list.

Study Population

The study was approved by the Australian Red Cross Lifeblood Ethics Committee (reference number Lee 03052019) and the New South Wales Ministry of Health. From July 31, 2018, all Victorian deceased donor kidneys meeting the IVRD criteria for within-state allocation (excluding multivisceral KTRs) were allocated to preconsented KTRs on a separate opt-in IVRD transplant waiting list.[21] All Victorian and New South Wales deceased donors for the 2-y period following this (July 31, 2018–July 31, 2020) were included in the study. Potential donors deemed medically unsuitable (and therefore not allocated to recipients), including those with evidence of active BBV infection, were excluded from the analysis.

Data and Outcomes

De-identified donor data were obtained from the national organ procurement organization DonateLife. Utilization and the number of offer declines, as a measure of allocation efficiency, of Victorian IVRD and non-IVRD kidneys during the 2-y study period were compared. De-identified baseline demographic data of utilized Victorian IVRD and non-IVRD kidneys and their KTRs were summarized. The Australian KDPI and Australian estimated post-transplant survival (EPTS) score (https://tsanz.com.au/guidelinesethics-documents/document-download.htm) of donors and recipients, respectively, were analyzed. The Australian KDPI, modified from the original US KDPI, does not capture donor HCV Ab status or ethnicity as variables.[22] Risk factors of IVRD, including NAT window period, increased risk behaviors and serology results, were collated.

Post-transplant surveillance results by serology (HBsAg, HBcAb, HCV Ab, and HIV Ab/Ag) and polymerase chain reaction (PCR) (HBV and HCV) testing, estimated glomerular filtration rate (eGFR) by Chronic Kidney Disease Epidemiology Collaboration, graft loss, and mortality of IVRD KTRs at 1 and 3 mo had been reported by transplant units to DonateLife prospectively as part of quality assurance and safety components of the IVRD allocation pathway. HIV NAT or PCR is not approved by the National Association of Testing Authorities, Australia, for diagnosing acute infection in seronegative nondonor individuals and was therefore not part of the post-transplant surveillance protocol for IVRD KTRs in Victoria.

For comparison of kidney function at 1 and 3 mo post-transplant, de-identified data were obtained from the Australia and New Zealand Dialysis and Transplant (ANZDATA) Registry. As IVRD status was not captured in the registry, eGFR from IVRD KTRs was compared with all Victorian deceased donor adult KTRs (both IVRD and non-IVRD KTRs), obtained

from DonateLife and the ANZDATA registry, respectively. This covered a period (October 1, 2017–September 30, 2018) 10 mo earlier than IVRD pathway implementation because of the lag time in reporting to ANZDATA.

Statistical Analysis

Data analysis was performed using GraphPad Prism 9.0.1 (GraphPad, San Diego, CA). Continuous variables were presented as median (interquartile range [IQR]), and comparisons between two groups were performed using the two-tailed Mann–Whitney U-test. Categorical variables were presented as numbers (percentage of group) and compared using Chi-square tests. A two-sided P value of <0.05 was considered significant.

RESULTS

Preconsent Rate, Utilization, and Allocation Efficiency of IVRDs

Kidneys from 44 IVRDs were allocated during the 2-y period. Of these, 7 IVRDs had kidneys accepted before withdrawal of support for donation after circulatory death and did not die within the 90-min time frame for accepted warm ischemia in Victoria, and 3 IVRDs had both kidneys allocated to interstate recipients. These were excluded from the analysis. Both kidneys from 3 medically complex IVRDs were declined by all recipients because of concerns with the kidney quality or unquantifiable cancer risk, leaving 31 IVRDs included in the analysis. Six of the 31 IVRDs had a single kidney utilized, with reasons for the other kidney being declined including severe acute kidney injury with pre-existing hypertension or diabetes (n = 2), renal cell carcinoma (n = 1), and unilateral surgical issues identified at retrieval (n = 3). After excluding 2 multi-visceral KTRs, 54 IVRD KTRs were included in the analysis (Figure 1). IVRDs (n = 31) comprised 13% of deceased donors during the study period (11% and 17% in the first year and second year, respectively). Waitlisted recipients who had preconsented to accept IVRD kidneys increased from 33% to 41% at 1 and 2 y postprogram implementation, respectively (Figure 2A). There was no significant difference in the preconsent rates from KTR candidates with a calculated panel reactive antibody (PRA) of >95% versus those with a calculated PRA of <95% at 2 y postimplementation (47% vs 39%; P = 0.16). IVRDs with zero kidneys utilized decreased from 17% to 0% during the first year and second year, respectively, whereas both kidneys being accepted increased from 61% to 88% (Figure 2B). Over the study period, deceased donors with zero kidneys utilized were similar in IVRD and non-IVRD groups (9% vs 11%) (Figure 2B).

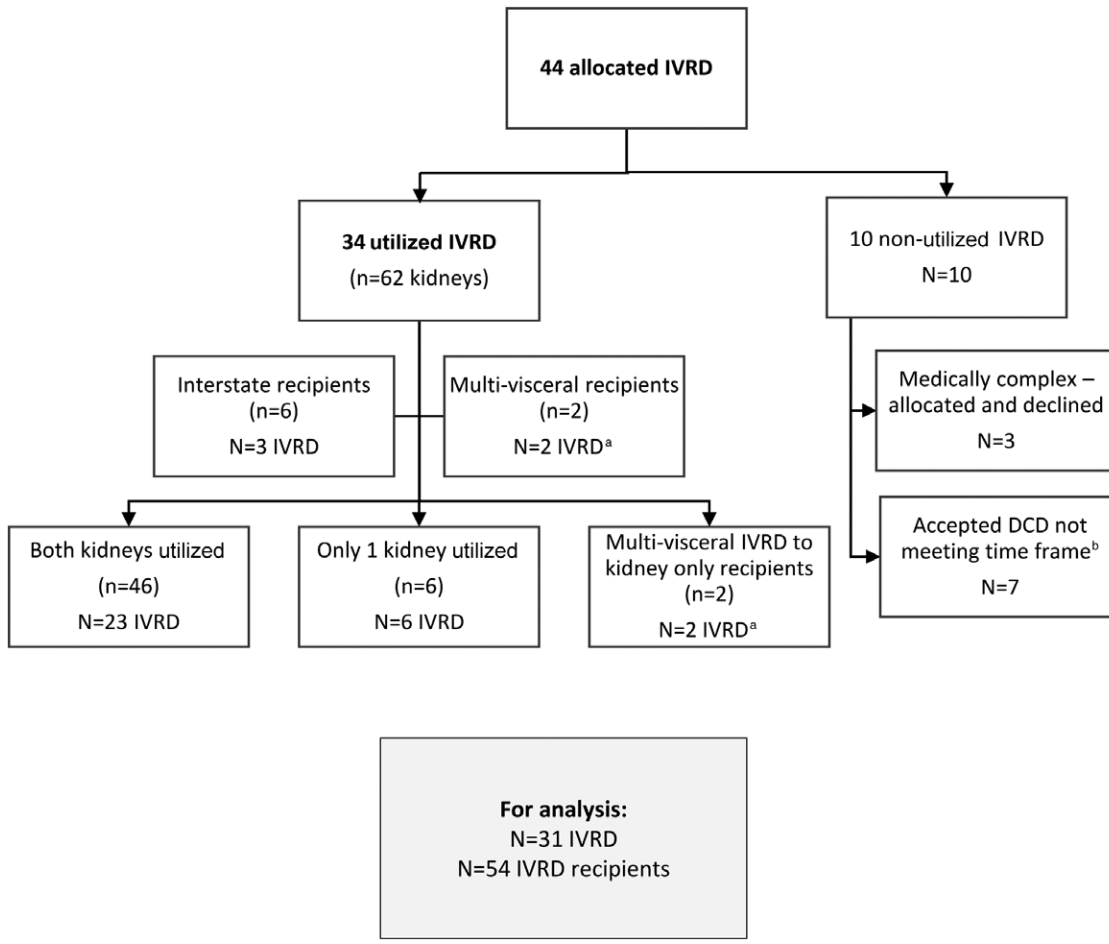

FIGURE 1. Schematic diagram of IVRD and their KTR included in the analysis. [a]Each of these two IVRD donated to one multi-visceral KTR (liver or pancreas with kidney) and one KTR (without other organs). [b]Accepted kidneys from DCD not meeting time frame (n = 7) excluded from the calculation of utilization rate. DCD, donation after circulatory death; IVRD, increased viral risk donor; KTR, kidney transplant recipients.

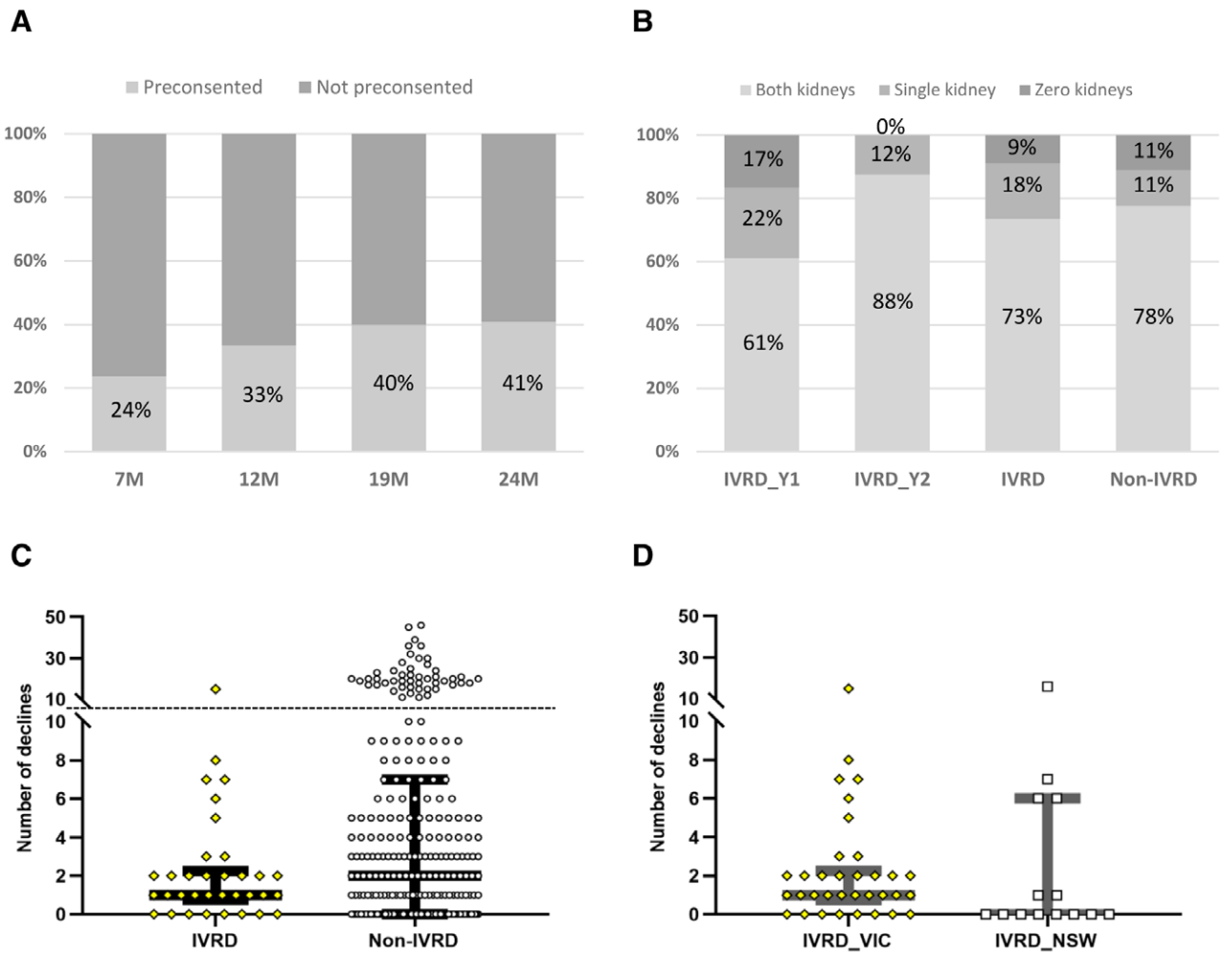

FIGURE 2. Preconsent rate, utilization, and allocation efficiency of IVRD kidneys. (A) Percentage of preconsented waitlisted recipients for IVRDs at 7, 12, 19, and 24 mo (n = 362, n = 335, n = 356, and n = 401 for all waitlisted recipients respectively). (B) Percentage of allocated IVRDs with both, single, or zero kidney(s) utilized from the first year (IVRD_Y1, n = 18) and second year (IVRD_Y2, n = 16) postimplementation and IVRDs and non-IVRDs from both years combined; accepted DCD donors not meeting time frames after withdrawal of support were excluded. (C) Number of offer declines of allocated kidneys from IVRDs (yellow) (n = 34) vs non-IVRDs (white) (n = 263) in Victoria (median 1 (IQR 1–2) vs 2 (IQR 0–7) declines; $P = 0.10$); dots above the horizontal dotted line represent each donor with >10 kidney offer declines [IVRD 3% (n = 1) vs non-IVRD 19% (n = 50); $P < 0.05$]. (D) Number of offer declines of allocated kidneys from IVRDs in Victoria (yellow) vs IVRDs in New South Wales (white) [median 1 (IQR 1–2) vs 0 (IQR 0–5); $P = 0.20$]. (C–D) Scatter plots (midline = median; error bars = 25th–75th percentile). DCD, donation after circulatory death; IQR, interquartile range; IVRD, increased viral risk donor; NSW, New South Wales; VIC, Victoria.

The number of KTR candidates preconsented to accept IVRD kidneys and the number of IVRDs with zero, single, or both kidneys utilized are presented (**Figure S1, SDC,** http://links.lww.com/TXD/A355), stratified for sensitization status (calculated PRA) and blood group. Blood group A had fewer preconsented waitlisted recipients than B and O, although those with calculated PRA <95% increased from 7 to 13 at 1 and 2 y postimplementation, respectively. Consequently, out of the 9 blood group A IVRDs with 18 kidneys allocated in the first year, there were 2 IVRDs with zero kidneys and 2 with a single kidney utilized. In contrast, all 6 blood group A IVRDs had both kidneys utilized in the second year.

To examine the allocation efficiency of IVRD kidneys, the number of kidney offer declines from each IVRD and non-IVRD in Victoria were compared. There was no significant difference between IVRD and non-IVRD groups ($P = 0.10$) (Figure 2C). However, the number of kidney offer declines >10 per donor was significantly less frequent in the IVRD than non-IVRD cohort (3% vs 19%; $P < 0.05$) (Figure 2C). Compared with New South Wales, IVRDs with zero kidneys utilized and the number of kidney offer declines for each IVRD were similar in Victoria. The proportion of deceased donors identified as IVRDs was lower in New South Wales, despite a similar number of kidney transplant centers and volume to Victoria (Figure 2D and Table 1).

Characteristics of Donors and Recipients

KDPI and Donor Age

Table 2 shows the baseline donor and recipient demographics grouped by IVRD status. IVRDs had a lower KDPI (Figure 3A) and were more likely to have a KDPI ≤20% and less likely >80%. They were younger and less likely to have hypertension (Table 2). There were no significant differences in the recipient age or EPTS between IVRD and non-IVRD groups.

TABLE 1.

Comparison of IVRD representation in the deceased donor pool, nonutilization, and allocation efficiency in Victoria vs New South Wales (July 31, 2018–July 31, 2020)

	VIC	NSW	*P*
Transplant centers	N = 6	N = 6	
Transplant volume[a]			
Donors	244	204	
Recipients	403	355	
IVRD[a]			
Proportion of deceased donors (n [%])	31 (13%)	14 (7%)	**<0.05**
Zero kidneys utilized (%)	3/34 (9%)	1/15 (7%)	0.80
Declined kidney offers per IVRD (median [IQR])	1 (1–2)	0 (0–5)	0.20

[a]Only within-state allocation to kidney transplant (single organ) recipients included.
IVRD, increased viral risk donor; IQR, interquartile range; NSW, New South Wales; VIC, Victoria.
P < 0.05 being statistically significant.

TABLE 2.

Baseline demographics of IVRDs vs non-IVRDs and their kidney transplant recipients

	IVRD	Non-IVRD	*P*
Donors	n = 31	n = 213	
Age (y) (median [IQR])	36 (30–44)	51 (35–60)	**<0.0001**
KDPI (%) (n [%])	25 (13–40)	57 (29–75)	**<0.0001**
1%–20%	12 (39%)	32 (15%)	**<0.001**
21%–80%	19 (61%)	141 (66%)	
81%–100%	0 (0%)	40 (19%)	
Gender (female) (n [%])	7 (23%)	79 (37%)	0.16
DCD (n [%])	11 (35%)	69 (32%)	0.73
Hypertension (n [%])	0 (0%)	47 (22%)[a]	**<0.01**
Diabetes (n [%])	2 (6%)	11 (5%)[a]	0.78
BMI (kg/m^2) (median [IQR])	27.5 (24.0–31.0)	26.8 (23.8–30.9)[a]	0.44
Terminal serum creatinine (μmol/L) (median [IQR])	72 (58–132)	70 (57–98)[a]	0.47
Recipients	n = 54	n = 349	
Age (y) (median [IQR])	54 (48–64)	57 (47–64)	0.52
EPTS (%) (median [IQR])	47 (27–74)	60 (33–78)	0.20
Blood group (median [IQR])			0.66
A/AB	22 (41%)	156 (45%)	
B	7 (13%)	54 (15%)	
O	25 (46%)	139 (40%)	
Dialysis duration (mo) (median [IQR])	24 (14–33)	27 (15–41)	0.21
Excluding bonus scores[b]	25 (16–33)	31 (15–42)	0.20
Blood group[b]			
A/AB	14 (12–21)	18 (13–30)	0.29
B	32 (24–53)	42 (37–59)	0.32
O	30 (24–34)	37 (25–42)	0.07
First y	27 (18–32)	37 (27–42)	**<0.05**
Second y	32 (26–36)	37 (18–47)	0.50
cPRA (%) (median [IQR])	0 (0–0)	0 (0–6)	0.09
>95%	0 (0%)	17 (5%)	0.10

[a]n = 210 (3 non-IVRD with missing data) for BMI, status of hypertension and diabetes, and terminal serum creatinine.
[b]Allocation based on dialysis duration only without bonus scores for sensitization, superior HLA mismatches or pediatric kidney transplant recipients (IVRD n = 50, non-IVRD n = 279).
BMI, body mass index; cPRA, calculated panel reactive antibody; DCD, donation after circulatory death; EPTS, estimated post-transplant survival; IQR, interquartile range; IVRD, increased viral risk donor; KDPI, kidney donor profile index.
P < 0.05 being statistically significant.

Kidney Function

Compared to Victorian deceased donor (IVRD and non-IVRD) KTRs in the ANZDATA cohort, IVRD KTRs had superior function with higher eGFR (Figure 3B) at 1 and 3 mo post-transplant. The mortality rate (0 [0%] vs 1 [0.2%]) and graft failure (2 [3.7%] vs 12 [2.1%]) at 3 mo post-transplant were similar.

Waiting Time

There was no significant difference in the dialysis waiting time for IVRD versus non-IVRD KTRs (Table 2). For blood group O IVRD KTRs, there was a trend toward shorter waiting time. The waiting time was significantly shorter during the first year post-implementation, but this benefit no longer existed in the second year (Table 2).

Infection Risk

Table 3 shows the infection risk characteristics of IVRDs. The most common increased risk behavior was injecting drug use, accounting for over 60% of IVRDs. The median timing of NAT performed posthospital admission was 3 d. All IVRDs were NAT negative by definition; however, 29% (n = 9) were HCV Ab positive, 2 of which were also HBcAb positive but HBsAg negative.

Post-transplant Surveillance

The program recommends that IVRD KTRs undergo surveillance by serology and PCR testing at 1 and 3 mo post-transplant. Seventy-four percent of IVRD KTRs adhered to these recommendations, while 2% (n = 1) had no testing performed (Figure 4). Partial adherence to testing was primarily due to inadequate surveillance by PCR. Fifteen percent (n = 8) of all IVRD KTR had no PCR testing at either time point, increasing from 8% (n = 2) to 21% (n = 6) during the first year and second year postimplementation, respectively. Reasons for PCR testing not being performed included (i) recipient not recognized as an IVRD KTR (n = 1), (ii) inadvertent omission of PCR testing request as part of the protocolized screening tests (n = 5), (iii) out-of-pocket costs by the external pathology provider (n = 1), and (iv) pathology provider of the transplant center declining the request (nonreimbursable in seronegative individuals). No transmission of active infection was detected in any IVRD KTR.

Of the 17 KTRs from 9 HCV Ab+/NAT– IVRDs, 16 KTRs were seronegative pretransplant. Fifty percent (n = 8) developed abnormal HCV Ab results at 1 and/or 3 mo post-transplant (**Figure S2, SDC,** http://links.lww.com/TXD/A355). All were HCV PCR negative.

DISCUSSION

To our knowledge, outside of North America and the United Kingdom, there are no studies reporting KTR outcomes utilizing IVRD kidneys. Our study confirmed the superior organ quality of IVRD kidneys.[4,6] At 3 mo post-transplant, we observed superior short-term graft function and comparable patient and graft survival in IVRD KTRs. This is consistent with the international experience.[6,23,24] Recently, Bowring et al demonstrated that accepting an IVRD kidney was associated with a 48% lower risk of death beyond 6 mo post-transplant compared with remaining on dialysis and waiting for another offer in the USA.[16] Part of the survival benefit likely derived from earlier transplantation in which the waitlist mortality is higher than most other jurisdictions.[25,26]

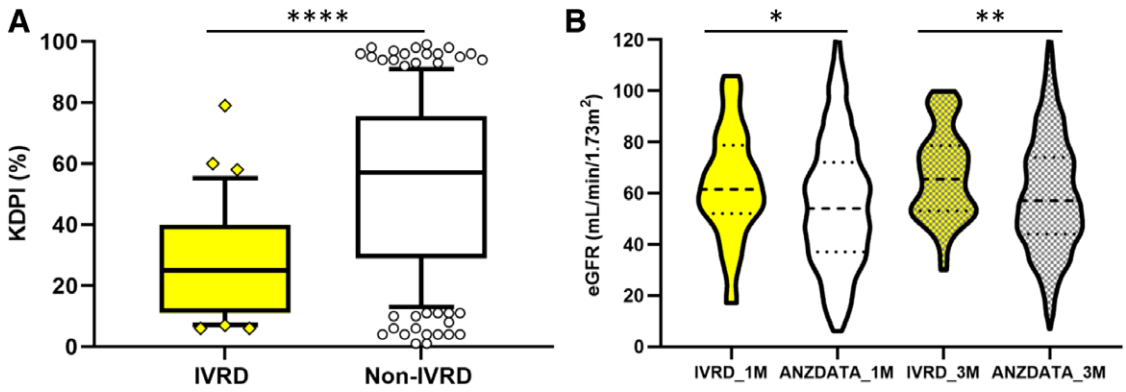

FIGURE 3. Donor quality and recipient kidney function. (A) Comparison of KDPI in IVRD (yellow) vs non-IVRD (white) (IVRD n = 31, non-IVRD n = 213); box-and-whisker plots (midline = median; box = 25th–75th percentile; error bars = 10th–90th percentile; whiskers = top and bottom 10th percentile). Median 25% (IQR 13–40%) vs 57% (IQR 29–75%) (****$P < 0.0001$). (B) Comparison of eGFR in IVRD KTR (yellow) (n = 48) vs ANZDATA Victorian deceased donor KTRs (white) (n = 565 at 1 mo, n = 557 at 3 mo) at 1 and 3 mo; density plots (midline long dashed line = median; dotted lines = 25th and 75th percentiles); **$P < 0.05$; *$P < 0.01$. ANZDATA, Australia and New Zealand Dialysis and Transplant Registry; eGFR, estimated glomerular filtration rate; IQR, interquartile range; IVRD, increase viral risk donor; KDPI, kidney donor profile; KTR, kidney transplant recipient.

The residual risk of NAT window period infection is low and likely to be lower in Australia compared with the USA.[2,3] Universal healthcare coverage in Australia, recommendations for antiretroviral treatment as soon as HIV diagnosis is made, the introduction of pre-exposure HIV prophylaxis in men who have sex with men, and publicly-funded direct-acting antiviral therapy for HCV infection targeting elimination are all factors likely to reduce the prevalence of BBV infections in at-risk groups, and therefore the residual risk in IVRD transplantation.[27,28] From approximately 18 000 IVRDs in the USA, only 1 HIV and 23 HCV donor-derived transmission events were reported in 2008–2018, suggesting that the actual risk of NAT window period infection is likely overestimated by modeling.[8] Furthermore, restricting the acceptance of kidneys from standard risk donors does not eliminate BBV infection risk given the imperfect nature of obtaining donor medical history.[4]

In our cohort over 2 y, only 2% of IVRD KTRs had no tests performed within 3 mo post-transplantation. However, PCR testing reduced from 92% to 79% in the first year and second year postimplementation. Relying on serological testing could lead to delayed detection of potential transmission and therefore delayed treatment. Strategies to increase adherence to PCR testing include the use of protocolized pathology request forms to avoid inadvertent omission of PCR tests, electronic reminders for testing, and improved communication with pathology providers regarding the established agreement for screening seronegative IVRD KTRs. Adherence to post-transplant surveillance in this cohort, however, still compares favorably with international experience.[7] HCV Ab+/NAT– donors comprised 29% of the IVRDs in this cohort. Consistent with previous reports, half of them developed abnormal HCV Ab test post-transplant without viremia, confirming the safety of use from these donors.[29,30]

TABLE 3.
Risk factors of IVRD

NAT performed posthospital admission (d)	
Median (IQR)	3 (2–4)
Minimum–maximum	0–8
Increased risk behaviors (n [%])	
Injecting drug use	15 (48.4%)
Sexual risk	11 (35.4%)
Imprisonment	1 (3.2%)
Injecting drug use and sexual risk or imprisonment	4 (13.0%)
Serology results (n [%])[a]	
Negative	22 (71.0%)
HCV Ab positive	9 (29.0%)

[a]Serology tests included HBsAg, HBcAb, HCV Ab, and HIV Ab/Ag combo; all IVRD were NAT negative.
HBsAg, hepatitis B surface antigen; HBcAb, hepatitis B core antibody; HCV Ab, hepatitis C antibody; HIV Ag/Ab, human immunodeficiency antigen/antibody combo; IVRD, increased viral risk donor; IQR, interquartile range; NAT, nucleic acid testing.

Despite a low residual risk of NAT window period infection and superior quality, IVRD kidneys have historically been under-utilized.[4,16-18] Our initiative to implement a preconsent opt-in process sought to ensure that KTR candidates have adequate time to make an informed decision before waitlisting. This avoided situations where multiple declines could risk prolongation of cold ischemia time. Maintaining a sufficient number of preconsented, nonbroadly sensitized KTRs is essential to reduce the risk of exhausting the opt-in IVRD waiting list, especially for blood group A. A collective effort was made by all Victorian units to increase the preconsent rate, which resulted in 0% of IVRDs (from 17% in the first year) having no kidneys utilized in the second year.

Historically, kidneys from IVRDs were difficult to allocate. The efficiency of the Victorian IVRD kidney allocation was at least comparable to that for non-IVRDs. Preconsented recipients were expected to be more likely to accept an IVRD kidney; however, the allocation efficiency and nonutilization of IVRD kidneys were similar in New South Wales, where there is no preconsent process or dedicated allocation pathway. Interestingly, New South Wales had a lower proportion of IVRD compared with Victoria. In addition to potential missed donation opportunities arising from IVRDs in New South Wales and labeling variation, another explanation is the significant year-to-year fluctuation of potential IVRD numbers.[31] Regardless of whether or not to pursue an opt-in allocation pathway, perhaps the most crucial element for optimizing IVRD kidney utilization is balanced education for both transplantation specialists and KTR candidates. Significant center variations in IVRD kidney utilization have been shown

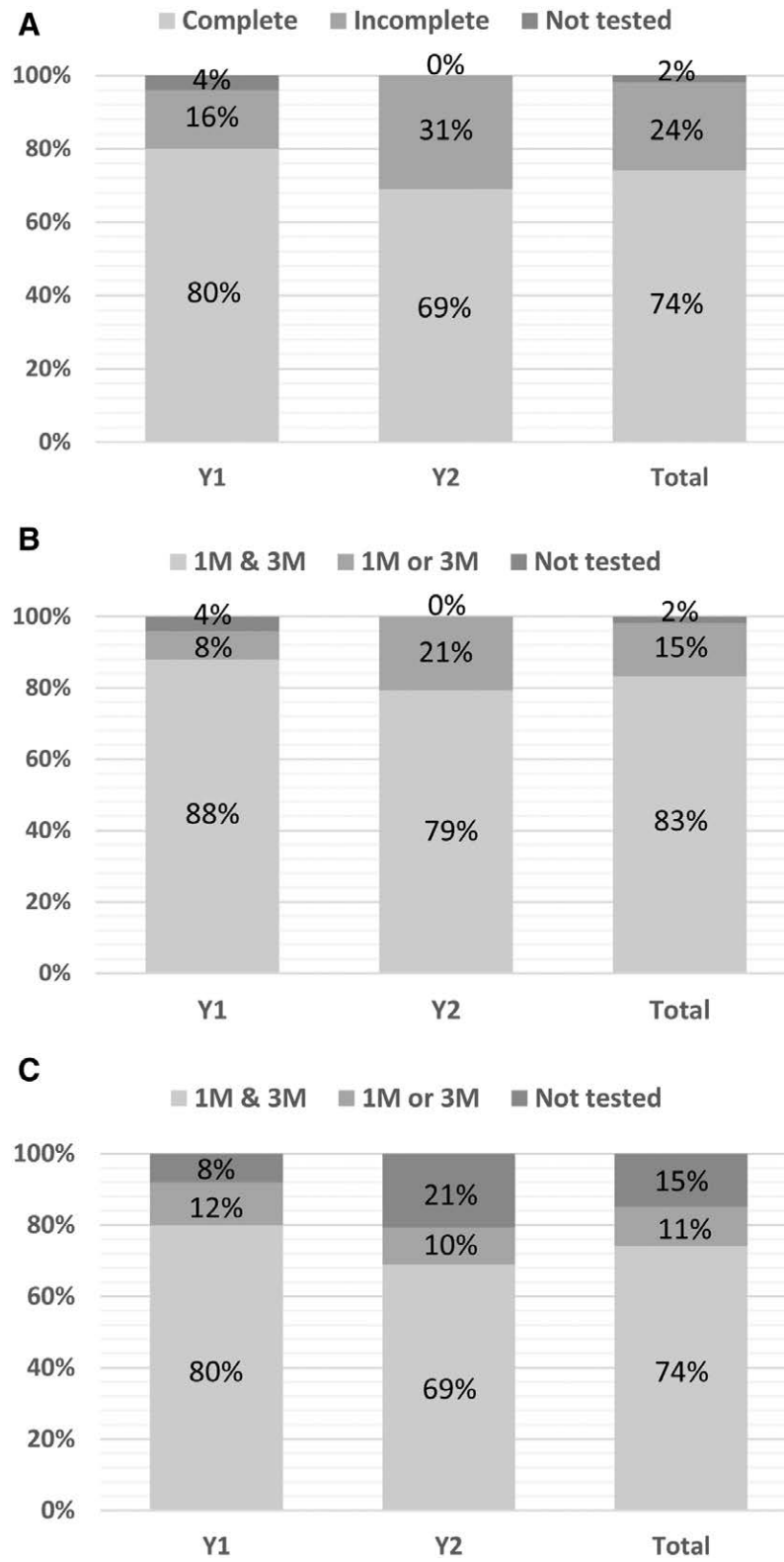

FIGURE 4. Adherence to post-transplant surveillance testing in IVRD recipients. (A) Adherence to serology and PCR post-transplant surveillance testing. Complete: both serology and PCR testing performed at 1 and 3 mo; incomplete: either serology or PCR testing performed at either 1 or 3 mo; not tested: no serology or PCR testing performed at 1 or 3 mo. (B) Adherence to serology testing (HBV, HCV, and HIV). (C) Adherence to PCR testing (HBV and HCV). (B, C) 1M and 3M: testing performed at both 1 and 3 mo; 1M or 3M: testing performed at only 1 or 3 mo. (A to C) or (A–C), not (A,C). Y1, first year (n = 25); Y2, second year (n = 29). HBV, hepatitis B virus; HCV, hepatitis C virus; IVRD, increased viral risk donor; PCR, polymerase chain reaction.

to reflect local surgeon and center acceptance practice.[32] In a single-center study, Asian American background and interpreter requirement were risk factors for declining an IVRD kidney. However, following further education, 12 of 13 of those having recently declined an IVRD kidney would reconsider accepting a future offer, suggesting the

importance of patient education in maximizing utilization.[33] This also highlights the need for ongoing review and discussion with our KTR candidates who have previously opted out of the Victorian IVRD waiting list. Concerningly, 53% of our broadly sensitized patients did not preconsent to accept an IVRD kidney, potentially missing out on a once-in-a-lifetime opportunity.

In 2020, the US Public Health Service updated recommendations regarding IVRDs.[8] A key recommendation was the removal of the label "increased risk donors." Specific written informed consent regarding the risk of BBV infections from the utilization of these donor organs is also no longer required, either at the time of waitlisting or transplant offer. These changes seek to improve IVRD organ utilization by more accurately reflecting the absolute risk posed by such donors and by simplifying the consent process. Before similar changes are adopted in Victoria, several local differences should be considered. First, the proportion of IVRDs in the USA is at least twice that of Victoria.[12] Declining all IVRD kidneys would therefore substantially reduce the donor pool in the USA compared to Victoria. Given the lower prevalence of injecting drug use in Australia compared to North America,[34] the IVRD rate is unlikely to reach that in the USA. Second, reimbursement for universal PCR testing on all KTRs post-transplant, rather than targeting those identified to have received an IVRD kidney, is unlikely in Victoria, hampering the early detection of potential transmission from IVRD. Third, with less than half of waitlisted recipients currently providing preconsent, removal of dedicated IVRD kidney allocation and preconsent could potentially lead to an increase in the number of declined IVRD kidney offers, compromising allocation efficiency and utilization. With ongoing pretransplant patient education regarding the favorable risk-benefit profile of IVRD kidneys, it is possible that a preconsent process might eventually become unnecessary without negatively impacting allocation efficiency and utilization.

There are several limitations to this study. First, the sample size is modest. Although there has been no transmission so far, a case of NAT window period infection is likely to occur eventually as more IVRD kidneys are utilized. Second, although graft function was superior at 3 mo, the evaluation of long-term patient and graft outcomes was not performed. Third, data on missed IVRD donation opportunities due to perceived BBV risk was not available. Finally, because of the lack of data on increased risk behaviors in potential and utilized donors in Victoria pre-IVRD waiting list implementation, we were unable to compare the allocation efficiency and utilization of IVRD kidneys preimplementation and postimplementation of the IVRD waiting list program.

The strengths of this study included granular contemporary data for comparison of IVRDs, non-IVRDs, and their KTRs, as well as complete reporting of post-transplant surveillance and high adherence to testing by international standards. Finally, the assessment of an opt-in, preconsent, dedicated IVRD waiting list program on allocation efficiency and utilization is unique in global practice, and our study provides perspectives absent from outside of the USA.

In summary, our opt-in IVRD transplant waiting list program for preconsented KTRs demonstrated excellent allocation efficiency and utilization of IVRD kidneys since its implementation. IVRDs now comprise 13% of the Victorian donor pool, the kidneys of which offer superior quality, with no BBV transmission so far. Maintaining a high preconsent rate through education for patients, nephrologists, and surgeons is essential to optimize IVRD kidney utilization and benefit more recipients.

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