Does the removal of anonymity reduce sperm donors in Australia?

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The National Health and Medical Research Council's guidelines implemented in 2005 removed a sperm donor's ability to remain anonymous in every Australian State except Victoria, which had removed anonymity completely by 1998. To assess the impact of these changes on sperm donor numbers in Australia, Assisted Reproductive Technology clinics were surveyed to obtain sperm donation figures between 2000 and 2012, with additional data collected from State-based oversight groups. There was an increase in total sperm donor numbers over the study period, including the year anonymity was removed as well as the non-anonymous period. Variations in total donor numbers and numbers of new recruits observed during the period could not be attributed to any specific change in policy or practice. As total sperm donor numbers have been increasing, the removal of a donor's ability to remain anonymous has not been detrimental to the availability of sperm donors in Australia.

INTRODUCTION

Prior to 2005, in Australia the use of donated sperm in assisted reproductive technology (ART) procedures occurred in an environment where anonymity was permitted. That is, identifying information about sperm donors was recorded but was not available to offspring born as a result of third party reproduction. The State of Victoria was the exception as legislation had removed anonymous donations completely by 1998.¹ However, the process was started earlier in 1988 with the creation of a central register and the ability for offspring to access the donor's identifying information if the donor had given consent.²

In 2005, the *Ethical Guidelines on the Use of Assisted Reproductive Technologies in Clinical Practice and Research* were implemented and included a new directive regarding the use of donated sperm.³ The guidelines clearly stated that "persons conceived using ART procedures are entitled to know their genetic parents".⁴ Furthermore, clinics offering third party reproduction were directed not to use donated sperm in treatment "unless the donor has consented to the release of identifying information about himself or herself to the person conceived using his … gametes".⁵ These directives were also maintained following amendments to reflect legislative change in relation to research involving human embryos and the prohibition of human cloning.⁶

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¹ Infertility (Medical Procedures) Act 1995 (Vic) s 79.

² Infertility (Medical Procedures) Act 1984 (Vic) s 22.

³ National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2004).

⁴ National Health and Medical Research Council, n 3, [6.1].

⁵ National Health and Medical Research Council, n 3, [6.1].

⁶ National Health and Medical Research Council, *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research* (2007).

628



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journals/permissions. For general permission queries, contact LTA.Permissions@thomsonreuters.com. In Australia, four of the eight States and Territories have legislation that regulates ART (Victoria, South Australia, Western Australia, and New South Wales). These Acts differ between each State. However, the National Health and Medical Research Council (NHMRC) guidelines are the only form of regulation that provides national consistency. While guidelines are not enforceable by law, compulsory accreditation of fertility clinics through the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia (FSA) requires that the guidelines be adhered to.⁷

When the NHMRC guidelines came into effect in 2005, the directive not to use anonymous donors applied across all States and Territories of Australia. Effectively then the use of anonymous donors ceased in 2005.

The removal of anonymity for sperm donors has concerned ART clinicians, with some making the following statements in the media:

[In reference to being asked how difficult it is to source donors, Dr Bernstein, the Medical Director of Fertility East, responded:] "Extremely difficult and I think with known donation it's becoming harder all the time".⁸

The head of the hospital's reproductive endochrinology [sic] and infertility department, Mark Bowman, says donor numbers are dropping because the new laws will allow children to contact their biological parents.⁹

Michael Chapman, a senior fertility specialist with IVF Australia, said that over the past few years, the number of sperm donors had dwindled from over 100 in Australia to less than 30, largely due to changes to the law governing anonymity.¹⁰

It is clear from the above statements that some clinicians view the practice of donor anonymity and the ability to recruit sperm donors as inextricably linked.

In 2005, the United Kingdom underwent a transition from a system using anonymous donations to one using only donors who agreed to identity release. Published data showed that overall numbers of donors increased following the removal of anonymity,¹¹ despite some individual clinics/centres experiencing a reduction in number.¹² One United Kingdom clinic also reported a decline in applications for the 10 years leading up to the removal of anonymity.¹³ As the transition to the non-use of anonymous donors in the United Kingdom was a more sudden change brought on by the outcomes of a case adjudicated by the High Court of Justice of England and Wales in 2002,¹⁴ it could be postulated that other factors influenced sperm donor recruitment than issues of anonymity in that instance. However, there was a similar fear in the United Kingdom that the removal of anonymity would influence a significant proportion of donors to make the decision not to donate,¹⁵ and it was

⁷ Reproductive Technology Accreditation Committee, *Code of Practice for Assisted Reproductive Technology Units* (Fertility Society of Australia, 2010).

⁸SBS, "Making Babies", *Insight*, 30 May 2006 (Joel Bernstein) <<u>http://www.sbs.com.au/news/article/</u>2006/05/30/making-babies>.

⁹ "Planned Laws Will Reduce Sperm Donor Numbers: Hospital", *ABC News*, 23 September 2006 <<u>http://www.abc.net.au/news/2006-09-23/planned-laws-will-reduce-sperm-donor-numbers/1270136</u>>.

¹⁰ Natasha Wallace, "Sperm Donor Shortage Dampens Aussie Hopes", *Minnpost*, 5 April 2010 <<u>http://www.minnpost.com/global-post/2010/05/sperm-donor-shortage-dampens-aussie-hopes</u>>.

¹¹ Human Fertilisation and Embryology Authority, New Donor Registrations <<u>http://www.hfea.gov.uk/3411.html</u>>.

¹² MJ Tomlinson et al, "Sperm Donor Recruitment Within an NHS Fertility Service Since the Removal of Anonymity" (2010) 13 Hum Fertil (Camb) 159.

¹³ S Paul, S Harbottle and JA Stewart, "Recruitment of Sperm Donors: the Newcastle-Upon-Tyne Experience 1994-2003" (2006) 21 Hum Reprod 150.

¹⁴ Rose v Secretary of State for Health and Human Fertilisation and Embryology Authority [2002] EWHC 1593.

¹⁵ L Frith, E Blyth and A Farrand, "UK Gamete Donors' Reflections on the Removal of Anonymity: Implications for Recruitment" (2007) 22 Hum Reprod 1675; SC Lui and SM Weaver, "Attitudes and Motives of Semen Donors and Non-donors" (1996) 11 Hum Reprod 2061.

suggested as a possible reason for the decline observed by Paul et al.¹⁶ By contrast, in Sweden a reduction in the number of donors was observed after a change in law that removed donor anonymity in 1984.¹⁷ The data showing the effect of anonymity removal on donor numbers are therefore conflicting.

The aim of the study discussed in this article was to collect and report on the numbers of sperm donors donating to Australian ART clinics since the year 2000 in order to determine what effect, if any, the implementation of non-anonymous donation had on sperm donor numbers in Australia.

MATERIALS AND METHODS

Ethical approval for this study was obtained from the Flinders University Social and Behavioural Research Ethics Committee. Data were collected between March and October 2013.

All ART clinics listed on the FSA website,¹⁸ as accredited by the RTAC, were sent a letter in March 2013. Eighty ART clinics in total were contacted. This number consisted of 32 "major" clinics and the remainder smaller satellite clinics. While a proportion of satellite clinics do not have their own donor recruitment programs, letters were sent to both major and satellite clinics to make sure all potential recruitment clinics had the opportunity to participate in the survey. The letter introduced the project and its aims and requested de-identified numerical data about sperm donors. The numbers of sperm donors available to the clinic each year from 2000-2012 inclusive were requested. These donors did not include those that were directed donations by friends or family (known donors), but rather donors who made their sperm available to others through the clinic. Donor numbers were not restricted to new recruitments, but also included the total number available, including those that were in storage. Each envelope contained a self-addressed, stamped envelope for return of the data spreadsheet. The data requested thereby included five years of data pertaining to the ability to use anonymous sperm donors (2000-2004) and eight years of data since the implementation of the NHMRC guidelines (2005-2012). For those clinics not in operation for the full period, they were requested to provide data only as far back as was possible (ie since the clinic began operation). A reminder letter was sent to clinics which had not responded by July 2013; however, no additional responses were received.

Data obtained from participating clinics were supplemented with additional State-wide data that were publicly available. Victoria, South Australia and Western Australia all collected and reported data about sperm donors in their respective States throughout this period, capturing donation figures for every clinic in each of those States. Data were obtained from the Victorian Assisted Reproductive Treatment Authority (VARTA), the South Australian Council on Reproductive Technology (SACRT), and the Reproductive Technology Council (RTC) and incorporated into this study. Combined clinic responses and State-wide data represented 62.5% (20/32) of the major clinics in Australia, or 47.5% (38/80) of the total ART clinics (including satellite clinics). Differences in percentages were due to the fact that some of the major clinics which did not respond had larger numbers of satellite clinics than others. One response was obtained from a satellite clinic of a major clinic and is therefore only a proportion of that clinic's data. The rest of the responses were complete data from the major clinics (including their satellite clinic data). One of the responses received indicated that the clinic did not have a donor program, another returned a blank spreadsheet. Additionally, five unopened letters were received by return mail as undeliverable.

Data were separated into three groups: Victorian data which were not affected by the introduction of NHMRC guidelines (Victoria), data from all other clinics in Australia, not including Victoria, that were affected by the introduction of anonymity removal by the NHMRC (Rest of Australia), and combined national data that included Victorian data as well (Combined).

¹⁶ Paul, Harbottle and Stewart, n 13.

¹⁷ K Daniels and O Lalos, "The Swedish Insemination Act and the Availability of Donors" (1995) 10 Hum Reprod 1871.

¹⁸ See <<u>http:\\www.fsa.com.au</u>>.

STATISTICAL ANALYSIS

A Poisson regression model was used to analyse the number of donors. As the number of donors is a count variable that appears to be discrete and measured by a relatively rare non-negative integer, these rare event counts are desirable to be modelled by a Poisson distribution. Compared to other ordinary or generalised least squares regression models, the more sophisticated model of Poisson regression can make use of the integer nature of the data and provide more precise estimates.¹⁹ In particular, the implied mean-variance restriction of Poisson regression model makes it an efficient technique.²⁰

RESULTS

The State of Victoria acted as a comparison group because anonymous donations had been completely removed prior to the introduction of the NHMRC guidelines,²¹ and also prior to the collection dates of this study. The national data are presented as a total number of donors per year as an entire nation (Combined), with Victoria excluded (Rest of Australia), and Victoria separately (Figure 1). While there was an observed drop in donor numbers in 2001, 2002, 2009 and 2011 for the Rest of Australia, and 2002, 2006, 2009 and 2011 in the Victorian and Combined data, there has been a relatively consistent increase in donor numbers per year over the entire study period, particularly for those jurisdictions affected by NHMRC guideline implementation. Victoria, by contrast, was relatively steady over the period, with some up and down variation, but with an exception of a large increase in donor numbers in 2012. More specifically in relation to the effect of anonymity removal, the first year of NHMRC guideline implementation (2005) saw an increase in total donor numbers in all groups.

FIGURE 1 Total number of sperm donors in Australia



¹⁹ Tim Futing Liao, Interpreting Probability Models: Logit, Probit, and Other Generalized Linear Models (Sage Publications, 1994).

²⁰ Ron Michener and Carla Tighe, "A Poisson Regression Model of Highway Fatalities" (1992) 82 Am Econ Rev 452.
²¹ Infertility (Medical Procedures) Act 1995 (Vic) s 79.

Adams, Ullah and de Lacey

No data were available as to whether any of the donors were duplicate donors across clinics as only non-identifying numerical data were obtained. As there is no State-wide or nationwide database of donors, identifying information is not typically shared between clinics and it may be possible for a donor to donate at more than one clinic. One major clinic reported that their donor numbers were new donors recruited each year as they would exhaust their supply within that year due to jurisdictional family limits. This limit ranges across jurisdictions; Western Australia has a limit of five families, Victoria has a limit of 10 women and New South Wales has a limit of five women per donor. Other States follow NHMRC guidelines stipulating that the number of offspring must be balanced with the risk of consanguinity. Victorian and Western Australian State-wide data reported were total donors in storage, including new donors, while SACRT reporting of donors for South Australia was ambiguous as to whether they were new recruits or total figures. Other clinics reported total donor numbers.

Three clinics provided data to the SACRT. However, only two provided data for this study for the period 2010-2012 as SACRT data were not available for 2010-2012 due to the dissolution of this council via State legislation.²² Subsequently the number of donors for this period (2010-2012) was lower than the actual figure due to missing data from one clinic. As South Australia was the only State with legislation that guaranteed anonymity,²³ it could be postulated that the removal of an institutionalised right to anonymity would have the greatest potential to reduce donor numbers in this jurisdiction. However, in 2005 when anonymity was removed there was an increase in donor numbers rather than a reduction, and therefore the postulation does not hold (2004 = 9 donors; 2005 = 23 donors). There was a 42% increase in donor numbers in Australia (excluding Victoria) in the year that anonymity provisions were removed.

Specific new donor recruit data were available for Victoria, Western Australia and one other major clinic. Western Australia observed a decrease in new recruits in 2005 of 12.5% (2004 = 27; 2005 = 24), even though total donor numbers increased (2004 = 48; 2005 = 61). The single clinic experienced an increase in new donors (2004 = 1; 2005 = 3). Victoria observed a 35.3% decrease in the same year (2004 = 23; 2005 = 17), while also experiencing an increase in total numbers (2004 = 198; 2005 = 222). This decrease in new donors in Victoria. Western Australia experienced an increase in new recruits of 37% in 2008 when compared to 2004 (2008 = 37), which was the highest number of new recruits it had during the entire study period. The major clinic also experienced increases in new recruits every year since 2004, with the exception of 2009 (2004 = 1; 2012 = 23). Victoria also experienced its highest number of new recruits in 2009, which was a 78.2% increase over the 2004 figure (2009 = 41).

To assess the ability of clinics to recruit donors in the two different eras, mean numbers of donors per year were grouped into the anonymous era (2000-2004) and non-anonymous era (2005-2012). The mean number of donors per year showed an increase in donors after the NHMRC guidelines came into effect in both groups, with and without Victorian data (Figure 2).

The incidence rate ratios for each of the eras are shown in Table 1. The number of donors had increased slightly over the last 13 years. For every year, an 8% increment (IRR = 1.08; 95% CI 1.06-1.10; P < 0.001) was observed for the Rest of Australia, a 4% increment (IRR = 1.04; 95% CI 1.03-1.05; P < 0.001) was observed in Victoria, and a 5% increment (IRR = 1.05; 95% CI 1.04-1.06; P < 0.001) was observed for combined data (all States). After implementing NHMRC guidelines, the number of donors increased by 86% (IRR = 1.86; 95% CI 1.64-2.10; P < 0.001) for the Rest of Australia, 18% (IRR = 1.18; 95% CI 1.09-1.28; P < 0.001) in Victoria, and 38% (IRR = 1.38; 95% CI 1.29-1.47; P < 0.001) for combined data.

²² Reproductive Technology (Clinical Practices) (Miscellaneous) Amendment Act 2009 (SA).

²³ Reproductive Technologies (Clinical Practices) Act 1988 (SA).





As there is a positive correlation between anonymity removal and mean donor numbers, there could be an underlying increased willingness of the male population to donate their semen, or improvements in recruitment strategies and campaigns. To assess this, we analysed the mean number of donors per year for Victoria over the entire time period, as Victoria is a comparison group that had non-anonymous donations during the entire period of this study. The number of donors varied per year, with increases recorded most years except 2002, 2006, 2009 and 2011 when decreases were recorded as previously stated. However, the decreases in 2009 and 2011 represented a drop of only 1% and 1.5% respectively. Generally, since 2006, there has been a gradual increase in numbers, although this trend was influenced by the 2012 data which were significantly greater than all preceding years. The incidence rate ratios for Victoria showed an increase of 18% (IRR = 1.18; 95% CI 1.08-1.28; P < 0.001) from 2005 when NHMRC guidelines removed anonymity provisions elsewhere in Australia, thereby highlighting an increased ability to attract donors in the post-2005 period that is independent of anonymity removal.

The data collection percentages of 62.5% of major clinics and 47.5% of all clinics including satellite clinics, while missing a sizable proportion of Australian data, fit within typical survey response rates. In a review of the literature on the comparison of web versus mail survey strategies, the response rate for mail-based surveys was found to be 45% (a higher response rate than that achieved with a web-based survey).²⁴ This is why we chose to use a mail-based survey instead of a web- or email-based one. There have also been reports that response rates from chief executive officers (CEOs) of small firms (which could perhaps be used to describe the corporate size of some clinics), has been 31% after follow up,²⁵ while for those seeking responses from physicians who are typically the CEOs or directors of these clinics, a response rate of 54% was observed.²⁶ Therefore the data were representative of what would normally be expected from a survey of this type.

²⁴ Tse-Hua Shih and Xitao Fan, "Comparing Response Rates from Web and Mail Surveys: A Meta-Analysis" (2008) 20 *Field Methods* 249.

²⁵ Susan Bartholomew and Anne D Smith, "Improving Survey Response Rates from Chief Executive Officers in Small Firms: The Importance of Social Networks" (2006) 30 Entrep Theory Pract 83.

²⁶ David A Asch, M Kathryn Jedrziewski and Nicholas A Christakis, "Response Rates to Mail Surveys Published in Medical Journals" (1997) 50 J Clin Epidemiol 1129.

	Rest of Australia			Victoria			Combined		
	IRR	95% CI	P value	IRR	95% CI	P value	IRR	95% CI	P value
Year (2000-2012)	1.08	1.07- 1.10	<0.001	1.04	1.03- 1.05	<0.001	1.05	1.04- 1.06	<0.001
Year (2000-2004 vs 2005-2012)	1.86	1.64- 2.10	<0.001	1.18	1.09- 1.28	<0.001	1.38	1.29- 1.47	<0.001

TABLE 1 Incidence rate	ratios (Poisso	n regression	model) of	donors	over the	entire				
time period of the study and between years 2000-2004 and 2005-2010										

DISCUSSION

This study has shown that the impact of removing donor anonymity in Australia is positively correlated with donor numbers. The effect on new donor recruitment rates is more complex. There were some observed decreases in new recruits immediately following the NHMRC guideline introduction. However, this was matched and was observed to be greater in Victoria, which was not affected by anonymity removal in 2005. This makes attributing the decrease in new donors to the introduction of NHMRC guidelines problematic. The finding that donor numbers increased over this period contradicts claims that the removal of donor anonymity would compromise donor insemination (DI) procedures through a reduction in donor numbers.

The conclusion that donor numbers were not adversely affected by the removal of anonymity is supported by data from the United Kingdom, which implemented changes within a similar time period.²⁷ Australia had an increase in total donor numbers of 42%, while the United Kingdom experienced a 6% increase in new donors²⁸ in the year that anonymity was removed. The difference in increases between the two countries may be partly due to total donors versus new recruits, as well as other factors such as the implementation of various recruitment campaigns.

Two individual clinics in Australia experienced a drop in the total number of sperm donors in the year after anonymity provisions were removed. In some subsequent years, those two clinics were able to improve recruitment and had higher numbers of sperm donors than in any year prior to anonymity removal. Additionally, our data collection failed to show an overall decrease in total sperm donor numbers in the year following anonymity removal; rather, for the clinics that we obtained data (on a whole, minus the comparison group Victoria), there was an increase of 42%. Concluding that any decline after 2005 is attributable to the change in policy is therefore problematic. There is evidence in the United Kingdom that a decline can occur in individual clinics,²⁹ despite a broader national data set that shows an increase in numbers,³⁰ which supports what we found in Australia. Other clinics in the United Kingdom have also reported an increase in donor numbers since the removal of anonymity but, more specifically, that they are also able to meet the demands on the supply of donated semen.³¹ More recently, the United Kingdom's largest sperm bank (London Sperm Bank), not only reported increased donor numbers to the point where it could meet the demand but also reported it was able to supply other clinics in the United Kingdom with sperm.³²

²⁷ Human Fertilisation and Embryology Authority, n 11; U Shukla et al, "Sperm Donor Recruitment, Attitudes and Provider Practices-5 Years After the Removal of Donor Anonymity" (2013) 28 Hum Reprod 676.

²⁸ "UK Sperm Donor Numbers Increase", BBC News, 3 May 2007 <<u>http://news.bbc.co.uk/2/hi/health/6618977.stm</u>>.

²⁹ Tomlinson et al, n 12.

³⁰ Human Fertilisation and Embryology Authority, n 11.

³¹ Shukla et al, n 27.

³² Kamal Ahuja, "Is the UK Sperm Donor Shortage a Myth?", *BioNews*, 18 May 2015 <<u>http://www.bionews.org.uk/</u>page.asp?obj_id=526622&PPID=526333&sid=820>.

While the States of Victoria, South Australia, Western Australia, and Tasmania had almost complete data capture for the entire period (mainly due to compulsory reporting in the former three States), the States of New South Wales and Queensland, which account for 63.8% (51/80) of all fertility clinics in Australia, had poor data capture rates of 27.6% and 22.7% respectively. The results therefore are a greater reflection of donation figures for Victoria, South Australia, Western Australia, and Tasmania.

What is not clear is whether any clinics adopted a different recruitment strategy pre- and post-NHMRC guidelines, and how this may or may not have affected the results seen in this study. If greater efforts were placed on recruitment post-NHMRC guideline introduction, this may explain why the data do not follow the suggested decline. It is a reason that the London Sperm Bank attributes to its rise in donor numbers.³³ Variation is observed during the entire period for Australia as a whole, for Victoria, as well as at the clinic level, with donor numbers going up and down year to year - but with an overall increase over the entire period surveyed. This variation could reasonably be expected as different recruitment strategies, as well as increased or decreased media coverage of donor conception stories and the subsequent need for sperm donors, may impact on the bottom line of sperm donor numbers from year to year. The influence that these factors may have on sperm donor numbers can be clearly seen in the comparison group Victoria, which had an increase of 66% in the year 2012. Subsequently, over the entire period studied, recruitment strategies and media coverage could potentially have a greater impact on sperm donor numbers than the removal of anonymity provisions. This may explain why Victoria also had a decrease in new recruits in 2005 when it should not have been affected by NHMRC guideline introduction, and also why new recruit figures for some years in the data available for the post-2005 period were higher than those recorded for the earlier period of this study.

It has been suggested that policy and practice should be changed to meet the demand for sperm donors.³⁴ On the basis of the data reported in Australia and those of the United Kingdom, imposing conditions of anonymity would not necessarily improve donor numbers. Rather, the data show that it is possible to increase total donor numbers if anonymity provisions are removed and an appropriate recruiting strategy is implemented.

In a review of studies of current and potential sperm donors, as well as non-donors' attitudes to donation, Van den Broeck et al³⁵ reported that if anonymity was removed, the majority of potential donors had negative attitudes toward anonymity removal in four of the studies analysed. The findings of our study, supported by the United Kingdom experience, show that the attitudes reported by Van den Broeck et al were not reflected in actual numbers, but rather that sperm donor numbers can increase after this policy change. While this may be due to improved or different recruitment strategies, there may also be a pool of potential donors in the community who did not donate previously because they were uncomfortable with the practice of anonymity. Whatever the reason, this study shows that in the Australian context, removal of anonymity does not result in a decline in sperm donors, but rather is positively correlated with an improvement in donor numbers.

LIMITATIONS OF THE STUDY

The data reported here are not comprehensive since data from all clinics could not be captured. The results therefore have limited power to describe the donation figures Australia-wide for the time period investigated. However, a strength of this study was the availability and inclusion of large State-based data collections.

³³ Ahuja, n 32.

³⁴ Nuffield Council on Bioethics, Human Bodies: Donation for Medicine and Research (2011) 84-90.

³⁵ U Broeck et al, "A Systematic Review of Sperm Donors: Demographic Characteristics, Attitudes, Motives and Experiences of the Process of Sperm Donation" (2013) 19 Hum Reprod Update 37.

Adams, Ullah and de Lacey

CLINICAL IMPLICATIONS

This study has demonstrated the value of large data collections that can be evaluated to answer clinical questions. Both policy-making and clinical practice could be guided positively by a national data collection and analysis of sperm donation figures. This could be achieved through the National Perinatal Statistics Unit, which already collects and reports data about other forms of infertility treatment and gamete use.

The removal of anonymity does not necessarily have the negative consequences proposed by some clinicians. Rather, changes in the regulation of sperm donation, and the removal of anonymity in particular, may harmonise clinic practice with the social context in which donor offspring regularly feature in the media searching for and meeting their donors. However, change requires adjustment and fresh approaches to recruitment. This study shows that the removal of anonymity, in conjunction with appropriate recruitment strategies, has the potential to result in improved, rather than decreased, numbers of sperm donors.