

A Review of Consent Documents From Canadian IVF Clinics, 1991 to 2014

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Abstract

Objective: We reviewed the content of IVF consent documents (i.e., consent forms and accompanying information sheets) used by Canadian IVF clinics in 1991, 2004, and 2014, paying particular attention to the inclusion of information that should be provided to patients in accordance with minimum ethical standards for disclosure.

Methods: We contacted all Canadian IVF clinics in operation in 1991 (17 clinics), 2004 (24 clinics), and 2014 (35 clinics) by mail and requested blank copies of their IVF consent documents. Documents received were reviewed for the inclusion of information about the nature of IVF, the potential benefits of IVF, the potential harms and inconveniences of IVF, confidentiality, voluntariness, and options for the use or discarding of embryos not transferred in the original stimulated cycle (sometimes referred to as supernumerary, excess, or spare embryos).

Results: We received responses from 11 of 17 clinics operating in 1991 (response rate 65%), 14 of 24 clinics operating in 2004 (response rate 58%), and 11 of 35 clinics operating in 2014 (response rate 31%). In general, comparisons of the 1991, 2004, and 2014 data sets showed a long-term decrease in documented disclosure of information that should be provided to patients in accordance with minimum ethical standards. The only cases in which this trend appeared to be reversed was with disclosure about the probability of supernumerary embryos, long-term risks of treatment, the right to revoke consent to the use or discarding of supernumerary embryos, and some of the options for the use of supernumerary embryos. In these few instances, there was a notable improvement in the disclosure of relevant information between 1991 and 2014.

Conclusion: The disclosure of information relevant to the interests of those undergoing IVF and those who are born as a result of IVF appears to be decreasing. Furthermore, the information that increasingly is being disclosed in consent documents appears to be directing the orientation and content of these documents away from the primary interests of the relevant women, couples, and children. These two trends are inconsistent with the goal of informed consent.

Key Words: In vitro fertilization, consent documents, consent forms, informed consent, disclosure

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Résumé

Objectif : Nous avons examiné le contenu de documents de consentement à la FIV (formulaires de consentement et fiches d'information complémentaire) utilisés par les cliniques canadiennes de FIV en 1991, 2004 et 2014. Nous avons accordé une attention particulière à l'inclusion des renseignements qu'on devrait fournir aux patientes, conformément aux normes de déontologie minimales de divulgation.

Méthodes : Nous avons communiqué par la poste avec toutes les cliniques canadiennes de FIV qui étaient en service en 1991 (17 cliniques), en 2004 (24 cliniques) et en 2014 (35 cliniques), en leur demandant de nous fournir une copie vierge de leurs documents de consentement à la FIV. Nous avons examiné les documents reçus afin de déterminer l'inclusion de renseignements sur la nature de la FIV, les avantages potentiels de la FIV, les dangers et les inconvénients potentiels de la FIV, la confidentialité, le caractère volontaire du consentement, ainsi que les options d'utilisation ou d'élimination des embryons non transférés (parfois désignés par les expressions « embryons surnuméraires », ou « embryons excédentaires ») lors du cycle de stimulation d'origine.

Résultats : Nous avons reçu des réponses de 11 des 17 cliniques en service en 1991 (taux de réponse de 65 %), de 14 des 24 cliniques en service en 2004 (taux de réponse de 58 %) et de 11 des 35 cliniques en service en 2014 (taux de réponse de 31 %). En général, la comparaison des ensembles de données de 1991, de 2004 et de 2014 a révélé une régression à long terme de la divulgation documentée des renseignements qu'on devrait fournir aux patientes, conformément aux normes de déontologie minimales. Les seuls cas dans lesquels cette tendance a semblé être inversée sont ceux qui traitent de la divulgation des probabilités relatives à la production d'embryons surnuméraires, des risques à long terme du traitement, du droit de révocation du consentement à l'utilisation ou à l'élimination des embryons surnuméraires, ainsi que de certaines des options d'utilisation des embryons surnuméraires. Dans ces rares cas, nous avons constaté une amélioration notable de la divulgation de renseignements pertinents entre 1991 et 2014.

Conclusion : La divulgation de l'information qui servirait les intérêts des personnes qui se soumettent à la FIV et de celles qui naissent grâce à la FIV semble aller en s'amenuisant. En outre, les renseignements de plus en plus divulgués dans les documents de consentement semblent en détourner l'orientation et le contenu des intérêts fondamentaux des femmes, des couples et des enfants concernés. Ces deux tendances entrent en contradiction avec le but du consentement éclairé.

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INTRODUCTION

In the early years of assisted human reproduction, Canadian IVF clinics operated without legal standards specific to consent for IVF. In the absence of legislation, there was considerable reliance on the substantive recommendations of the Royal Commission on New Reproductive Technologies Final Report, which was published in 1993 as a review and analysis of the “social, ethical, health, research, legal and economic implications” of new reproductive technologies in Canada.¹ Building on this report, the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynaecologists of Canada in 1999 issued the joint Policy Statement, “Ethical Issues in Assisted Reproduction.”² Then, in 2004, the Assisted Human Reproduction Act (AHR Act) received royal assent. The AHR Act (s.2(d)) stipulates that “the principle of free and informed consent must be promoted and applied as a fundamental condition of the use of human reproductive technologies.”³ Written consent from patients for the use of their reproductive materials to create an embryo, and for any subsequent use of their embryo(s), is required in the Act (s.8).³ In December 2007, the Assisted Human Reproduction (Section 8 Consent) regulations came into force.⁴

From an ethics perspective, for consent to be free and informed it must be undertaken intentionally and voluntarily by a competent person with an understanding “of the nature and foreseeable consequences of alternative courses of action or inaction,” following adequate disclosure of all necessary and relevant information.⁵ Such disclosure is required to properly ground the patient’s choice to authorize or refuse treatment. In this study we critically examine the content of IVF consent documents (i.e., consent forms and accompanying information sheets) used by Canadian IVF clinics in 1991, 2004, and 2014 in terms of their compliance with accepted minimum standards for adequate disclosure of relevant information.

By way of background for our own findings, we first begin with a discussion of the findings from a Royal Commission study on informed choice,⁵ in which informed consent is understood as a process of informed decision-making or choosing.⁶ To motivate concern for these issues, we briefly explain some of the purposes of consent documents and why disclosing information in writing is important for a variety of reasons, including the “value add” for patients. In this regard, we include a summary review of some of the evidence from a study for the Royal Commission on Canadian patients’ views regarding what information they

considered to be most important for consent to IVF treatment.

The Purposes of Consent Documents and Why They Matter

Signed consent forms for medical care serve to document that the consent process took place and that the patient authorized treatment.^{7,8} Historically, there have been (polarizing) debates on whether the need for a signed form is primarily a requirement for the protection of patients’ or health care providers’ and/or institutions’ interests.^{7,9} For example, several critics^{7,10} defend the view that the goal of consent forms first should be to promote the interests of patients. When used most appropriately, consent forms act as an adjunct to discussions between patients and health care providers that facilitate and document the informed consent process.⁷ According to Berg and Appelbaum, “(o)nly secondarily, and only insofar as they document actual informed consent, should they serve the interests of physicians, researchers, and institutions when questions of liability arise.”⁷ On the other hand, some view consent forms as a tool for shaping “what is intended as a process of dialogue and discussion into a discrete paper-signing event.”¹¹

Still, there are a number of reasons to take consent documents seriously. Consent documents are a form of medical record. Experiments for more than three decades show that these documents can serve as more than a health care provider’s work sheet or documentation of professional tasks performed and services delivered. As Fischbach et al. have noted, “[t]he record may become a vehicle for enhancing communication and collaboration between patient and provider.”¹² In this regard, consent documents (as quality assurance instruments⁹) have been used in some cases as proactive educational tools to better inform patients and to foster their sense of control and mutual responsibility for decision-making in partnership with their health care providers.^{7,13,14} A review article on implementing shared decision-making¹⁵ cited by the Royal Commission showed that facilitating the capacity of women and couples to assume a more active role in their care improved results obtained through IVF, whereas a lack of information or choice could increase the risk of negative outcomes.¹

Unfortunately, there is a dearth of research on the role that consent documents play in the IVF consent process. Evidence from other medical contexts, however, shows that written information documents promote disclosure and facilitate patient understanding. For instance, in a study of the quality of information given to participants

in a gynaecological trial, Lynöe et al. found that patients who received both oral and written communications scored better than those who received only oral communications on measures of knowledge regarding the aim of the study, the possibility for withdrawal, and the pros and cons of participation.¹⁶ Moreover, several studies of postoperative patient recall confirm that patients who received written communications were significantly better able to recall relevant information than were control patients who received only verbal communications, with the implication being that those who received written communications entered surgery better informed.^{17–19}

In addition to the practical benefits of having a written record to which both patients and health care providers can refer, written consent is preferable to oral consent from a legal perspective because it usually is more precise²⁰ and it can be used as evidence should a dispute arise in the future.^{21,22} As Nelson argues, “the content of the consent form can provide an evidentiary basis for conclusions about the content of the dialogue between the health care provider and the patient.”²¹ And according to the Canadian Health Facilities Law Guide, “(i)deally, the form should set out what the patient was actually told: the patient’s condition should be outlined, the proposed procedure, along with its risks, should be described, and the alternative courses of treatment available should be set out.”²⁰

Disclosure Requirements for Quality Consent to IVF Treatment

What should be the minimum informational content of IVF consent documents? According to Freedman,²³ to answer this question properly one must first know the purpose for which information is needed. Why must the patient be informed? Obviously, the patient must be informed so that she or he will know what she or he is getting into, what she or he may expect from the procedure, what her or his likely alternatives are—in short, what the procedure (and refusing it) will mean, so that a responsible decision on the matter may be made. This is not only the legal stance but what seems like the logical and “commonsensical” way to think about it.²³ Freedman concludes by pointing to Capron’s²⁴ astute observation that in a valid consent, “the information component derives in law from the recognition that information is ‘necessary to make meaningful the power to decide.’”²³

If the informational content required for a valid consent is to be determined by what is necessary for the patient to be able to make a sound decision to pursue or refuse IVF

treatment, then answering the question “what should be the minimum informational content of IVF documents?” is also an important step towards patient empowerment. However, very few studies have provided in-depth insights into patients’ perspectives with respect to infertility care,²⁵ and physicians seem to have underestimated the importance of patient-centredness.²⁶ As documented by the Royal Commission, women undergoing IVF reported that a lack of information seriously hindered their ability to make informed decisions. The following four areas of concern were identified: 85% of respondents believed it most important for them to know about their personal chances of having a child, 82% prioritized knowing about the long-term effects of treatment, 81% wanted information about the emotional demands of IVF, and 80% placed strong significance on knowing the short-term effects of treatment.¹ Less than 50% were satisfied with the information received in these areas.^{1,27} Regrettably, in the more than 20 years since the Royal Commission’s 1993 report, there have been no comparable follow-up studies in Canada documenting information about what patients say they need to know before undertaking or refusing IVF treatment. For other jurisdictions, more recent discussions of some patients’ concerns about the validity and quality of informed consent in IVF clinics are available.^{28,29}

METHODS

On March 22, 1991, all 17 Canadian IVF clinics in operation at that time were sent a letter requesting blank copies of written processes, consent forms, and educational materials in their use at that time. On July 19, 2004, a similar letter was sent to all 24 Canadian IVF clinics in operation at that time requesting blank copies of present and past consent documents. And, most recently, on March 29, 2014, all 35 Canadian IVF clinics in operation at that time were sent a letter requesting blank copies of the following specific consent documents: (1) consent to use one’s own oocytes to create embryos to be used for one’s own IVF treatment, (2) consent to use one’s own embryo(s) for the purposes of one’s own IVF treatment or the IVF treatment of one’s partner, and (3) consent to undergo IVF treatment. With the 2014 request, specific consent documents were enumerated in an effort to streamline the request, given the recent proliferation of consent documents for various interventions.

The documents from 1991, 2004, and 2014 were reviewed for the inclusion of information elements regarding the nature of IVF, the potential benefits of IVF, the potential harms and inconveniences of IVF, confidentiality,

voluntariness, and options for the use or discarding of embryos not transferred in the original stimulated cycle (sometimes referred to as supernumerary, excess, or spare embryos). These particular disclosure elements were drawn from previous work by one of this study's authors (F.B.) for the Royal Commission.⁵

Specific guidance on consent requirements for IVF is either lacking or underdeveloped in Canada. Even though the joint policy statement by the Canadian Fertility and Andrology Society and the Society of Obstetricians and Gynaecologists of Canada, "Ethical Issues in Assisted Reproduction," includes consent recommendations for various AHR technologies, these recommendations address adjunct interventions such as gamete donation and not the core intervention of IVF.² The AHR (Section 8 Consent) regulations, which came into effect in December 2007, focus narrowly on rules for the creation and use of human embryos. These regulations specify that before making use of human gametes (sperm and oocytes) for the purpose of creating human embryos, the gamete donors must sign two documents—one document attesting to the fact that they have been informed in writing of a limited set of permissible options for the use of any resulting embryo(s), including use for one's own reproductive purposes (AHR (Section 8 Consent) regulations, s.3) and a second document authorizing the specific use(s) of any embryo(s) created (AHR (Section 8 Consent) regulations, s.4). The regulations are silent on consent requirements other than those related to the use of embryos (Table). Furthermore, even though the SOGC has published "Informed Consent to Donate Embryos for Research" guidelines,³⁰ it is silent on other consent requirements relevant to IVF treatment.

The most comprehensive recommendations specific to consent to IVF treatment and published in Canada are those provided by one of this study's authors (F.B.) to the Royal Commission.⁵ According to those recommendations, for patients with infertility or research participants to make informed choices about whether to refuse or authorize a specific AHR intervention (including IVF), they require a range of information, including the following⁵:

1. A description of the patient's or research participant's current medical status (i.e., diagnosis and prognosis);
2. Information about the nature and objective(s) of the proposed intervention and similar information about available alternatives and adjunct interventions;
3. Information about the nature and probability of the known and possible consequences (i.e., benefits, harms, and inconveniences) of the various options (i.e.,

the proposed intervention, alternative interventions, and the option of no intervention);

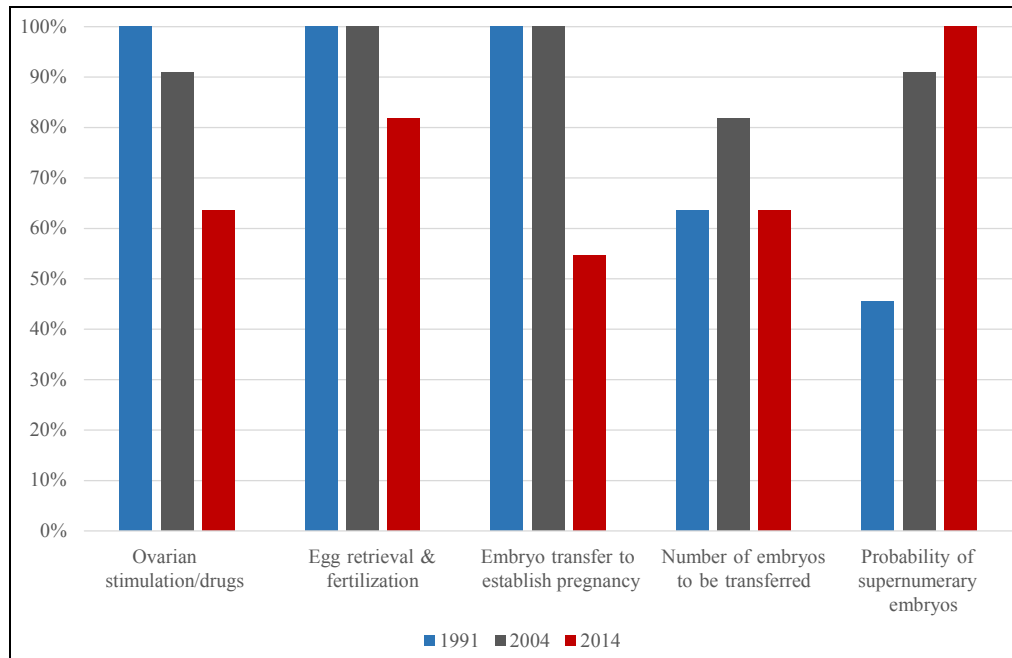
4. Information about the qualifications and experience of the various team members;
5. Information about the costs involved;
6. Additional information that may assist a prospective patient or research participant to make an informed choice;
7. A statement that the research participant or patient may ask questions now and later;
8. A statement that confidentiality will be respected;
9. A statement that the patient or research participant may refuse to participate without jeopardizing access to health care; and
10. A statement that consent and refusal are revocable (i.e., in principle, the patient or subject may withdraw her/his consent or overturn her/his previous refusal without jeopardizing access to health care).

It was recommended that, at a minimum, these 10 discrete items of information should be disclosed to patients (or prospective research participants) in order to allow (and empower) them to make informed choices.⁵

These ethical standards for full disclosure, developed at a time when AHR arguably was an innovative practice and not a therapy, are closely allied to the legal norms of disclosure for consent to medical treatment. Dickens has stated that, in principle, a physician who is seeking consent from a patient for a proposed medical treatment must disclose the information elements 1, 2, 3, and 7 in the aforementioned list in addition to "the limits of relevant knowledge, and the areas in which it appears that more needs to be learned," "matters concerning which the patient specifically enquires" (arguably captured by the aforementioned information element 6), and "the physician's recommendation about whether treatment should be undertaken."³¹ Furthermore, Rozovsky has argued that adequate disclosure of information for medical treatment includes the aforementioned information elements 2, 3, 4, and 5 in addition to "the impact of treatment on the patient's lifestyle" (arguably captured by the aforementioned information element 6) and "who is to perform the procedure" (arguably captured by the aforementioned information element 4).⁹ As such, the ethical standards for disclosure (including information elements 1 to 10) as outlined in the above study provided to the Royal Commission are not to be understood as aspirational; they are, instead, minimal requirements of disclosure that also have been asserted by leading Canadian legal academics.⁵

Table. Information Elements for Informed Consent to IVF

Information about the nature of IVF	1991	2004	Regulations (2007)	2014
Ovarian stimulation/drugs	100%	91%	—	64%
Egg retrieval and fertilization	100%	100%	—	82%
Embryo transfer to establish pregnancy	100%	100%	—	55%
Number of embryos to be transferred	64%	82%	—	64%
Probability of supernumerary embryos	45%	91%	✓	100%
Information about the potential benefits of IVF	1991	2004	Regulations (2007)	2014
Pregnancy rates	64%	45%	—	9%
Live birth rates	55%	9%	—	9%
Information about the potential harms and inconveniences of IVF	1991	2004	Regulations (2007)	2014
Risk of multiples	91%	100%	—	73%
Risk of egg fertilization failure	64%	91%	—	45%
Risk of not establishing a pregnancy	91%	100%	—	64%
Risk of miscarriage/spontaneous abortion	73%	64%	—	36%
Risk of birth abnormalities in offspring	73%	100%	—	73%
Risk of ovarian hyperstimulation	82%	73%	—	55%
Risk of tubal/ectopic pregnancy	73%	64%	—	55%
Long-term risks are possible or are unknown	27%	9%	—	45%
Information about confidentiality	1991	2004	Regulations (2007)	2014
Statement about respect for and/or limits to confidentiality	55%	36%	—	27%
Information about voluntariness	1991	2004	Regulations (2007)	2014
Statement about alternatives to IVF, and/or option of no treatment, and/or right to refuse treatment	27%	36%	—	27%
Statement about right to revoke consent to (or refusal of) IVF treatment	55%	55%	—	55%
Statement about right (and/or limitations) to revoke consent to the use or discarding of supernumerary embryos	0%	45%	✓	100%
Information about options for the use or discarding of supernumerary embryos	1991	2004	Regulations (2007)	2014
Cryopreservation	27%	100%	—	82%
Reproductive use by third party	0%	55%	✓	55%
Improving AHR	0%	9%	✓	100%
Providing instruction in AHR	0%	0%	✓	100%
Specific research project	0%	73%	✓	55%
Discard	18%	100%	—	73%
Information about options for the use or discarding of supernumerary embryos in the event of the donor's death	1991	2004	Regulations (2007)	2014
Partner's use	0%	45%	✓	82%
Reproductive use by third party	0%	18%	—	18%
Improving AHR	0%	0%	✓	55%
Providing instruction in AHR	0%	0%	✓	55%
Specific research project	0%	27%	✓	45%
Discarding	0%	64%	—	64%
Information sheet	1991	2004	Regulations (2007)	2014
Information sheet named in consent form	55%	73%	—	100%
Information sheet made available to authors	82%	55%	—	18%

Figure 1. Information about the nature of IVF

Even though 10 information elements for consent to IVF were recommended to the Royal Commission, only five of these elements (2, 3, 8, 9, and 10) were reviewed for this study. Information elements 1, 4, 6, and 7 were not reviewed because, although relevant written information for these elements may be included in consent documents, such information simply could be discussed with patients and the conversation then documented in the patient's chart. Although these are essential information elements for informed consent, it is not essential that they be included in written consent documents. Information

relevant to element 5 (about the cost of IVF) should be provided in writing, but there are good reasons for this information to be provided in a separate document.

More than 500 pages of written documents from 1991 through 2014 were reviewed for the inclusion of information elements regarding (1) the nature of IVF (captured by the aforementioned element 2); (2) the potential benefits (captured by the aforementioned element 3) and (3) the potential harms and inconveniences of treatment (also captured by the aforementioned element 3); (4) assurances that confidentiality will be respected (captured by the aforementioned element 8); and (5) voluntariness (captured by the aforementioned elements 2, 9, and 10). This refined list captures most of the priority information elements identified by patients undergoing IVF (as previously described) and most of those prescribed by the *Canadian Health Facilities Law Guide* for the ideal consent form.²⁰

A binary scoring system was used to indicate whether an information element was present or absent. An information element was deemed present if there was any mention of the element (e.g., use of relevant word[s] without any accompanying explanation, or reference to only one part of a composite information element). Each data set was reviewed at least twice. The findings are reported in aggregate form as a percentage of the total clinics in each data set that were found to have included the relevant information element under review.

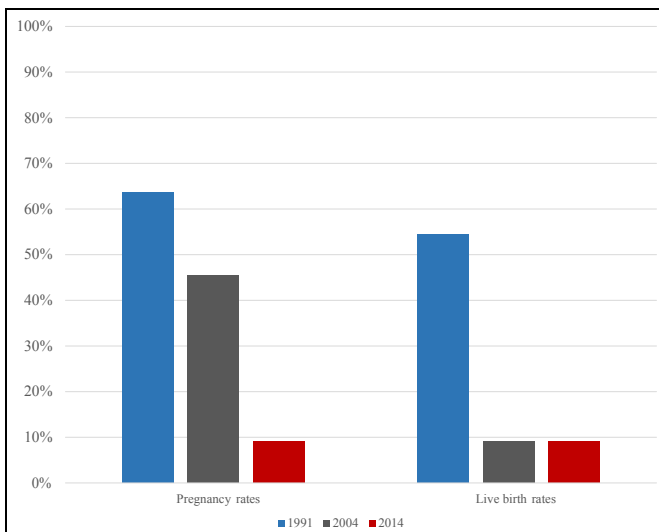
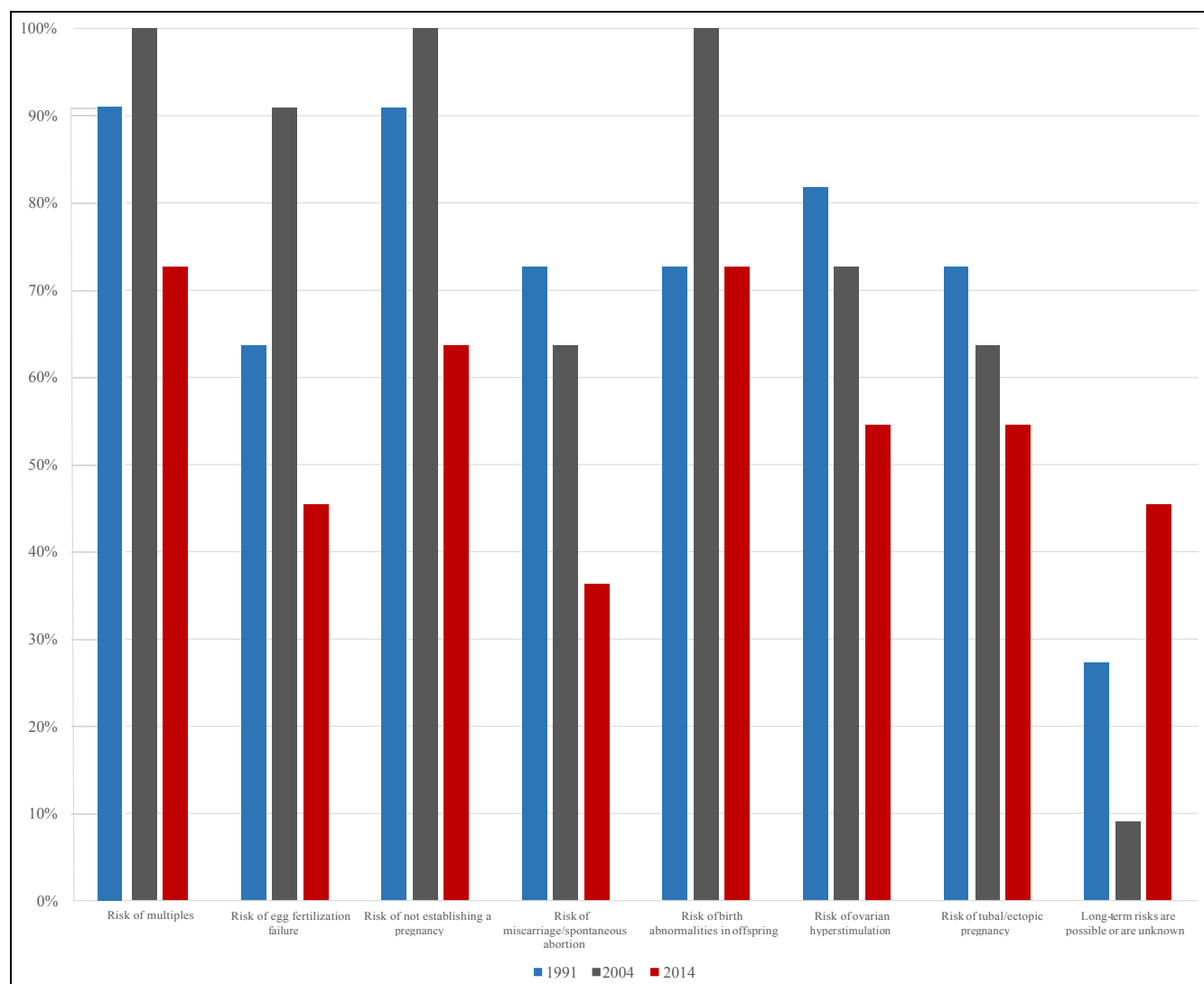
Figure 2. Information about the potential benefits of IVF

Figure 3. Information about the potential harms and inconveniences of IVF

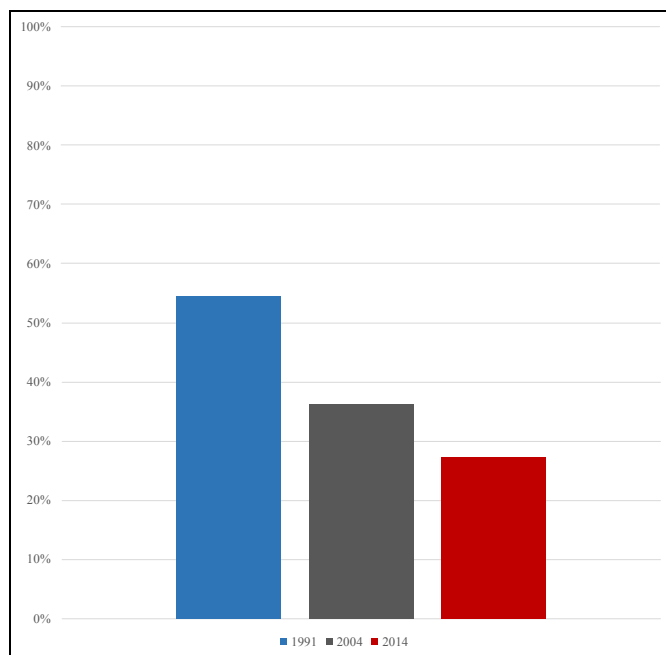
RESULTS

Eleven of 17 clinics responded in 1991 (response rate 65%), 14 of 24 clinics responded in 2004 (response rate 58%), and 11 of 35 clinics responded in 2014 (response rate 31%). In general, comparisons of the 1991, 2004, and 2014 data sets (Figures 1 to 7; see Table) show a long-term decrease in documented disclosure of information that should be provided to patients in accordance with minimum ethical standards. The only cases in which this trend appears to be reversed is with disclosure about the probability of supernumerary embryos (see Figure 1), long-term risks of treatment (see Figure 3), the right to revoke consent to the use or discarding of supernumerary embryos (see Figure 5), and some of the options for the use of supernumerary embryos (see Figures 6 and 7). In these few instances, there has been a notable improvement in

the disclosure of relevant information between 1991 and 2014.

DISCUSSION

Information given to patients about the nature of a proposed intervention (and available alternatives) usually involves a description of its different stages and the measures required to get to each of these stages. IVF normally is broken down into at least five stages, including the administration of drugs for controlled ovarian stimulation, oocyte retrieval, semen collection, in vitro fertilization, and embryo transfer. Disclosures about the number of embryos to be transferred in an IVF cycle and the probability that there will be more embryos created in the initial cycle than will be transferred are shown in Figure 1. The information elements relevant to the stages of IVF treatment

Figure 4. Information about confidentiality

are all proportionately more present for the 1991 and 2004 data sets than for the 2014 data set. Information regarding the number of embryos to be transferred is highest for the 2004 data set and is almost equal in the 1991 and 2014 data sets. In each succeeding study sample, information pertaining to the likelihood that IVF will result in supernumerary embryos becomes proportionately more present, with 100% documented disclosure of this information in the 2014 data set.

With regard to information elements related to the benefits of IVF, patients not only want to know their chances of getting pregnant, but more importantly their chances of having a healthy child. As Baylis noted in her review for the Royal Commission: “In deciding whether to authorize or refuse IVF, couples typically weigh the potential benefit of having a child against the potential harms of IVF. For their choice to be informed, the take-home-baby rate (which is consistently lower than the pregnancy rate) must be disclosed and emphasized.”⁵ Information about pregnancy rates and live birth rates are shown in Figure 2. These information elements are more strongly represented in the 1991 data set than either of the subsequent data sets.

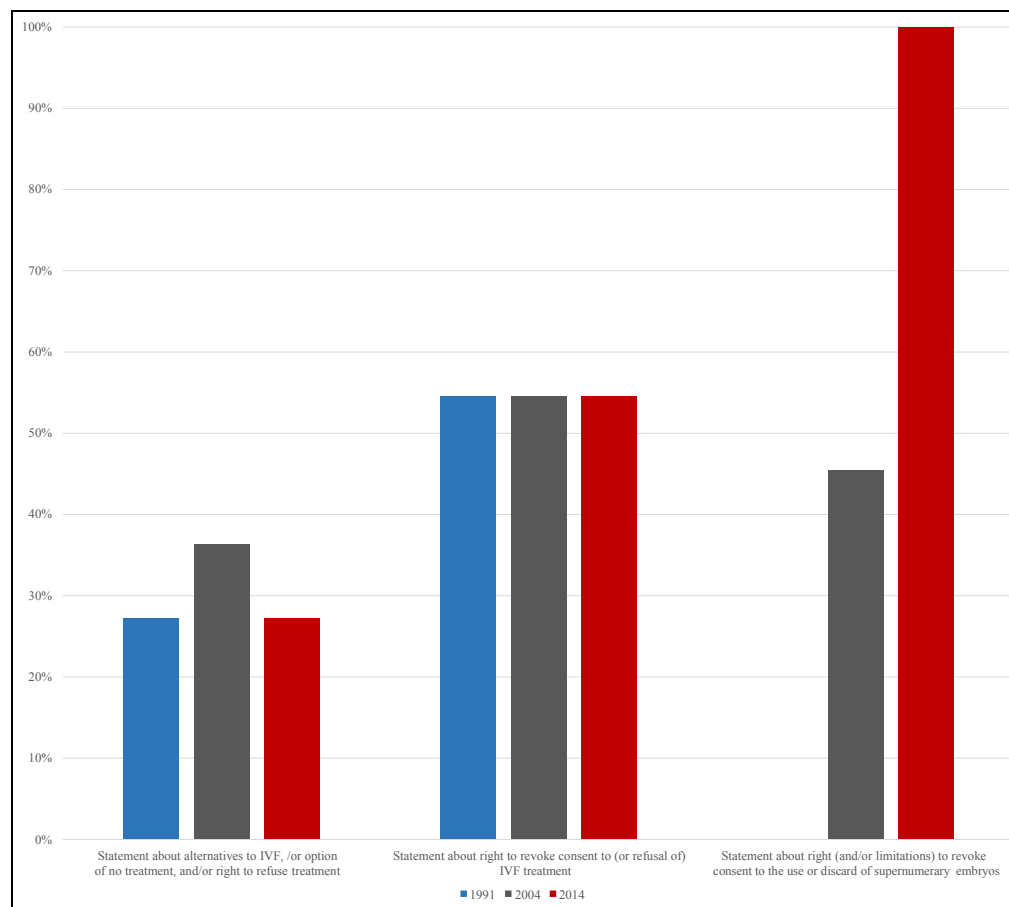
In discussing the needs of former IVF patients, Su and Chen have noted that “(i)nformed consent for IVF infertile women should include both the positive and the negative information.”²⁹ The potential harms include the risk of multiples, the risk of failure of fertilization, the risk of not establishing a pregnancy, the risk of

miscarriage/spontaneous abortion (i.e., risk of not achieving a live birth), the risk of abnormalities in the offspring, the risk of ovarian hyperstimulation syndrome, and the risk of tubal/ectopic pregnancy. In addition, there are “possible” or “unknown” long-term risks. For every comparative measure of the potential harms or inconveniences listed in Figure 3, the 1991 data set is more comprehensive in the disclosure of these information elements than the 2014 data set, with the exception of the last entry (that long-term risks are possible or are unknown). For some of these information elements there is more disclosure in the 2004 documents than the 1991 documents, but this difference is not sustained over time.

Whether the consent documents included information about any measures taken to respect patient confidentiality and whether any limits were imposed on this obligation is shown in Figure 4. All data sets show that a large proportion of clinics do not ensure that patients are informed of respect for (and limitations on) confidentiality, with a stronger showing from the 1991 data set and a steady decline subsequently.

The availability of informational content relevant to ensuring that patients’ choices regarding treatment are both informed and voluntary is shown in Figure 5. Infertile women in an IVF clinic may be situationally vulnerable insofar as they function “in a dependent relationship with those who potentially have the power to help them overcome their infertility.”⁵ In this regard, consent must be informed to avoid the potential for coercion.^{27,32,33} As Raab has noted, “disclosure should always include the possibility of no treatment at all and the anticipated consequences of that course. Any undisclosed treatment alternatives, or withholding the option to do nothing, can be construed as an imposition of the physician’s choices upon the patient’s power to decide.”¹¹ This is further discussed by Morris.³⁴

The inclusion of statements to ensure that patients received information about alternatives and that steps were taken to ensure the voluntariness of their consent also is shown in Figure 5. More specifically, the content analysis sought statements about: (1) alternatives to IVF, including the option of no treatment (and/or the right to refuse treatment); (2) the right to revoke consent to, or refusal of, IVF treatment (i.e., the right to change one’s mind); and (3) the right (and/or possible limitations on this right) to revoke consent to the future use or discarding of supernumerary embryos. For the first measure, the 1991 and the 2014 data sets are almost equivalent, with a modest improvement in the 2004 data set. For the second measure, the 1991, 2004, and 2014 data sets are almost equivalent and all are below

Figure 5. Information about voluntariness

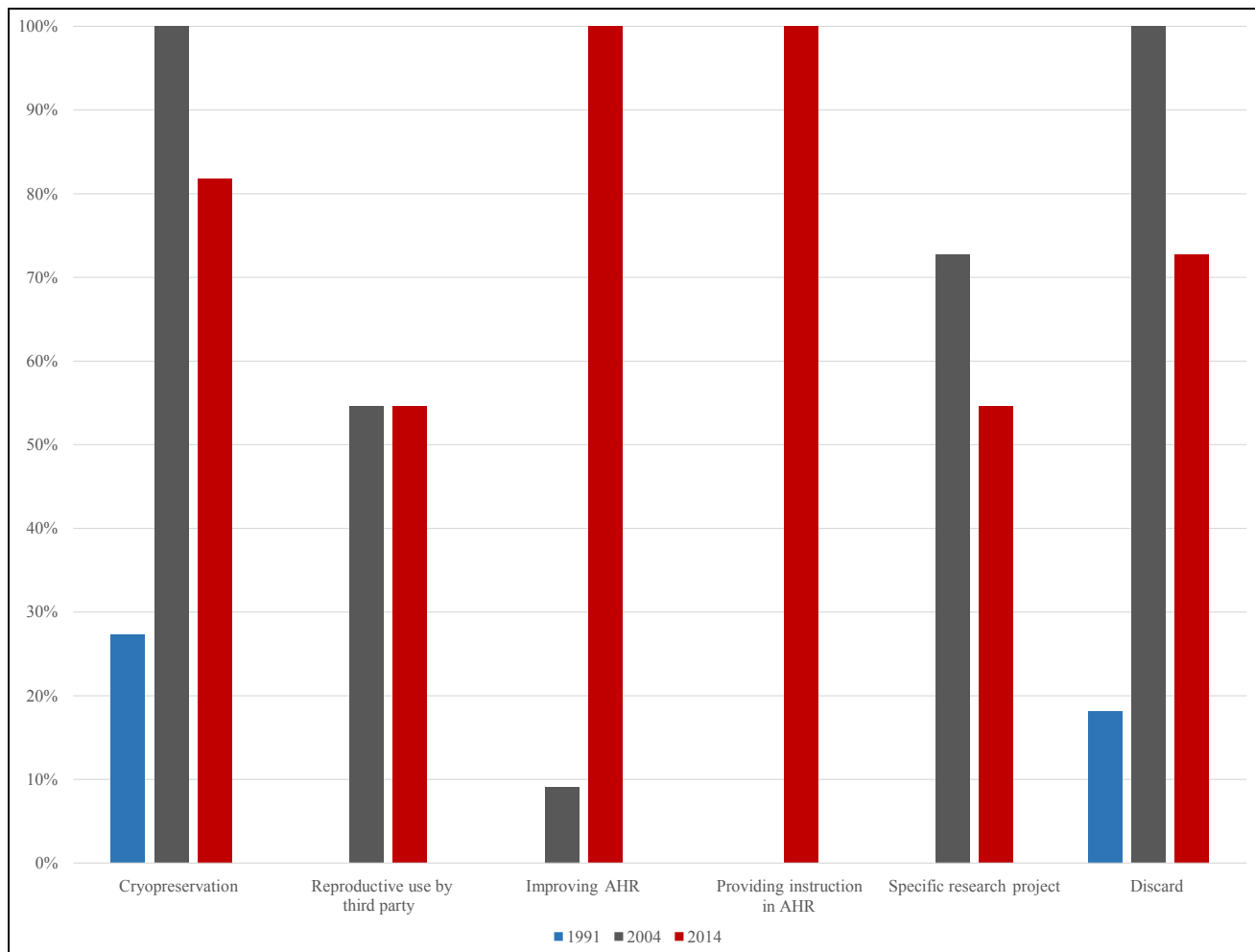
55% compliance. Only the third measure shows steady improvement, from 0% in 1991 to 100% in 2014 (see Figure 5).

Whether patients received information about options for the use or discarding of supernumerary embryos is shown in Figure 6. These options, consistent with clinical practice, include (1) cryopreservation for own reproductive use; (2) reproductive use by a third party; (3) improving assisted reproduction procedures; (4) providing instruction in assisted reproduction procedures, (5) a specific research project, and (6) discarding. The options of cryopreservation for own use (option 1) and discarding (option 6) are disclosed in 27% and 18%, respectively, of the 1991 data set, in 100% for both options of the 2004 data set, and in 82% and 73%, respectively, of the 2014 data set. We cannot explain these variations. For the remaining options there is no disclosure in 1991, but by 2014 there is 100% disclosure with respect to two of the options, namely improving assisted reproduction procedures (option 3) and providing instruction in assisted reproduction procedures (option 4). Because options 2, 3, 4, and 5 have been entrenched in law and regulation since 2007

(see Table), we would have expected 100% compliance for all of them in the 2014 data set.

Disclosures about options for use and discarding of embryos that a donor may consent to in the event of her own death are shown in Figure 7. None of these are discussed in the 1991 consent documents, but they are discussed in both the 2004 and 2014 documents. Even though there is near equivalence for disclosure of the options of donation for reproductive use by a third party (option 2) or discarding (option 6), there is a notable improvement from 2004 to 2014 in terms of the options of donation for partner's use (option 1), improving assisted reproduction procedures (option 3), providing instruction in assisted reproduction procedures (option 4), and donation to a specific research project (option 5). Of note, the AHR (Section 8 Consent) regulations (see Table) only require the disclosure of information for options 1, 3, 4, and 5 listed in Figure 7. Arguably, the option of discarding is not included in the regulations because the regulations are about "use." What then are we to make of the fact that option 2, reproductive use by a third party in the event of the donor's

Figure 6. Information about the options for the use or discarding of supernumerary embryos



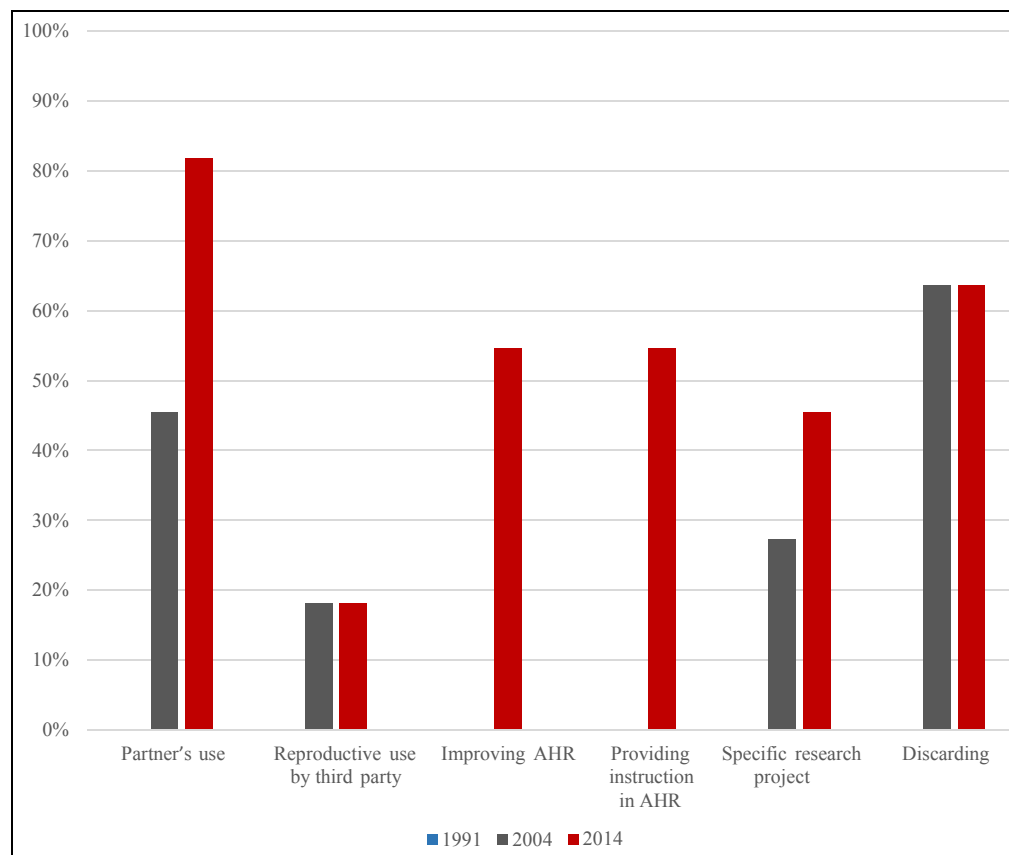
death, is not a required disclosure element? This raises important questions for the 2014 consent documents (created after the AHR (Section 8 Consent) regulations) that include this option.

For almost all information elements assessed, comparisons of the 1991 and 2014 data sets show a decrease in quality with respect to the documentation demonstrating compliance with minimum standards for the disclosure of information necessary for informed choice. As such, the results of this study are worrisome. Relevant Canadian law and regulation are focused primarily on matters concerning the creation and use of human embryos and virtually silent on matters concerning treatment of the relevant patients and protection of their interests. The consent documents are getting longer and the language used is becoming more technical and complex. The content and style seem increasingly geared to providing legal protection for IVF clinicians and clinics, rather than clarity of understanding for patients.^{35,36}

Presumably the ideal of consent always should be to offer as much control as possible to patients by giving them the appropriate information for them to make informed choices about whether to authorize or refuse treatment. Falling short of this ideal may be rooted in structural factors despite the best efforts of many health care providers. In 1993 the Royal Commission reported that “there was no uniformity in programs’ information and procedures and that many did not measure up to the standard of informed choice for patients.”¹ The data from this content analysis suggest that this limitation persists, which means that little has changed since Baylis reported to the Royal Commission that “different facts and different policies at different clinics constrain decision making in different ways.”⁵

Although there is some division in the literature on the suitability of consent documents for obtaining consent in all contexts, and although consent (regardless of context) is a process involving much more than consent documents,^{21,37,38} documentation of consent nonetheless is

Figure 7. Information about options for the use or discarding of supernumerary embryos in the event of the donor's death



“an indispensable step in responsible oversight.... A satisfactory consent process requires more than a good consent form, but a bad consent form not only makes a satisfactory process unlikely, it makes documenting whether the process was satisfactory ... extremely difficult.”³⁹ The failure to meet minimum disclosure standards across Canadian IVF clinics’ consent documents suggests the need for high-quality standard templates that could be used to ensure quality of consent. The challenge in Canada is how best to effectively promote the development of such templates and motivate their widespread use.

A limitation of this study is that certain information elements deemed to be missing routinely may be provided to patients in print or web-based documents that were not provided to us for review. With each succeeding data set, the proportion of clinics citing an information sheet on their consent form(s) increased, yet the proportion of clinics making information sheets available for review decreased (see [Table](#)).

Another limitation of this study is the marked reduction in clinic participation over time. Participation was voluntary,

and the 2014 data set represents at most one third of Canadian IVF clinics (excluding satellite clinics). However, the total number of clinics responding to each request has remained relatively stable. In fact, most of the clinics that participated in 1991 continued their participation in 2004 and 2014.

CONCLUSION

We reviewed the content of consent forms and accompanying information sheets used by Canadian IVF clinics (obtained in 1991, 2004, and 2014) with respect to documented inclusion of information that should be provided to patients in accordance with minimum ethical standards for disclosure. This included information about the nature of IVF, the potential benefits of IVF, the potential harms and inconveniences of IVF, confidentiality, voluntariness, and options for the use or discarding of embryos not transferred in the original stimulated cycle. In general, comparisons of the reviewed data sets showed a decrease over time in the documented disclosure of information on consent documents. The only cases in which this trend appeared to

be reversed was with disclosure about the probability of supernumerary embryos, long-term risks of treatment, the right to revoke consent to the use or discarding of supernumerary embryos, and some of the options for the use of supernumerary embryos.

Overall, the disclosure of information in Canadian IVF clinics relevant to the interests of those who use IVF and those who are born following IVF appears to be decreasing. The information that increasingly is being provided on the relevant IVF consent forms and information sheets appears to be distorting the orientation and content of these consent documents away from the primary interests of women, couples, and children. These two trends are inconsistent with the primary goal of informed consent, which should be to promote the interests of patients and ultimately empower them.

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