Title:

Fertility Preservation Toolkit: A clinician resource to assist clinical discussion and decision making in pediatric and adolescent oncology

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Abstract

Purpose: Discussions of Fertility Preservation (FP) in children with cancer presents unique challenges due to ethical considerations, lack of models-of-care and the triadic nature of discussions. This study evaluated a fertility toolkit for clinicians involved in FP discussions with pediatric, adolescent and young adult patients and parents.

Methods: A survey-based, longitudinal study of clinicians at The Royal Children's Hospital Melbourne involved in FP discussions undertaken at three time-points: 2014, alongside an education session for baseline assessment of oncofertility practices (Survey 1); After each toolkit use to evaluate case-specific implementation (Survey 2); 2016, to evaluate impact on clinical practice (Survey 3).

Results: Fifty-nine clinicians completed Survey 1. Over 66% reported baseline dissatisfaction with the existing FP system; 56.7% did not feel confident in providing up-to-date information. Only 34.5% "often" or "always" provided verbal information; 14.0% "often" or "always" provided written information. Survey 2 was completed after 11 consultations. All clinicians were satisfied with the discussions and outcomes using the toolkit. Thirty-nine clinicians completed Survey 3. Over 70% felt confident providing up-to-date FP knowledge, 67.7% "often" or "always" provided verbal information, and 35.4% "often" or "always" provided written information.

Conclusions: Clinicians desire improvement in FP practice. A FP toolkit provided significant perceived and actual benefits.

INTRODUCTION

Over 80% of children, adolescents and young adults (AYA) diagnosed with cancer survive to adulthood.¹ As a result, the focus of clinical management has broadened

to include survivorship issues. Fertility impairment is a major survivorship consideration, and is impacted by the cancer diagnosis and treatment.² Impaired fertility can affect long-term wellbeing, relationships and life decisions, with childless cancer survivors at risk of infertility-related traumatic stress symptoms, as well as other traumatic sequelae.^{3, 4}

Discussing treatment effects on fertility is important to patients and their families.⁵ Lack of fertility information increases distress, while empowerment and reduced anxiety is reported when fertility discussions occurred or when fertility preservation (FP) procedures are actually undertaken.⁶⁻⁹ Previous research has shown only 25% of parents of children aged 10-14 years had a fertility discussion with their oncologist, less than 30% of parents of patients aged over 14 years were satisfied with the amount of fertility information provided, and over 60% wanted to discuss fertility preservation further.^{10,11}

International bodies now recommend discussion of fertility risks and options prior to cancer treatment as part of routine care.^{12,13} However, such discussions can be difficult for clinicians due to feeling underprepared for initiating the topic, time constraints, the volume of information already given at diagnosis, or deciding it is not necessary as a component of providing the best care for the patient.¹⁴ Other barriers include a lack of efficacy data for treatments and models of FP care, and a dearth of educational resources, training and access to fertility specialists.¹⁵⁻¹⁸ A survey of clinicians organising haematopoietic cell transplants in the United States showed that the majority of clinicians did not provide FP educational materials to patients, even though available, because 65% felt the material was irrelevant.¹⁶

It is known that pediatric oncology clinicians would greatly appreciate and welcome a systemized approach to discussing FP, and the requirements of such a system have been established.^{15,19} While the need for a systemized approach to FP has been identified, the way this should be conducted is yet to be established. Oncofertility management is time sensitive and potentially requires the oncology team to collaborate and coordinate between disciplines, departments, and even hospitals. The inclusion of clear oncofertility guidelines to inform practice will assist in establishing a consistent approach to FP, allowing patients and families an equal opportunity to receive the most efficient, up-to-date information possible.

This study employed the use of a FP toolkit for clinicians to facilitate the communication of up-to-date, consistent information about fertility risk and preservation options to all newly diagnosed pediatric oncology patients/families. This practical resource included a clinician instruction booklet, checklist, referral forms, reference information regarding fertility risk of cancer treatments, and handouts for patients and families. The aim of this study was to evaluate clinician responses before and after the introduction of a newly developed FP toolkit and their perceptions on its acceptability and efficiency in facilitating FP discussions.

METHODS

This longitudinal study was conducted at the Children's Cancer Centre (CCC), Royal Children's Hospital (RCH) Melbourne. Research ethics approval was obtained through the RCH Human Research Ethics Committee (HREC 34062 & 36016). The RCH offers FP discussions and procedures (sperm collection, oocyte collection,

ovarian and testicular tissue collection) under three levels of governance: i) institutional governance as a novel technology; ii) research ethics governance for collection of safety and efficacy data; iii) clinical ethics governance for individual cases. Prior to the development of the FP toolkit, fertility discussions and procedures were undertaken in an ad hoc manner.

Materials

Toolkit

A FP toolkit was created by the Fertility Preservation Taskforce at The RCH, Melbourne. The Fertility Preservation Taskforce is a collaborative association of oncologists, fertility specialists, gynaecologists, and paediatric providers. The toolkit was designed to include educational materials for clinicians, families, and patients. The individual components of the toolkit are listed in Table 1.

Procedure

The study was carried out in 3 separate phases. Phase 1 (April-June 2014) served as a baseline assessment and evaluated current FP clinical practice and the perceived potential impact of the FP toolkit. Following this evaluation, the toolkit was implemented in clinical practice. Phase 2 (June-August 2014) assessed clinicians' attitude to the toolkit after clinical use. Phase 3 (June-August 2016) evaluated the actual impact on FP clinical practice after 2 years of use.

Phase 1

All clinical staff involved in the care of oncology patients at the RCH Melbourne were invited to participate, including medical, nursing, and allied health disciplines. Clinical

staff were excluded if they are only involved in fertility care for non-oncology patients. Participants also attended an education session designed to introduce staff to the toolkit and provide training on the concept, contents, and use of the toolkit. Immediately following the education session, participants completed an 18-question survey assessing baseline FP practice pre-toolkit implementation (Survey 1). The survey assessed participants' confidence levels in discussing FP, their satisfaction with the current system, and their understanding of and predicted benefits and weaknesses of the proposed toolkit (e.g. "How confident are you in your ability to provide up-to-date knowledge regarding fertility preservation?" "How often do you provide verbal information to new patients and families at diagnosis?"). The survey was developed based on existing research literature and the clinical and research expertise of the research team. Survey responses were recorded on a 5 point Likert scale ranging from "strongly agree" to "strongly disagree", or with free text.

Phase 2

Clinical staff who had completed a FP consultation at the RCH Melbourne in the 8-week period following the introduction of the toolkit were invited to participate.

Participants were invited to complete a survey immediately after each new patient FP consultation where the FP toolkit was used (Survey 2). A 25-question survey developed specifically for the study was utilized. The survey assessed details of the patient (including stage of pubertal development, gender and diagnosis), the time required for preparation and duration of discussion, discussion topics, any problems, deviations or improvements regarding the kit, as well as the satisfaction levels of those involved in the discussion (e.g. "Was the patient present for the discussion regarding fertility preservation?" "Was the discussion dedicated to fertility alone?").

Phase 3

In June-August 2016, two years after toolkit introduction, all clinical staff involved in the oncofertility care at the RCH Melbourne were invited to participate, including medical, nursing, and allied health disciplines. Participants were invited to complete a 13-question survey assessing their attitudes and practice towards FP (Survey 3). Questions around confidence levels in discussing FP, satisfaction with oncofertility care, and their provision of written and verbal information were identical to those in Phase 1 (2014). In the two years since implementation, there were no significant modifications made to the toolkit.

Statistical analyses were conducted using Stata/IC 11.11 (StataCorp, 2013). Results were summarised and reported largely as a descriptive study.

RESULTS

Phase 1

Figure 1 shows the target and recruited study population by discipline. Fifty-nine of a potential 104 (56.7%) recipients responded. Forty-one were nursing staff, 13 medical staff, and 5 allied health. This is representative of the intended participant group. Of the nursing staff, 32 (78%) were registered nurses and 9 (22%) were clinical nurse specialists. Of the medical staff, 1 was a trainee, 8 were oncologists and 3 were gynaecologists.

Pre-toolkit implementation evaluation of FP practice: Table 2 shows participant roles in FP discussions and confidence in providing FP information.

Fifty-five participants (93.3%) had some prior involvement in FP discussions, with 34 (57.6%) involved frequently. The denominator changed during the survey as some participants did not answer certain questions or responses were not applicable.

Sixteen participants (16/48; 33.3%) were satisfied with the FP system prior to implementation of the toolkit. The most common reasons for dissatisfaction were a lack of a systematic approach to FP discussions, discussions occurring too late, and a lack of clarity regarding reasons for referral and FP options.

Twenty-three participants (23/57; 40.4%) felt confident in providing up-to-date FP information to parents and families. Figures 2 and 3 show the breakdown of information provision according to participant discipline. Only 34.5% of participants (20/58) often or always provided verbal information, and only 14.0% (8/58) often or always provided written information. Most participants (54/56; 96.4%) expressed the desire to improve in their ability to discuss FP with parents and patients.

TABLE 1. Contents of Fertility Preservation Toolkit

	Toolkit Resource	Description
Clinician information tools	Clinician instruction booklet titled “Fertility Preservation Toolkit”	A clinician introduction and instruction booklet including how to talk to patients and families about fertility, clinical information, risk stratification tables, procedures, checklists, and principles
	Children’s Bioethics Centre Ethics checklist for FP procedures	Describes the ethical requirements for FP in children, and advises when an ethics review is required
	RCH Melbourne Restricted Drug List	Drug Usage Committee exemptions document for information on use of gonadotropin-releasing hormone analogues
Referral forms	RCH FP Principles for females with cancer	Principles, eligibility, procedures for female oncology patients
	RCH FP Principles for males with cancer	Principles, eligibility, procedures for male oncology patients
	Referral forms for specialist female fertility preservation consultation	Clinical information sheet documenting patient flow through FP pathway
Clinical information and consent forms	Referral forms for consideration of sperm or testicular tissue storage	Clinical information sheet documenting patient flow through FP pathway
	RCH Ovarian Tissue Harvest Information Sheet	Information sheet to be reviewed and completed with parents of female patients undergoing ovarian tissue cryopreservation
	Melbourne IVF Consent by parent or guardian for collection and storage of ovarian tissue	Consent form regarding potential risks and benefits of ovarian tissue preservation
	Long-term frozen storage of ovarian tissue for oncology patients	Information sheet for storage of tissue at Monash IVF
	Storage of ovarian tissue consent form	Consent form for ovarian tissue storage at Monash IVF
	RCH Male Fertility Preservation Information form	Information sheet to be reviewed and completed with parents of male patients undergoing testicular tissue cryopreservation
	Melbourne IVF—consent to collection and storage of testicular tissue	Consent to Melbourne IVF for the collection, storage, limitations, responsibilities, posthumous use, and use of personal information before testicular tissue cryopreservation is undertaken
	The Women’s Andrology Unit request for sperm storage	Consent form regarding potential risks and benefits of sperm storage
	Monash IVF semen storage consent—minor	Consent form for sperm storage at Monash IVF
	Parent information sheet and survey	Parent survey contained questions evaluating the fertility preservation kit from a patient/family perspective
Research information and consent forms	Audit Fertility Preservation Information and Consent	Consent form for invitation to participate in an ethics approved clinical audit of fertility preservation outcomes, approval for data linkage with other registries and permission for future contact for research
Patient handouts	“Maybe Later Baby” booklet	An information booklet for patients and families published by CanTeen
	Having children after cancer: fertility preservation options for young women having cancer treatment	2-page information leaflet for female adolescents and young adults considering FP options
	Having children after cancer: fertility preservation options for young men having cancer treatment	2-page information leaflet for male adolescents and young adults considering FP options
	“Can I still have children?” booklet—female version	A colorful brochure produced by Reproductive Services at the RCH outlining how treatment may affect their fertility and potential options for the future
	“Can I still have children?” booklet—male version	A colorful brochure produced by Reproductive Services at the RCH outlining how treatment may affect their fertility and potential options for the future

FP indicates fertility preservation; RCH, Royal Children’s Hospital.

Perceived toolkit impact: All participants attended an education session where the toolkit was introduced and training was provided on its use. At the conclusion of this session, the majority of participants (50/58; 87.2%) understood the various toolkit components, with 98.3% (58/59) understanding how to use the toolkit during FP discussions. All participants (58/58; 100%) agreed to use and promote the toolkit. Figure 4 describes the participants’ opinion of the expected impact of the toolkit on clinical practice and FP discussions. No participants felt the toolkit would negatively impact on clinical practice. The most common expected benefits on clinical practice

were an increase in FP discussion rates, improving the quality of FP discussions, and providing ease-of-access to relevant information.

FIGURE 1. A) Phase 1 study participants according to discipline, n (%); B) Phase 1 eligible participants according to discipline, n (%).

FIGURE 2. Phase 1 participant provision of verbal fertility information according to discipline.

FIGURE 3. Phase 1 participant provision of written FP information provision according to discipline.

Phase 2

The toolkit was evaluated over a period of 8 weeks. During this time, 26 patients were newly diagnosed. Documentation of use of the toolkit was received in 11 of these cases (42.3%). Table 3 provides a summary of the FP discussions using the toolkit. The toolkit was not used in cases where fertility discussions were not appropriate or where the clinician had not been trained in its use.

Characteristics of the toolkit discussions are as follows: 6 patients were pre-pubertal (54.5%), 4 diagnosed with a solid tumour (36.4%), 7 discussions were in an outpatient setting (63.6%), and the patient was present for 7 of the discussions (63.6%). In most of the discussions (10/11; 90.9%) the clinician using the toolkit was taking a leading role in the FP discussion.

The clinician was satisfied with the toolkit in 63.6% of discussions (7/11), and extremely satisfied or satisfied with the FP discussion in 100% of cases (11/11). The most frequent reasons for dissatisfaction with the toolkit were missing documents within the toolkit, organisation of the documents within the toolkit, and the perception that there was too much written information which could overwhelm families and clinicians. The clinician perceived the patient or family to have extremely well understood or reasonably well understood the FP discussion in 90.9% of cases (10/11) and were perceived to be satisfied with the FP discussion in 100% of cases (11/11).

Phase 3

Figure 5 shows the target and recruited study population in 2016, by discipline. A comparison between the study populations in 2014 and 2016 is shown in Table 4. Thirty-eight of a potential 65 (58.5%) recipients responded. Ten were nursing staff, 22 medical staff, and 6 allied health or supportive care. This is representative of the intended participant group. Of the nursing staff, 5 (50%) were registered nurses and 5 (50%) were clinical nurse specialists. Of the medical staff, there was 1 endocrinologist, 1 urologist, 2 nephrologists, 10 were oncologists and 8 were

gynaecologists. There is a wider range of disciplines and an increase in the number of medical staff involved in phase 3 when compared to phase 1.

Twenty-eight participants (73.7%) had some prior involvement in FP discussions, with 20 (52.6%) involved frequently. The denominator changed during the survey as some participants did not answer certain questions or responses were not applicable. Twenty participants (20/37; 54.1%) were satisfied with the FP toolkit system. One participant reported that since the toolkit has been in use, clinical practice has seen “a great improvement”. The most common reason for dissatisfaction was that the toolkit was “inefficient” and “some aspects needed tweaking”.

Twenty-six participants (26/37; 70.3%) felt confident in providing up-to-date FP information to parents and families; 67.7% of participants (21/31) ‘often’ or ‘always’ provided verbal information, and 35.5% (11/31) ‘often’ or ‘always’ provided written information.

Table 4 details the comparison between phase 1 and phase 3 of this study. There was an overall improvement in participant confidence levels in providing up-to-date FP information, and in the provision of verbal and written information post toolkit use.

FIGURE 4. Phase 1 participants predicted impact of FP Toolkit on clinical practice.

DISCUSSION

This is the first study examining the feasibility of a FP toolkit in a pediatric oncology setting. It is established that the FP needs of pediatric patients and their families are not being met.^{10,11} There are many clinician barriers to FP discussions that need to be overcome to improve clinician and patient satisfaction with oncofertility care.

Treating oncologists need to begin the fertility discussion prior to treatment commencement, and promptly refer patients to fertility specialists for expedited detailed FP discussions as appropriate. Oncology clinicians may lack training in how to engage in such conversations and may not have up to date knowledge of FP options. In addition, oncofertility management is time sensitive and the oncology team are required to collaborate and coordinate between disciplines, departments,

and hospitals. Systematisation of oncofertility processes will improve consistency. The introduction of a user-friendly instructional toolkit that is able to lead a relatively untrained clinician through the oncofertility process via fertility information provision, scripting, practical tips, checklists and handouts may improve clinician confidence in navigating FP processes and effective oncofertility information delivery to young people and their families. It may also allow a broader range of clinicians, such as clinical nurse specialists, medical fellows and trainees, to be involved in the oncofertility process. This may in turn lead to more supported decision making by families and improved oncofertility outcomes.

TABLE 3. Details of the Fertility Discussion Using the Toolkit (Phase 2)

Role of Clinician	Role of Clinician in Discussion	Age of Patient (Range) (y)	Discussion Preparation Time Using Toolkit (min)	Dedicated FP Discussion*	FP Discussion Time (min)	Total Discussion Time (min)
Nurse	Helping	0-5	20	No	70†	70
Oncologist	Leading	0-5	10	Yes	30	40
Endocrinology fellow	Leading	11-15	20	Yes	20	20
Gynecology fellow	Leading	0-5	10	Yes	60	60
Gynecology fellow	Leading	11-15	15	Yes	20	20
Gynecology fellow	Leading	11-15	10	Yes	20	20
Oncologist	Leading	16+	0	No	10	40
Oncologist	Leading	0-5	0	No	< 10	60
Endocrinology fellow	Leading	0-5	10	Yes	20	20
Endocrinology fellow	Leading	0-5	10	Yes	20	20
Endocrinology fellow	Leading	0-5	10	Yes	20	20

*Fertility stand alone and not embedded in other aspects of oncology care.

†2×20 minute sessions and 1×30 minute session.

FP indicates fertility preservation.

In our study, prior to the toolkit introduction, 93.3% of participants had some involvement in FP discussions, with 57.6% involved frequently. However, only 40.4% felt confident in providing up-to-date FP information to patients and families. The provision of verbal or written information to patients as part of FP discussions is extremely low with 65.5% and 86% of clinicians not providing this information respectively. It is unlikely this is due to a lack of wanting to engage in FP discussions or to provide information, as almost all participants expressed the desire to improve their FP knowledge and discussion skills. Rather, this is likely reflective of the continuing need for coherent robust FP pathways, maintained up-to-date resources,

and training embedded within departmental educational frameworks. This is supported by other studies where clinician based surveys have demonstrated a lack of knowledge about fertility risks from cancer treatment and a lack of educational resources that were a barrier to FP discussions.^{15,16} It was hypothesised that the availability of a FP toolkit for clinicians may remove such a barrier.

Prior to the toolkit introduction, most participants in this study (31/33, 94%) agreed or strongly agreed that the toolkit would improve clinician knowledge and all participants agreed or strongly agreed that the toolkit would improve clinician provision of verbal and written FP communication. Following 2 years of toolkit use, 70.3% felt confident in providing up-to-date FP information to patients and families and the provision of verbal or written information to patients as part of FP increased to 67.7% and 35.5% of clinicians respectively. This result is important as it has been reported that only a small number of patients are satisfied with the information they received regarding FP, and around 90% of patients do not even recall a discussion occurring.¹⁰ The provision of written resources in addition to verbal information may improve the quality and consistency of the FP discussion, more adequately support decision making for families and increase patient and family satisfaction. The significant improvements in clinician confidence and provision of verbal and written information show that the availability of a FP toolkit may provide clinicians with the FP knowledge and educational resources required to effectively participate in fertility discussions and meet patient needs. However, the differences in participant populations from phase 1 to phase 3 may account for some of the improvements observed, with a larger number of phase 3 participants being medically trained and more frequently involved in fertility discussions.

All clinicians were satisfied with the quality of the FP discussions using the toolkit.

Clinician rated perception of patient or family understanding of the fertility information provided and their satisfaction with the FP discussion was “high” in 90.9% and 100% of discussion using the toolkit. A contributing factor to clinician satisfaction was having up-to-date clinical FP information and an increased understanding of FP pathways and guidelines within the hospital. It has previously been established that clinicians would greatly appreciate clear FP guidelines and pathways of care.^{15,21}

Our study shows that clinicians feel the provision of a toolkit including this information addresses this need. The majority of clinicians (31/33, 94%) felt the toolkit would increase their FP knowledge and 97% (32/33) felt the toolkit would assist them to adhere to a FP policy and to a consistent clinical pathway.

Whilst all clinicians were satisfied with the FP discussions after implementation of the toolkit, only 64.6% of clinicians were satisfied with the toolkit itself. Reasons for dissatisfaction were related to the structure and organisation of the kit rather than the content. The toolkit contained a large amount of paperwork, not all of which was relevant for each patient, and required ongoing maintenance. These challenges are likely to be overcome by altering the format of the toolkit or converting it to an electronic toolkit.

FIGURE 5. A) Phase 3 study participants according to discipline, n (%); B) Phase 3 eligible participants according to discipline, n (%).

This study had several limitations. This was a small study and only 56.7% of clinicians involved in oncofertility care participated. However, the participant sample is representative of the intended participant group, and it is the first study of its kind in a paediatric oncology population. The toolkit was only used in 42% of discussions during Phase 2. Nonetheless, during the entire study period (2014-2016), the toolkit has become an integral part of oncofertility practice, as the paperwork required for proceeding with oncofertility consultations had to be utilised for all fertility consultations.

This study has shown that the introduction of a FP toolkit for clinicians provided significant perceived benefit to oncofertility care by improving the quality of FP discussions and providing ease-of-access to relevant information. Implementation of an electronic version of the toolkit should address the identified barriers to hardcopy use and provide an enhanced widely utilised resource. Ongoing evaluation of clinician and family experience with the toolkit will be of paramount importance to achieve an optimal model of oncofertility care.

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