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Full Protocol

Field testing of the Begin Exploring Fertility Options, Risks and Expectations (BEFORE) decision aid

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1. Background

Approximately 1,195 young Canadian women (under age 40) were diagnosed with breast cancer in 2016.[1] Young women are diagnosed with more aggressive breast cancer and face unique challenges compared to older women. In particular, future fertility is of great concern to young women and can influence cancer treatment decisions.[2,3] Chemotherapy regimens containing alkylating agents, commonly used to treat breast cancer, are gonadotoxic reducing fertility.[4] Exposure to these chemotherapy agents can result in the inability to naturally conceive and those who regain ovarian function after treatment can experience early menopause.[5] Additionally, young women with breast cancer who are hormone receptor positive will be prescribed 5 to 10 years of antiestrogen therapy, and during this time these women will experience normal declines in fertility. While the impact of cancer treatment on the fertility of young women with breast cancer varies,[3] treatment related infertility can have a long-term impact on psychosocial distress and quality of life in survivors.[6-8]

Fortunately, fertility preservation including established (cryopreservation of embryos and/or oocytes) and experimental (ovarian suppression, ovarian tissue banking, in vitro maturation) options are available for women to complete before commencing cancer treatment.[9] Guidelines released in 2006 and updated in 2013 by the American Society of Clinical Oncology (ASCO) recommend that health care providers discuss the risk of infertility with any women of reproductive age who will be completing cancer treatment and/or refer patients to appropriate reproductive specialists.[9,10] However, few young cancer patients are referred to reproductive specialists in Canada and a study assessing health care providers fertility knowledge found that most lacked knowledge surrounding reproductive technologies.[11,12] Patients find onco-fertility decision-making challenging and they often experience decisional conflict due to limited support and knowledge on the resources and services available.[13] Currently Canadian specific fertility decision support resources to address these issues are lacking.[14]

To help address these challenges, we have developed a fertility decision aid titled Begin Exploring Fertility Options, Risks and Expectations (BEFORE) (REB# 15-220) for young breast cancer patients in Canada. The goals of the BEFORE decision aid are:

1. To provide information to young breast cancer patients on the available fertility options prior to treatment that may cause infertility in survivorship;
2. To assist young breast cancer patients in making fertility-related decisions that align with their values; and
3. To act as an adjunct to consultation and help young breast cancer patients and health care providers discuss treatment-related fertility risks and make fertility preservation decisions more effectively.

The BEFORE decision aid was systematically developed in partnership with breast cancer survivors, breast cancer advocacy groups, multi-disciplinary health care providers, decision-making experts, and a patient education specialist (Appendix 1). Multiple studies have demonstrated the benefits of decision aids including improvements in participants' knowledge

and other attributes of the decision-making process and final choices made,[15] however limited research is available on the best implementation method for decision aids in clinical settings.[16] Decision aids are also not commonly utilized in clinical settings being referred to as "*…one of the best-documented but underused interventions in American medicine*." This statement resonates and is also deemed true by multiple experts in the Canadian setting.[17] Therefore, following best practices for decision aid development by the International Patient Decision Aid Standards[18] we will: (1) field test the BEFORE decision aid with young women who are newly diagnosed with breast cancer at the point of fertility decision-making and (2) test implementation methods in clinical settings across Canada as a sub-study of an existing study for young breast cancer patients, Reducing the Burden of Breast Cancer in Young Women (RUBY) (REB # 15-078).[19]

RUBY is a pan-Canadian study aiming to address critical issues faced by young breast cancer patients related to survival and quality of life. The proposed BEFORE decision aid field testing study will be incorporated into the existing RUBY study (operating out of the University of Calgary) and recruiting participants from the RUBY cohort. Confirmation and support for the use of the RUBY cohort has been obtained by Dr. May Lynn Quan (Co-Project Lead of the RUBY study) and Dr. Ellen Warner (Principal Investigator of the fertility sub-project). The use of the RUBY cohort provides an opportunity to align the field testing of the fertility decision aid with existing work to improve fertility discussions and decision-making with young breast cancer patients in Canada.

2. Objective

I. The objective of this study is to assess the feasibility, acceptability, suitability, and usability as well as barriers and facilitators to use of the BEFORE decision aid. Our goal is to complete interviews to gain an in depth understanding on the impact of introducing the BEFORE decision aid in clinical practice for young breast cancer patients.

II. Evaluate the effectiveness of an advertising and education intervention on the use of the BEFORE decision aid with young women diagnosed with breast cancer

III. Determine the barriers and facilitators to use of the BEFORE decision aid in clinic from the perspectives of nurses and support staff

3. Research Methodology

3.1 Objective I

Overview

Access to the BEFORE DA

We will incorporate the BEFORE decision aid (www.before.offtomarket.ca) (approved by St. Michael's Hospital Communications) into the RUBY study communication portals including Twitter (www.twitterRUBY.com), Facebook (www.facebook.com/wecanruby/), and the web portal for RUBY participants using a standard message (Appendix 2). The web portal is a site that provides participants with information on a range of topics including fertility, as well as further resources and support. The anticipated launch date of the web portal is early 2018.

We will complete telephone interviews with a sub-set of the participants who reviewed the BEFORE decision aid through any RUBY communication portal (Figure 1).

Sampling and Recruitment

a. Patients

Inclusion criteria – young women diagnosed with histologically-confirmed breast cancer will be eligible to participate if they: 1) are age ≥18 years and prior to their 41st birthday, and 2) are able to provide verbal informed consent and complete the interviews in English or French.

RUBY participants will be recruited through self-referral for this study. The RUBY communication portals will provide the link to the BEFORE decision aid (www.before.offtomarket.ca) including a customized message asking patients if they would be interested in providing more information on the BEFORE decision aid through a telephone interview (Appendix 2). The message will include the contact information (email and phone number) for the study research coordinator (BS). RUBY participants will email or phone the study research coordinator (BS) expressing interest in participating in an interview.

If the RUBY participant contacts the study research coordinator by phone, the coordinator will inform the participant of the study and ask for their email address and permission to send the Cover Letter (Appendix 3), Information Letter (Appendix 4), and Patient Email Consent Form to communicate by email (Appendix 5). If the RUBY participant contacts the study coordinator by email, the coordinator will email the potential participant a Cover Letter (Appendix 3), Information Letter (Appendix 4), and Permission to Email Consent Form (Appendix 5). Participants will be asked to reply with written consent for the study and to be contacted by email. We will recruit until saturation has been met and a diverse group of participants are interviewed in terms of age, location, use/non-use of the BEFORE decision aid, and children before their cancer diagnosis.

We will follow-up with potential participants through email or telephone one week from initial contact if no consent was provided to confirm their receipt of the Information Letter and to address any concerns they may have (Appendix 6). We will follow-up with participants in the format that they originally contacted the study research coordinator (e.g., if the RUBY participant called the coordinator we will follow-up by phone and if they emailed the coordinator we will follow-up by email).

Data Collection

Interviews will be completed within one-month from the participant contacting the study research coordinator (BS). Interviews will be conducted using a semi-structured interview guide (Appendix 7), during which participants will discuss aspects surrounding their use of the BEFORE decision aid, usability and comprehensibility of the decision aid, acceptability, and the feasibility of the tool. Interviews will be completed with participants who fully used and did not fully use the BEFORE decision aid to gather important information on the perceived barriers and facilitators to use of the tool when making fertility decisions. Interviews will be conducted over telephone to ensure representation from participants across Canada and are anticipated to be 30 to 40 minutes in length. Towards the end of the interview, the interviewer will ask how the decision aid can be improved to enhance fertility decision-making.

The interviews will explore patients' opinions about the BEFORE decision aid in relation to their decisional needs, the decision quality and decision support provided, aligning with the Ottawa Decision Support Framework (ODSF).[20] The ODSF framework asserts that decision support (e.g., a decision aid) can improve decision quality by addressing unresolved decisional needs.

After each interview, the interviewer will send the participant a list of resources (Appendix 9) that they can contact if they are experiencing any anxiety or distress from the discussion of fertility during the interview.

Analysis and Security

A qualitative descriptive approach using thematic analysis will be used to identify themes.[21,22] The analysis will involve multiple reads of the transcripts to get a holistic sense of participants' responses. The first stage of the analysis process involves inductive coding with descriptive codes. The codes will allow for the development of a coding guide and identification of themes in the data. NVivo, a qualitative data management software program, will be used to organize the data and facilitate analysis between two independent coders. The two coders will meet regularly to discuss the coding and analysis process to ensure in depth exploration of collected data.

Interviews will be digitally audio-recorded for verbatim transcription with the participant's agreement. If participants do not consent to audio-recording they will still be able to participate and detailed notes will be taken by the interviewer as a substitute. All audio recordings will be destroyed after they have been transcribed and verified for accuracy. Any identifying information such as names of individuals will be removed from the transcripts during the process of transcript verification. Each study participant will be assigned a unique identifier consistent with their RUBY

identifier and will be referred to only by this code number. The Master Log (Appendix 8) linking names to study codes will be password protected and stored on a secure network drive. Anonymized interview transcripts will be password protected and stored on a password protected server. Any interview transcripts that are printed for coding and analysis purposes will be stored in a locked filing cabinet. Only the investigators and study team will have access to this confidential data.

Data Storage and Privacy

Demographic Data: Names of participants who consent to participate in an interview will be securely sent to the University of Calgary through an encrypted system (e.g., through SMH Big File system) following the completion of standard operating procedures for data transfer between the University of Calgary and St. Michael's Hospital. Participants' demographic information will be sent back to the study research coordinator (BS) such as current age, treatment, education level, ethnicity, relationship status at diagnosis, and children at diagnosis. Data sent from U of C to the study coordinator will include the participants' RUBY study ID number. After the study coordinator has received this information, they will delete the names of participants and only refer to them by their RUBY study ID number. The participants will then be double coded and assigned a new unique patient ID number. If participants do not want their name sent to the U of C then we will ask all background/fertility questions during the interview and will not collect their RUBY questionnaire data from the U of C.

The interviews will be recorded and transcribed upon the participants' agreement. The transcriptionist will also be bound by the St. Michael's Hospital's research ethics standards of confidentiality. The audio files will be stored on the secure server at St. Michael's Hospital. Only the principal investigators and research support staff will have access to this confidential data. The information that is collected for the study will be kept in an electronic file on the secure server by the study investigator for 5 years. Audio recordings from the interviews will be deleted after 1 year (following transcription and verification of the transcripts). No documents will have the names of any individuals participating; ID numbers will be used to protect their identity.

3.2 Objective II (Figure 2)

Overview

Research Ethics Board (REB) approval will be obtained for the 29 actively recruiting RUBY sites.

To assess strategies to increase awareness and use of the BEFORE decision aid we aim to conduct a randomized stepped-wedge cluster trial to sequentially implement the decision aid in actively recruiting RUBY sites (29 potential RUBY sites for implementation).

The BEFORE decision aid will be available to all women in the RUBY study through the communication portals (as described in Objective 1). The PI (NB) will inform the RUBY site PIs

and RUBY site research coordinators about the BEFORE decision aid through email and at one monthly research coordinator teleconference. The email will provide access to information on fertility (e.g., the American Society of Clinical Oncology fertility guidelines and other resources) and provide an opportunity for them to ask questions surrounding the tool.

Limited uptake of the tool is expected with this passive approach to implementation and as such this will be the baseline for the stepped wedge trial.

Experimental Intervention
In the intervention, we aim to evaluate more intensive strategies to promote use of the BEFORE decision aid and an educational strategy with nurses and support staff.

1. We will advertise the availability of the BEFORE decision aid with posters (Appendix 10) placed in clinic areas at the 29 sites, and will have small handouts (Appendix 10) available to be distributed in clinic. The poster content has already been approved by St. Michael's Hospital communications.

2. We will conduct an educational intervention describing and promoting the use of the BEFORE decision aid and general oncofertility information to nurses and support staff at each site. This will include informational webinars, direct outreach and training of nurses/support staff on the use of the tool. The content of these sessions will be based on the feedback from health care provider interviews on the barriers to fertility discussions with patients completed previously completed for this study (REB #13-136). Guided by Cabana's Framework, we will aim to address barriers in knowledge, attitudes, and behaviour through the information sessions and provide support on issues faced by nurses/support staff when bringing up and discussing fertility with newly diagnosed breast cancer patients.

   The webinar will be 1hr in duration using GotoWebinar (https://www.gotomeeting.com/en-ca/webinar) to ensure the session includes both didactic and active strategies as both have benefits to learners.[23] The webinar will cover a breadth of topics surrounding fertility (e.g., fertility preservation options, barriers to fertility discussions, etc.) (Appendix 11). We will provide the webinars one week before the sites cross over from control to intervention. A total of 8 webinars will be completed for each of the clusters before they cross over from control to intervention. During each webinar, 10 minutes will be dedicated to discussing the goals, content, and anticipate use of the BEFORE decision aid allowing for any questions from the sites. A reminder email will be sent to all RUBY site coordinators and participants of the webinars on the intervention start date at their site to remind them of the intervention and study.

   Email's will be sent to webinar participants 10 weeks after their participation in the webinar to invite them to participate in the next set of webinars if they would like a

refresher (e.g., participants from group 1 will be invited to attend group 3's webinar series, group 2 will be invited to attend group 4's webinar series, etc.)

Data Collection and Analysis

Cluster Grouping and Randomization

First, REB will be obtained from all recruiting RUBY sites (currently 29 actively recruiting). The RUBY sites have been grouped into clusters by location and average recruitment numbers to ensure each cluster recruits on average of 2 patients every 2 months in the RUBY study (Appendix 12). From the 29 original sites, 16 clusters were created. Using a complete randomized stepped-wedge cluster design, we will sequentially roll out the intervention (BEFORE decision aid and educational strategies) during 8 steps of 5 weeks duration, simultaneously switching 2 clusters from control to intervention at each step. The time-point of when clusters will be switched from control to intervention will be centrally randomized. None of the clusters will be switched from control to intervention during the first 5 weeks. The first two clusters randomized to be switched from control to intervention will undergo implementation of the intervention by posting poster in clinical waiting rooms and conducting webinars with nurses/support staff at the end of week 5, and start the intervention at the beginning of week 6, continuing to receive the intervention and recruit patients until the end of week 45. The next two clusters randomized to be switched from control to intervention will undergo implementation at the end of week 10, and start the intervention at the beginning of week 11, again continuing to receive the intervention and recruit patients until the end of week 45. This pattern will continue until all clusters have switched from control to intervention (Figure 3).

Blinding

It is not possible to blind the research team or clinics to implementation of the BEFORE decision aid educational intervention. Although no blinding can occur, the primary outcome is objective based on a questionnaire response. Additionally, analysis is designed as a time series where each RUBY site will receive the intervention of the BEFORE decision aid.

a. Outcomes

Primary Outcome

The primary outcome will be the number of patients reporting that fertility tools were recommended to them. The primary outcome data will be retrieved from an existing fertility questionnaire sent to RUBY participants' 3-months after their enrollment (Appendix 13).

We hypothesize that following the intervention a 20% difference will be observed, from 10% in the control to 30% in the intervention, in the number of patients who report that someone in their care team recommended a fertility tool.

Secondary Outcomes

Secondary outcomes include the number of patients who identified the BEFORE decision aid as the most helpful fertility-related tool they received and the number of patients who report they were recommended and used the BEFORE decision aid. Additional questions on the 3-month fertility questionnaire will also be reviewed as secondary outcomes (Table 1).

We will also determine the number of patients who viewed the BEFORE decision aid using the 2 strategies for implementation (1. passive advertising on the RUBY communication portals, 2. poster/pamphlet advertising in clinics and distribution following educational webinars and outreach in clinics), counted as the number of people who completed an online survey, Appendix 6. The online BEFORE decision aid will include a popup survey that participants can complete once they review the decision aid. The short survey (Appendix 14) will include questions on who informed them about the tool and how they knew to access the tool (by accessing the web portal, by the poster, or by their doctor/nurse/support staff). Survey completion will be used as a proxy to determine the number of patients who used the BEFORE decision aid using the different implementation strategies. Survey questions will also ask if they were satisfied with the way they were directed to the BEFORE decision aid.

Exploratory Outcomes

a. Google Analytics

An additional, exploratory outcome will include using Google Analytics during the intervention period to obtain general usage information about the intervention. No personal identifying information is collected using the BEFORE decision aid or collected through Google Analytics. Data will focus on the basic analytics including: number of visits, length of visit, most/least visited page, number of people who downloaded the paper decision aid, user location by province in Canada, etc.

Data obtained through Google Analytics will show all the individuals who accessed the BEFORE decision aid (health care providers, nurses, support staff, RUBY participants, non-RUBY patients, family members, etc.) so it will not be used as a primary outcome since there is no way to distinguish the number of patient users through each of the implementation strategies.

Sample Size Calculation

This trial is powered for the analysis of the primary outcome of patients who were recommended a fertility tool by doctors/nurses/support staff. Following the use of the *stepped wedge* command in Stata, assuming with an intra-cluster correlation coefficient of 0.05, we found that 1 to 3 patients (1.5 patients on average) in each of the 16 clusters during the 8 steps plus a baseline step would yield a total of 1.5x9x16 = 216 patients. This sample size results in greater than 85% power to detect a 20% difference in the percentage of patients who report receiving a recommendation for a fertility tool at a two-sided alpha of 0.05, from 10% with the control intervention to 30% with the experimental intervention.

Data Analysis

This is a pragmatic trial, as the BEFORE decision aid educational intervention is being introduced into an existing data collection framework. The only additional information collected will be surrounding usage from the pop-up survey (Appendix 14) and Google Analytics. SAS statistical software will be used for the analysis.

Data will be collected and analyzed starting at baseline when the BEFORE decision aid is accessible on the RUBY communications portal and then at each step thereafter. The data for the primary outcome will be accessible 3 months after recruitment into the study. For example, if the intervention was delivered to the first cluster during step 3 in May 2018 the data from the 3-month fertility questionnaire for patients included during step 3 in the first cluster would not be available for collection until August 2018.

The primary outcome of patients with fertility tools recommended will be analyzed using a mixed effects logistic regression model using a random intercept at the level of clusters as well as a fixed effect to account for temporal trends. Coefficient estimates, 95% confidence intervals and p-values (where relevant) will be reported. An intent-to-treat (ITT) approach will be used for all subjects in the period that they were originally allocated to. The following baseline covariates will be controlled for as they may influence recommendation of tools and discussions surrounding fertility preservation: age, highest level of schooling completed, income, ethnicity, marital status, number of children (parity), and dedicated fertility programs at sites. Secondary outcomes will be analyzed following the same approach as the primary outcome. Descriptive statistics will be calculated for the additional, exploratory outcome based on Google Analytics.

Data Transfer and Security

RUBY study participants' demographic information and 3-month fertility questionnaires will be securely sent from the University of Calgary through an encrypted email following the completion of standard operating procedures for data transfer between the University of Calgary and St. Michael's Hospital. Participants' demographic information will be sent back to the study research coordinator (BS) such as current age, treatment, education level, ethnicity, relationship status at diagnosis, location/ diagnosis site, and children at diagnosis. Data sent to the study coordinator will only identify participants by their RUBY study ID number and all data will be de-identified. The research coordinator will not be provided with the master linking log for the RUBY participants, therefore no names or contact information for the RUBY participants will be sent from the University of Calgary.

Objective III

Interviews (Nurses and Support Staff)

Data Collection and Sampling

Nurses and support staff will be recruited through purposeful sampling to obtain a diverse range of participants in terms of location and profession. Approximately 10 to 15 participants will be

recruited or until saturation is met. Dr. Nancy Baxter (PI) will contact potential participants who attended the educational webinars by email (Appendix 15) with an attached Information Letter (Appendix 16). Interested participants will respond with their written interest and consent to participate in the study. The study research coordinator (BS) will then follow-up with the participant to schedule a telephone interview. If no response is provided a follow-up email (Appendix 17) will be sent after one week and if no response is provided to the follow-up email then we will consider the participant to be not interested. Recruitment will be ongoing throughout the study period as clusters switch from control to intervention.

Interviews will be conducted using a semi-structured interview guide (Appendix 18), during which participants will discuss interactions with young cancer patients who used the BEFORE decision aid prior to their fertility consultations as well as the feasibility of the BEFORE decision aid implementation strategy at their site. The interviews will also be guided by Cabanas Framework looking at the concepts of barriers to adoption to new interventions including awareness and familiarity with the intervention, motivation and self-efficacy.[24] Interviews will be conducted over telephone to ensure representation from participants across Canada and are anticipated to be 30 minutes in length.

Data Analysis and Security

The analysis and security will follow the same process as outlined in Objective I (page 6); **excluding** the collection of RUBY study information from the University of Calgary as these interviews are occurring with nurses/support staff and all background information will be asked in the interviews (Appendix 18). All personal identifying information will be provided by the participant during recruitment to conduct the interviews and it will be kept in a password protected Master Linking Log (Appendix 8) for the duration of the study period on the secure server at St. Michael's Hospital.

Data Storage and Privacy

The data storage and privacy process will be the same as outline in Objective I for patient interviews (page 7); excluding the storage and privacy of demographic data from the University of Calgary. All demographic data will be collected by nurse/support staff participants during the interviews (Appendix 18).

4. Potential Impact and Relevance

Our research will be a contribution to the existing literature by: i) understanding how a fertility decision aid is feasible in clinical settings to help inform patients of their fertility options; ii) understand the barriers and facilitators to use of the BEFORE decision aid in clinical practice to help inform a wider implementation study of the decision aid across Canada; iii) determining the most useful dissemination method for decision aids to help inform wider dissemination of the BEFORE decision aid and other decision aids; iv) identifying barriers and facilitators to decision aid implementation from the perspective of nurses and support staff. Importantly, upon completion of this study we will have developed a decision aid that is ready for wide

dissemination to clinical settings across Canada and use by all young breast cancer patients. The aim of the BEFORE decision aid is to support patients and health care providers when making and counseling patients through difficult fertility decisions to improve the quality of their decision-making. This work will represent both a practice and research innovation for Canada.

5. Project Timeline

Objective I

We estimate that REB approval at St. Michael's Hospital and the University of Calgary will take approximately 2 months to complete. The RUBY web portal will become live in early 2018 and we anticipate recruitment will take 2 months with interviews occurring concurrently. The transcription and analysis will be ongoing with interviews over a 5 month period (January 2018 to May 2018), with findings used to help inform a subsequent study focusing on implementation of the BEFORE decision aid. Finally in April we will consider/make any recommended changes to the BEFORE decision aid.

Objective II and III

We estimate that REB approval at SMH and all RUBY sites will take 3 months to complete a delegated REB submission. Total duration of the study is estimated at 45 weeks (5 weeks duration for baseline plus 5 weeks duration for each of the 8 steps). Interviews will begin with nurses/support staff 10 weeks after the first site switches from control to intervention (estimated at July 2018), with analysis ongoing through May 2019. The data cleaning and analysis for the stepped wedge trial will take place from July 2018 to July 2019. Revisions to the BEFORE decision aid will take place in July 2019 as well as a manuscript and the wider Canadian dissemination plan for the BEFORE decision aid.

Month	Details
Objective I	
Dec. – Jan. 2017	Obtain SMH and University of Calgary REB approval for the study
Jan. – Feb. 2018	Participant recruitment for interviews
Jan. – May 2018	Data cleaning and analysis
May 2018	Revisions to the BEFORE decision aid as identified in the field testing
May 2018	Manuscript preparation
Objective II and III	
Jan. – Mar. 2018	Obtain SMH and RUBY sites REB approval for the study
April 2018	5 weeks baseline period
May 2018	First cluster switches from control to intervention (step 1)

June 2018 – April 2019	All clusters switch from control to intervention (step 2 to step 8)
July 2018 – July 2019	Data collection/analysis– obtaining outcome data by reviewing 3 month follow-up survey responses
July 2018	Begin interviews on use of the BEFORE decision aid
July 2018 – May 2019	Analyze nurse/support staff interview data
July 2019	Revisions to the BEFORE decision aid
July 2019	Manuscript preparation and BEFORE decision aid dissemination plan to all Canadian hospitals

6. Budget

The funding for this study will be provided by a Canadian Cancer Society Quality of Life grant (grant #702601). Since the large proportion of the study will be completed using the RUBY study resources the funding needed for the field testing are estimated at $6,613.22 as outlined below.

Transcription for up to 20 participants: 0.5 hour interview (~2 hrs of transcription) x $25/hour x 20 = **$1000**

Applied Health Research Centre methodological support to assist with the design of the study: estimated 20 hours of support @ $130 per hr = $2,600

Webinar for 100 people at a time: cost for GoToWebinar monthly fee (for up to 100 people per meeting) is $104. It is estimated that we will need GoToWebinar for one year to schedule the webinars ($104/month x 12 months = $1,248). The webinar sessions will cost $1,248.

Graphic Designer for posters and handouts: $1,084.80

***Printing Costs** for 29 RUBY sites: (1) Posters 1 poster per site = $14.99 per coloured poster +HST (13%) x (29 sites) = $491.22 (2) Pamphlet/Handout for 29 RUBY sites: 500 for $190

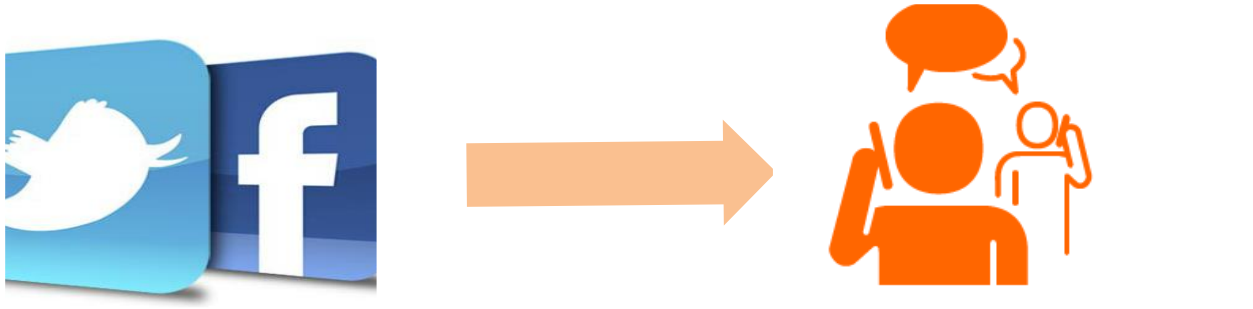
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7. Research Team

Dr. Nancy Baxter is Principal Investigator at the host institution (St. Michael's Hospital) will collaborate with Dr. May Lynn Quan who is Co-Principal Investigator of the RUBY study and Dr. Ellen Warner who is the Principal Investigator of the RUBY fertility sub-study. Dr. Kelly Metcalfe and Dr. Adena Scheer are decision-making experts with experience in developing decision tools and prior involvement in the development of the BEFORE decision aid. These investigators will ensure data confidentiality and security measures are taken during all steps of data collection and analysis stages. The grant study team (grant #702601) includes experienced scientists with proven track records in decision-making, health services and outcomes research.

8. Figures

Figure 1. Steps for Objective 1



Post BEFORE Decision Aid on RUBY Communication Portals

- Web Portal
- Facebook Page
- Twitter Account

RUBY Participant Interviews

- Participant uses BEFORE decision aid
- Participant contacts study RC (BS) if interested in an interview
- Conduct a 30-40 min telephone interview with participant

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Figure 2. Steps for Objective II



Baseline

- BEFORE decision aid on RUBY communication portals

Active Intervention

- Posters in clinic and handouts
- Educational strategy (Webinars, Tumour Boards, Other avenues (site specific)

Primary Outcomes

- Fertility questionnaire (number of patients who are recommended a fertility tool)

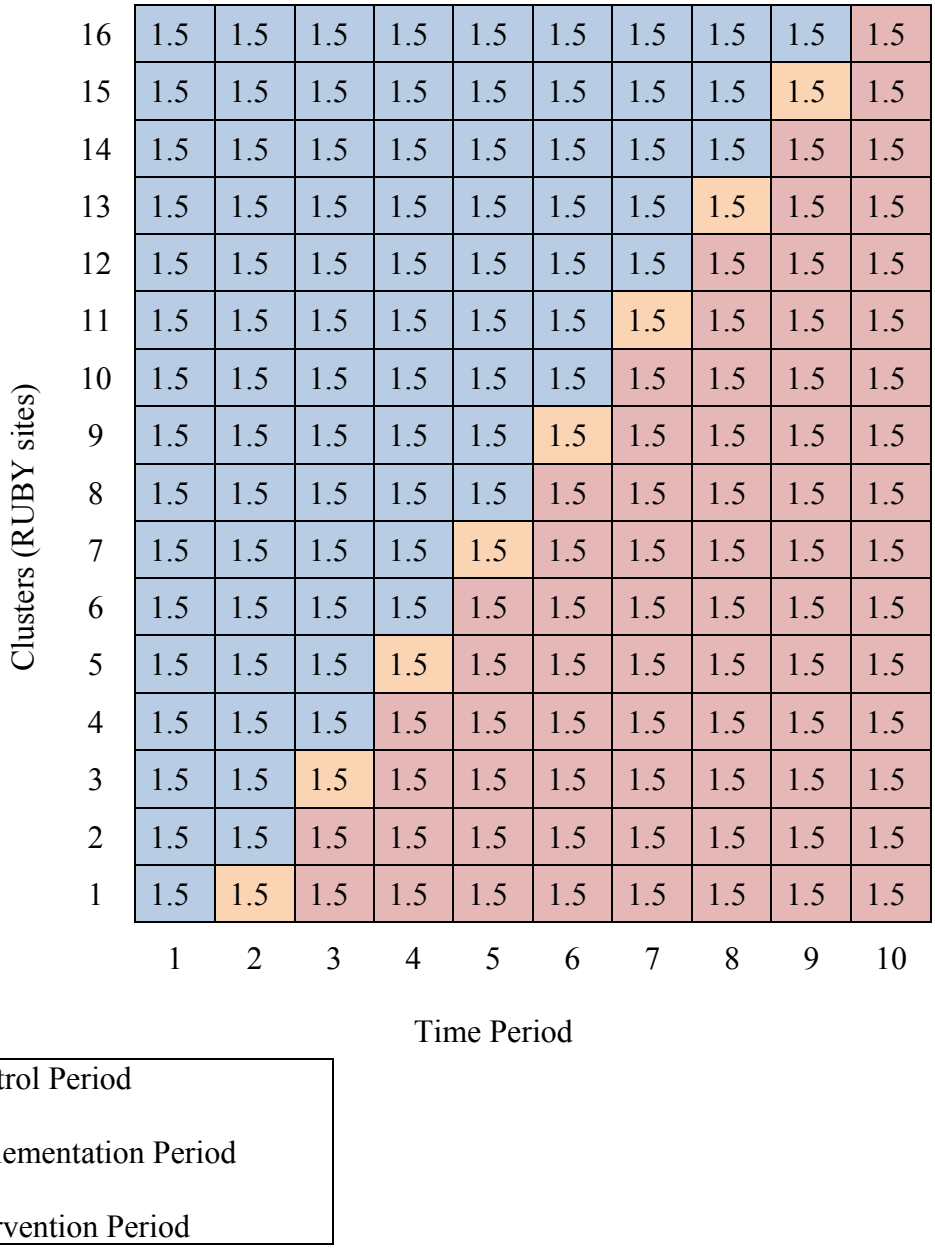
Secondary Outcomes

- Online survey (5 questions)
- Fertility questionnaire (number of patients who (1) list the BEFORE tool as most useful and (2) were recommended and used the BEFORE tool)

Exploratory Outcomes

- Google Analytics

Figure 3. Stepped-wedge design (Objective II)



Note: Total of 16 clusters with an average cluster size of 1.5 patients, 8 steps (2 clusters randomized per step) including baseline and implementation time.

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