

Title: One Key Question, Pilot Study Phase II

Study EH#: 18-343

NCT03947788

September 19, 2019

## **Detailed Protocol Narrative**

Title: One Key Question-System Team Patient: A Pilot Study Phase II

### **1. Background**

Effectively delivered preconception counseling leads to healthier pregnancy behaviors (1), and high quality contraceptive counseling leads to more effective birth control use (2-4), both of which improve outcomes for women and their offspring (5-7). The Centers for Disease Control and Prevention (CDC) recommend that primary care and reproductive health providers routinely ask reproductive age patients about their personal goals regarding pregnancy and offer preconception and contraceptive counseling guided by the patient's preferences (8). However, only 14% of ambulatory visits by reproductive age women in the United States include any preconception or contraceptive counseling (9). Many clinicians miss opportunities to provide this counseling because they lack tools to identify women who would benefit from it, and may not have the care processes in place to provide appropriate counseling and access to evidence-based care once the need is identified. This need is addressed through our intervention: the One Key Question® (OKQ), a program run through the nonprofit *Power To Decide* to help clinicians efficiently address women's pregnancy intention and provide evidence-based care (Appendix A). Clinicians are trained to ask patients, "Would you like to become pregnant in the next year?" and address contraception and preconception health in a supportive, patient-centered manner. The program provides clinician and staff training, evidence-based clinical tools, and efficient workflows to implement the CDC recommendations (10, 11). We have collected baseline needs assessment data by surveying patients at 6 obstetrics and gynecology and family medicine groups within Northshore University Health Systems (EH 18-015). All 6 of these clinics (see page 3) have agreed to participate in future trainings and post-intervention survey collection at their sites.

### **2. Purpose**

The purpose of this pilot study is to build upon baseline data on pregnancy intention and receipt of contraceptive and preconception counseling. 2 of the 4 participating practices will be randomly selected to receive comprehensive One Key Question® training through the nonprofit *Power To Decide*. All trained sites also have access to technical support in implementing OKQ. This training and technical support will act as the intervention and be given to help improve the quality of preconception and contraceptive counseling in Primary care and Obstetrics/Gynecology. All participating practices will then be surveyed again to determine changes in contraception and preconception counseling. Following this second round of surveys, the remaining practices will have the option to receive *Power To Decide*'s One Key Question ® training.

### **3. Methodology**

#### **Part I: Trainings**

- a. 2 of the 4 participating NorthShore Medical Groups will be selected to receive *Power To Decide* OKQ trainings. These become the *intervention practices* and the remaining 2 become *control practices*. The selection of these sites will be determined based on site availability, willingness to participate, and clinic characteristics.
- b. Trainings will be provided to clinicians and staff from the intervention practices.
- c. Trainers from *Power To Decide* will execute OKQ trainings
- d. Trainings consist of:
  - Up to seven hours of training, in-person certification training (Appendix B)
  - Provider and Patient Materials
  - Five hours of consulting (prior to and following training)
  - Post training webinar
  - Provider OKQ Certification (two years for the price of one)
  - Access to a OKQ Provider Portal (only available to certified providers)

### **Part II: Survey Collection – Starts at least 4 weeks after OKQ Training**

- a. The research team will work with physicians and practice managers at all participating NorthShore practices to select mutually agreeable days for data collection at each site.
- b. On data collection days, patient surveys will proceed using the same procedures as those used for baseline data (EH 18-015). Specifically:
  1. A research assistant (RA) will approach a patient in the waiting room before her appointment. After verbal recruitment and consent, the RA will determine if she qualifies for the study.
  2. If the patient is eligible, the RA will explain the study and ask that she comes back to the waiting room after her appointment to fill out a post-exam survey. The RA will instruct the participant to place completed survey in an envelope.
  3. The RA will collect the survey and offer a \$10 Walgreens or CVS gift card as a token of appreciation for participating in the study.
- c. After patient data collection is complete, the RA will return to each practice to collect surveys from clinicians and staff (Appendix C) at the intervention practices to assess the experience of implementing OKQ and their perceptions of its utility for patients.
  1. OKQ staff will attend clinic staff meetings at intervention practices to introduce the survey in-person in order to increase buy-in among respondents.
  2. Clinicians and staff will receive the survey through an emailed link as well as in paper form:
    - i. A paper survey with a cover letter (Appendix F) attached will act as our consenting process. This cover letter will also include a link to the online version of the survey if they choose to complete the survey online.
    - ii. All clinician and staff will receive an email that includes a copy of the cover letter and a link to the survey online.
  3. All individuals taking these surveys on paper forms will be asked to leave their completed surveys at their clinic in a secure location for the RA to pick up.

#### **4. Locations**

Niles Northshore Medical Group (OB)  
Vernon Hills Northshore Medical Group (OB)  
Glenbrook Hospital Family Care Center (FM)

Lincolnwood Northshore Medical Group (FM)

**5. Special precautions**

All collected information will be confidential and will not contain any identifying information. Surveys will be immediately placed in an opaque envelope by the researcher and stored in a locked cabinet. Electronic data compilation will be saved on a secure NorthShore Shared Drive.

**6. Experimental controls and use of placebos**

There will be two clinics that will not receive the initial round of OKQ trainings. After all surveys are collected, these clinics will be offered the opportunity to receive this training.

**7. Type and number of experimental subjects**

Up to 100 clinicians and staff that take part in the OKQ Training. Up to 234 patients from OB and FM clinics will be approached for to be surveyed.

**8. Statistical analysis**

A simple frequency and chi square analysis will be used to describe outcomes at each time point: baseline and post-OKQ.

To compare the effect of OKQ on preconception and contraceptive counseling, a difference-in-differences analysis will be conducted, comparing change in rate of counseling at the intervention practices vs. at the control practices.

**9. Potential risks and benefits**

The only risk includes loss of confidentiality if patients decide to share personal information while being verbally consented in the waiting room where other patients could overhear. However consenting will be done as privately as possible and patients will be encouraged to only provide the information necessary for the survey. All surveys are anonymous thus there should be not be a loss of confidentiality. There are no direct benefits to participants for participation.

**10. Monitoring of safety**

Patients will be asked during recruitment and consent whether they are able to safely participate in the study. Some questions could cause emotional distress due to the nature of the questions and if any adverse events occur during participation, the researcher will contact the patient's doctor, a counselor, or 911 (if necessary) and then report the event to the study PI and IRB as soon as possible.

**11. Payment**

A \$10 Walgreens or CVS gift card will be offered after participation to patients as a token of our appreciation and compensation for their time.

The clinicians and staff will not receive gift cards or other monetary incentives or compensations.

**12. Procedures to obtain and record informed consent**

- a. While in the waiting room, a researcher will approach a patient who appears to be 18-49, non-pregnant, and female after the patient checks in for her appointment.
- b. The researcher will read the oral recruitment and consent script. The patient has to agree to hear more about the study (after oral recruitment), provide verbal consent, and meet study criteria in order to participate. A one page information sheet (Appendix G) about the study and their rights

as a participant will be given while verbally consenting and if desired patients can take the one pager home to keep. See **Part II: Survey Collection** for more details on the overall recruitment and consenting process.

- c. An information sheet cover letter explaining the study (Appendix F) will be included in both the paper version and electronic version of the survey provided to clinicians and staff. The cover letter will be in the body of the email which contains the link to the survey. The link will be listed after the cover letter. Please see section **Part II: Survey Collection subsection c** for more information.

### **13. Confidentiality**

No identifying information will be collected during consent or study participation. Participants will be asked to place completed surveys in an opaque envelope before handing over the survey to the RA. At the end of the collection day, the surveys will be stored in a locked unit. All electronic information will be secured on a NorthShore encrypted server.

### **14. Bibliographic references**

- [1] Williams L, Zapata LB, D'Angelo DV, Harrison L, Morrow B. Associations between preconception counseling and maternal behaviors before and during pregnancy. *Maternal and child health journal*. 2012;16(9):1854-1861.
- [2] Dehlendorf C, Henderson JT, Vittinghoff E, et al. Association of the quality of interpersonal care during family planning counseling with contraceptive use. *Am J Obstet Gynecol*. 2016;215(1):78.e71-79.
- [3] Dehlendorf C, Krajewski C, Borrero S. Contraceptive counseling: best practices to ensure quality communication and enable effective contraceptive use. *Clin Obstet Gynecol*. 2014;57(4):659-673.
- [4] Shannon GD, Alberg C, Nacul L, Pashayan N. Preconception Healthcare and Congenital Disorders: Systematic Review of the Effectiveness of Preconception Care Programs in the Prevention of Congenital Disorders. *Maternal and child health journal*. 2013.
- [5] Temel S, van Voorst SF, Jack BW, Denktaş S, Steegers EA. Evidence-based preconceptual lifestyle interventions. *Epidemiol Rev*. 2014;36(1):19-30.
- [6] Mohllajee AP, Curtis KM, Morrow B, Marchbanks PA. Pregnancy intention and its relationship to birth and maternal outcomes. *Obstetrics and gynecology*. 2007;109(3):678-686.
- [7] Gavin L, Moskosky S, Carter M, et al. Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. *MMWR Recomm Rep*. 2014;63(RR-04):1-54.
- [8] Bello JK, Rao G, Stulberg DB. Trends in contraceptive and preconception care in United States ambulatory practices. *Fam Med*. 2015;47(4):264-271.
- [9] Bellanca HK, Hunter MS. ONE KEY QUESTION®: preventive reproductive health is part of high quality primary care. *Contraception*. 2013;88(1):3-6.
- [10] Allen D, Hunter MS, Wood S, Beeson T. One Key Question(®): First Things First in Reproductive Health. *Matern Child Health J*. 2017;21(3):387-392.
- [11] Frayne DJ, Verbiest S, Chelmow D, et al. Health Care System Measures to Advance Preconception Wellness: Consensus Recommendations of the Clinical Workgroup of the National Preconception Health and Health Care Initiative. *Obstetrics and gynecology*. 2016;127(5):863-872.

### **15. Recruiting methods**

- a. RA will approach female patients in waiting room that appear to be w/in study age range and not pregnant

- b. The RA will ask (following the oral recruitment/consent script) if the patient would like to participate in the study
- c. The patient will be seen by the provider
- d. The patient will then return and approach the RA to complete the survey
- e. As for clinician and staff recruitment, research staff will attend clinic staff meetings at intervention practices to introduce the survey in-person in order to increase buy-in among respondents. For more details see section **Part II: Survey Collection subsection c.2.**

**16. How the subject's primary physician will be notified**

The participant's physician will not be notified if the she has consented to participate.

**17. Anticipated coordination between inter-departmental faculty**

We will schedule a meeting at the beginning and end of this study phase to ensure that OB and FM offices know the status of this study.

**18. Rational for excluding women, minorities, and/or children from participation**

Pregnant women and children are excluded from participation because the care they receive will not provide the data we need for this study's objectives.