Study Protocol

Study Title: Supporting Parents to Choose Wisely: A Multi-Method Study to Increase Knowledge and Manage Expectations for Common Acute Childhood Conditions

Personnel:

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Funding: This project is funded by a 2021 Women and Children's Health Research Institute (WCHRI) Innovation Grant.

Location of Study Materials: Common drive: Z:\common\ARCHE_ECHO\KT\WCHRI 2021 Choosing Wisely

Purpose and Justification

A key driver of inappropriate care is patient expectations; that is, patients want something done when they seek care, whether that be a diagnostic test or some form of intervention such as a prescription[1, 2].There is a growing body of literature providing evidence that increasing knowledge and awareness among patients can influence their behaviours in terms of deciding to seek care or expectations of healthcare professionals if they do seek care[3, 4]. Moreover, behaviour theory indicates that precursors to behaviour change are awareness, knowledge, and intentions.[5-7] Knowledge translation (KT) is concerned with the communication of evidence to improve such outcomes.

In the context of pediatric healthcare, connecting parents and legal guardians to research evidence has the power to improve health decision-making and reduce health system costs[8]. The heaviest users of unscheduled healthcare are children, who also make up a large proportion of emergency department (ED) attendances that may have been treatable elsewhere (e.g. primary care or home)[9]. There are multiple complex factors and circumstances that can influence parents' decision-making regarding where, when and why they seek unscheduled healthcare for their children. A recent systematic review highlighted that pressure to be seen as 'doing the right thing' as a parent was related to care seeking[10]. However, fear of wasting a doctor's time for a minor illness was perceived as a barrier for seeking care[10]. Subsequently, parents and caregivers should be the target of efforts to promote empowerment. Parent empowerment can be defined as the "process through which parents are able to increase the control they have over decisions and actions affecting their child's health[11]". One mechanism for supporting and empowering parents could be through KT of the Choosing Wisely Canada (CWC) recommendations.

It has become increasingly clear that parents need knowledge and confidence to be involved in healthcare decisions. CWC is a national movement launched in 2014 in partnership with the Canadian Medical Association. The campaign aims to help physicians, patients and families engage in conversations around unnecessary tests, treatments and procedures, which often do more harm than good and result in significant waste in the Canadian healthcare system. The central tenant to the movement is specialty-specific lists of "Things Physicians and Patients Should Question" aimed to assist physicians and patients in making informed health choices. Further, parents often seek care for these conditions either from their primary care provider or through the ED, representing a large burden on healthcare resources[13-17]. While there are a number of pediatric specific CWC recommendations[18, 19], there is currently no outward facing CWC campaign that targets parents in the community.

In the pediatric context, conditions such as ear infections, the common cold, sore throat, bronchiolitis and asthma are extremely common among children in Canada. These are conditions in which antibiotic treatment is usually unnecessary, however antibiotics are often prescribed[12]. Our goal is to co-design with parents an intervention and evaluation of CWC recommendations that align with common childhood conditions. We have previously evaluated different means of sharing health information with parents and found that blogshots compared to plain language summaries and Wikipedia pages showed significant differences in terms of parent preferences, knowledge and usability[13]. This study will include all four elements of the CWC patient

engagement framework[14]. We will **partner** and **engage** with parent stakeholders to design and create blogshots that are tailored to parents. We will then assess the effectiveness of the blogshots at **informing** and educating parents on CWC recommendations and **empowering** them to make educated, evidence-based choices for their child's health. To our knowledge, this study will be the first of its kind in Canada, and has the potential for widespread scale and implementation.

Objective

Our objective is to assess the effectiveness of blogshots to increase parent awareness, knowledge and expectations with respect to CWC recommendations that align with common childhood conditions.

Research Methods/Procedures

This is a multi-method study including a randomized control trial (RCT) and qualitative interviews. While the RCT will provide quantitative estimates of effectiveness, the qualitative component will help us understand how the intervention works. Ethics approval will be sought through the University of Alberta Human Research Ethics Board (HREB). The trial will be registered on the ClinicalTrials.gov database after ethics approval.

Inclusion Criteria

- Over the age of 18 years
- Parent or legal guardian of a child under 5 years of age
- Live in Canada
- Able to complete the questionnaire and interview in English (speak/read)
- Access to an electronic device (e.g. computer, tablet or smart phone), Internet and email.

Exclusion Criteria

- Under the age of 18 years
- Does not identify as a parent or legal guardian of a child under 5 years of age
- Does not live in Canada
- Unable to complete the interview and questionnaire in English (speak/read)
- No access to an electronic device (e.g. computer, tablet or smart phone), Internet and email.

Recruitment: Recruitment will begin once the study has received ethics approval. We will engage with our Pediatric Parent Advisory Group (P-PAG) to co-develop a recruitment strategy with our target stakeholders [15]. Parents will be recruited from across Canada using an online approach. Recruitment will take place primarily via social media and other networks such as the P-PAG and the Pediatric Parent Consultation Network (P-PCN) with which we have established connections. The ARCHE and ECHO research teams are well positioned to perform social media recruitment as we have an established social media presence on Twitter: @arche4evidence, @echoKTresearch, @ArcheEchoKT, Instagram: arche4evidence, ArcheEchoKT, Echoktofficial, Facebook: Echo Research and Reddit: u/ArcheEchoKT.

We have developed a list of stakeholder networks with social media handles and will perform an extensive social media recruitment campaign. A recruitment email will be sent to stakeholder groups in Canada to inform about the study and ask to share the study materials with their contacts.

Consent Process: Implied consent by overt action will be sought for the questionnaire portion of the study. Participants will confirm consent by continuing on and completing the questionnaire. Participants will be able to access and read the informed consent document and have the option to download the consent form from the questionnaire platform hosted by Nooro. For the qualitative interview portion, verbal consent will be obtained on Zoom video conferencing software prior to starting the interview and documented in the study verbal consent log.

Study Design**:** RCT

Participants will be randomized to two groups: Group A or Group B: each will receive messages over 4 weeks that will consist of blogshots for different CWC recommendations [18]. Participants who complete the baseline questionnaire will receive one blogshot via email every week for three weeks and the fourth week will include a summary of all three blogshots. This will be automated through the Nooro platform. Through the Nooro platform we will monitor if participants have opened the email and viewed the blogshot. If an email has not been opened for 3 days, a reminder email will be sent. At the end of the four-week campaign, participants will be asked to complete a follow-up questionnaire after the intervention at week 5 and then at three and six months post-intervention. The group topics will be:

Group A;

- *Don't routinely do a throat swab when children present with a sore throat if they have a cough, rhinitis, or hoarseness;*
- *Don't recommend the use of cough and cold remedies in children under six years of age;*
- *Don't use antibiotics for acute asthma exacerbations without clear signs of bacterial infection.*

Group B;

- *Don't routinely use antibiotics in children with uncomplicated sore throats*;
- *Don't prescribe antibiotics in adults with bronchitis/asthma and children with bronchiolitis;*
- *Don't use antibiotics in adults and children with uncomplicated acute otitis media.*

Randomization: Blocked randomization with randomly chosen block sizes will be used to ensure equal distribution of participants to each study arm. The blocked randomization sequence will be computer generated. Parents will be randomized to either group A or group B when completing the demographic and baseline questionnaire on the electronic platform.

Sample Size: We will aim to recruit 180 parents (90 participants per group). This is based on assuming a 10% difference between groups in knowledge scores and a standard deviation of 2.0

with 80% power. This would require 64 participants per group and we have increased this number by 25% to allow for dropouts.

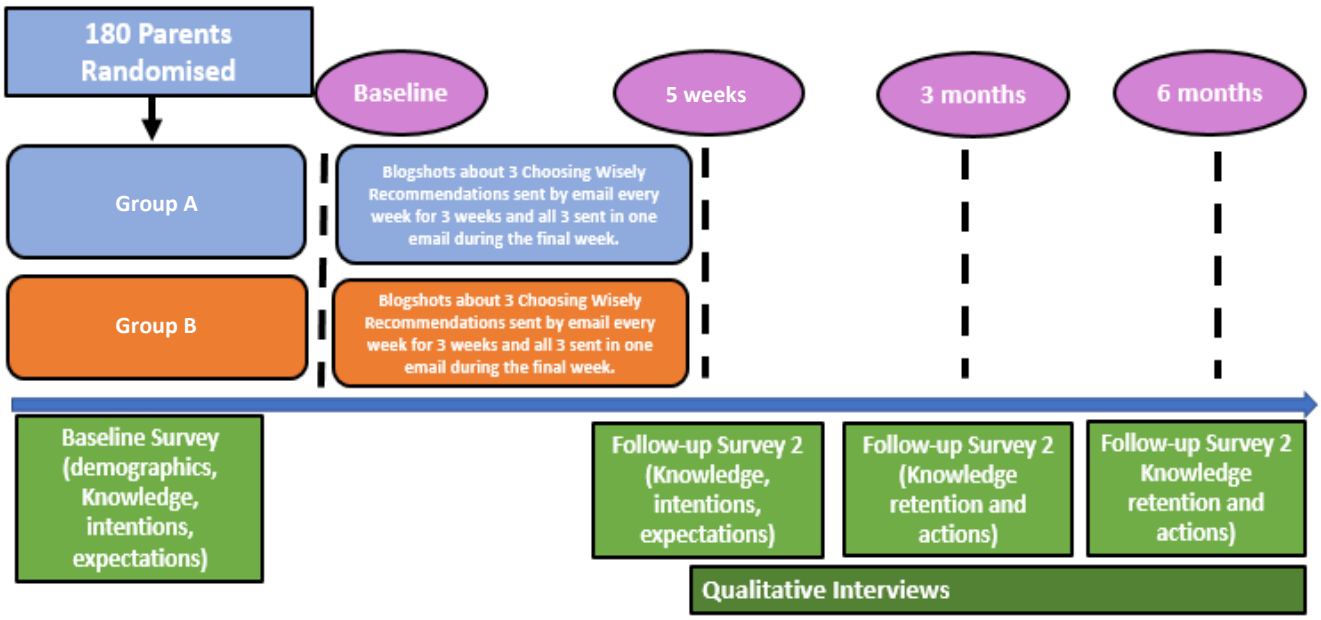

Figure 1: Study Design

Blogshot Development: Six blogshots were developed with the assistance of a graphic designer. Members of the P-PAG provided feedback on the language, design and content of the blogshots.

Online Questionnaire Development: The research team developed four questionnaires (baseline and 3 follow-up questionnaires). The questionnaires consist of multiple choice knowledge questions based on the information presented in the blogshots, questions about participant's intentions for managing common acute childhood conditions and actions participants took if their child developed symptoms of one of the conditions from the blogshot during the duration of the study. A series of 7 questions about the usability of the blogshots will be included in the questionnaire as well.

The questionnaire is designed and housed in the Nooro platform (https://nooro.com). An overview of each question category is listed below:

Baseline Questions: Four baseline questions will be included about parent's experience with the common acute childhood conditions included in the blogshots as well as number of times they went to the emergency department or received a prescription for antibiotics for their child. A question about information seeking is also included. **These questions are asked at baseline.**

Knowledge Questions: Each topic will have three "core" knowledge questions that will be included at baseline and all three follow-up questionnaires. An additional knowledge question will be included for each topic in which a participant received a blogshot. For example, group A will

receive one extra question for the sore throat swab, cough and cold medication and bronchiolitis topic and group B will receive an extra question on acute otitis media, asthma exacerbations and sore throat. **These questions are asked at baseline, follow-up 1, follow-up 2 and follow-up 3.**

Expectation Questions: Each blogshot topic will have 1 expectation question that asks parents about their expectations from a healthcare provider on the management and treatment of each condition. **These questions are asked at baseline and follow-up 1.**

Intention Questions: Each blogshot topic will have one intention question that asks parents about their intentions on the management and treatment of each condition. **These questions are asked at baseline and follow-up 1.**

Actions Questions: Participants will be asked about actions they took during the course of the **study in follow-up 2 and 3.** For example if their child had symptoms related to information in the blogshot and the actions they took i.e. went to a physician, filled a prescription for antibiotics, etc.

Usability Questions: Usability questions about the blogshot **will be included at follow-up 1**. These are usability questions previously developed by ARCHE ECHO.

Study Design: Qualitative Interviews

Qualitative interviews will be conducted with a sub-set of participants (approx. 30). This sample size is based on qualitative research methodology for performing on-one-one interviews [16, 17]. Participants will be invited to participate in the semi-structured interview while completing the week 5 follow-up questionnaire 1. Participants who are interested in participating in an interview will leave their first name and email address and will be contacted by the project coordinator to schedule an interview.

The purpose of the interviews is to further understand and contextualize participant's responses and perspectives on the efficacy of the blogshots to increase knowledge, influence intended behavior and expectations on the common acute childhood conditions [18]. The honeycomb model of user experience was used to guide the development of the interview questions [13, 19]. We will also explore parent preferences regarding format and mode of information delivery and study recruitment, which could inform future campaigns and evaluations

Incentives: Participants will be compensated a $10 CAD electronic gift card per questionnaire completed (not including baseline) to a maximum of a $30 CAD electronic gift card for completing all three follow-up questionnaires. For the qualitative component, we will compensate participants an additional $25 CAD electronic gift card for participation in the interview. This incentive will come in the form of an electronic CAD gift card to the participant.

Data Collection

The following data will be collected over the course of the study:

1. **Baseline questionnaire:** Participants will complete a pre-intervention questionnaire that includes demographics, knowledge about antibiotic use and common acute childhood conditions, intentions about whether they would seek healthcare for their child for a

common childhood condition and their expectations on management by healthcare providers.

2. **Follow-up questionnaire 1 (5 weeks after baseline):** Participants will re-do all knowledge, intentions and expectation questions as well as provide feedback on the blogshot design.

3. **Follow-up questionnaire 2 (3 months after baseline):** Participants will re-do knowledge questions (knowledge retention). They will also be asked action questions about whether their child experienced any of the conditions and what actions they took (e.g. sought healthcare services, over the counter medications, filled prescriptions.

4. **Follow-up questionnaire 3 (6 months after baseline):** Participants will re-do knowledge questions and action questions.

5. **Qualitative Interviews (post intervention):** Interviews will be conducted over zoom video conferencing software and recorded and transcribed using a third-party transcriptionist.

Outcomes

The will be knowledge immediately after the campaign; we will compare change from baseline between groups (i.e. average change in knowledge scores specific to CWC recommendations, expecting that knowledge will improve with respect to the content received). Secondary outcomes will be intentions, expectations of care and usability of the blogshots. We will explore if outcomes were influenced by whether a child had one of the conditions (and identify actual behaviour). All outcomes will be assessed both quantitatively through questionnaire responses and qualitatively though the semi-structured interviews.

The outcomes will focus on the following 5 domains:

Knowledge: Knowledge will be assessed by comparing participant's scores on baseline questionnaire to follow-up questionnaire 1 (knowledge change) and comparing scores to follow-up questionnaires 2 and 3 (knowledge retention).

Expectations: Participants will be asked questions about their expectations of healthcare professionals at baseline and follow-up 1 questionnaires. We will compare at baseline and follow up to assess if the blogshots led to a change in expectations of healthcare professionals.

Intentions: Participants will be asked questions about their intentions at baseline and follow-up 1 when they seek healthcare i.e. are they seeking antibiotics from a healthcare professional.

Actions: Participants will be asked about actions they took during the course of the study in follow-up questionnaires 2 and 3. For example if their child had symptoms related to information in the blogshot and the actions they took i.e. went to a physician, filled a prescription for antibiotics, etc.

Usability of the blogshots: Participants will complete usability questions about the blogshots focusing on topics such as if the blogshots increase knowledge, aid in decision-making and are relevant to parents. This will be completed at follow-up 1.

The semi-structured interviews will include questions on all 5 of these domains to clarify, expand on and provide to context to the questionnaire responses.

Plan for Data Analysis

Questionnaire Data: Demographic data will be collected to evaluate how representative our sample is to the Canadian population. We will use descriptive statistics, including numbers, frequencies, and means, to present demographic data. Group differences will be evaluated using independent t-test or chi squared and baseline and follow-up will be evaluated using paired t-tests or Wilcoxon signed rank test, dependent on distribution of data. In all analyses, statistical uncertainties will be expressed in 95% two-sided confidence intervals. A p value of <0.05 will indicate statistical significance. Analyses will be conducted based on intention-to-treat[20].

Interview Data: The project coordinator will perform and inductive thematic analysis of the interview data[21]. Interview coding and analysis will occur concurrently with data collection using an iterative approach. In this approach, data will be categorized into codes, forming categories that are then combined into themes that can be thoroughly described in the results. Lincoln and Guba's criteria will be used to establish trustworthiness of the analytic process[22]. Qualitative data analysis software NVIVO will be used to organize and code the data[23].

Data Storage

All data will be stored on secure Canadian servers that are compliant with data privacy and security regulations to safeguard medical information as per the Health Insurance Portability and Accountability Act of 1996. Data will initially be stored on the Nooro servers. Nooro is a secure, password protected web application managed by Mr. Edward Knight in Barrie, Ontario. This company has been used for previous research studies approved by the University of Alberta HREB. Data will be stored in locked racks at Pathway Communications in Markham, ON. This Canadian data center is ISO 27001 certified, SOC2, PCI and HIPAA compliant. The server is protected by a firewall and encryption technology, and is backed up daily. Data will be downloaded regularly (e.g., weekly) by the researchers for quality control, cleaning and analysis, and long term, secure storage. Once data collection is complete, all data will be deleted from the Nooro servers.

All digital materials (e.g., audio recordings, electronic documents) will be stored long-term on a secure server in the PI 's faculty (Faculty of Medicine & Dentistry) at the University of Alberta. Upon completion of the study, the data will be archived on the Faculty of Medicine & Dentistry server. The Faculty of Medicine & Dentistry has shared secured drives accessible by password-protected computers and the data will not be accessible to anyone outside of the research team. Hard copy files will not be stored. De-identified data will be kept for a minimum of 5 years. Participants' email addresses and first names will be collected for purposes of sending the follow-up questionnaire, reminders for completing the follow-up questionnaire, and links to the blogshots used in the study. Participants' email addresses and first names will be removed from the data files

once data collection is complete. In reporting of the results, individual participants will not be identified by name or be identifiable by their responses.

Zoom interview data will be captured and stored locally, then transferred between the research team and the third-party, transcription contractor via a secure, online portal. Transcripts will be de-identified. All data will be transferred to the researchers for analysis and long term, secure storage, and deleted by the third-party contractor once transcription is complete. Master participant lists will be stored on a secure Canadian server only accessible to the research team.

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