

**Developing a Communication Strategy to Increase Awareness of Clinical Research at
Eastern Health**

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Abstract

Background: Clinical research is important for advancing the diagnosis and treatment of disease, and improving the quality of life for patients. A lack of awareness of clinical research in patients, nurses, and physicians leads to poor recruitment into research studies. As a result, research studies do not meet target recruitment goals and studies take longer to complete. Advances in the diagnosis and treatment of disease are slowed due to regulatory bodies requiring evidence from rigorous research prior to approval of new therapies.

Purpose: The purpose of this practicum project was to develop a communication strategy to increase awareness of clinical research at Eastern Health.

Methods: An integrative literature review was conducted to discuss barriers to clinical research awareness, identify strategies to increase awareness, and support the development of a communication strategy. Consultations were completed to learn the logistics of developing a communication strategy and explore expert opinion regarding communication, education, and the importance of engaging staff and the public. An environmental scan was completed to determine current research communication methods at Eastern Health and explore existing communications at other institutions.

Results: Evidence of a lack of clinical research awareness was highlighted in patient and healthcare providers. Multiple barriers and strategies to increase awareness of clinical research were identified. Themes from consultations included organizational transparency, use of technology, targeting Registered Nurses, and use of audience- tailored content. A communication strategy was informed and developed based on these key findings.

Conclusion: It is anticipated that this communication strategy will be used to increase awareness of clinical research at Eastern Health. Increasing awareness of clinical research will improve research study enrollment to advance the diagnosis and treatment of disease. Registered Nurses can play a pivotal role in communication about clinical research.

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Introduction

Clinical research is a service offered to patients at Eastern Health. By availing of this service, patients often receive therapies that would otherwise not be an option, or they are providing vital information to help answer questions about the diagnosis and treatment of health conditions. To ensure that this service is being optimally utilized, it is necessary that patients and healthcare professionals have an awareness of clinical research at Eastern Health. To foster this, communication strategies have been developed to increase awareness of a variety of health issues and the clinical research that explores them. The development of a communication strategy about clinical research may increase awareness of this service at Eastern Health. Given their privileged position within the health care system, nurses can play a vital role in any research communication strategy.

Background of Study

Clinical research is important for advancements in the diagnosis and treatment of disease (Madsen et al., 2014). Poor enrollment rates into studies negatively impacts the progress of research (Madsen et al., 2014). If studies do not meet target recruitment goals, they may not be able to answer their primary research questions (Masset et al., 2017). In an attempt to meet recruitment goals, research studies may take longer to complete or there may be a lack of representation from “hard to reach” populations thus introducing bias (Masset et al., 2017). In addition, poor enrollment rates impact approval of new therapies as regulatory bodies responsible for approvals often require evidence from rigorous research (Ellis, Butow, Tattersall, Dunn, & Houssami, 2001). Increasing awareness of clinical research offers a chance to access treatment options that would not be available otherwise, advances testing and development of

effective treatments, removes treatments that are not effective, and improves access to healthcare professionals (Biedrzycki, 2010).

Current Issue

A lack of awareness of clinical research has been identified as an issue by the Clinical Research Division at Eastern Health. Awareness of clinical research is essential for contributing to study enrollment rates as a lack of awareness and limited understanding are associated with poor enrollment (Flood-Grady et al., 2019; Madsen et al., 2014). This lack of awareness of clinical research at Eastern Health is present in patients and healthcare providers such as Registered Nurses and physicians. Therefore, communicating about clinical research might lead to an increased awareness. Currently, there is no communication strategy regarding clinical research at Eastern Health.

Communication strategies have been developed and implemented with success for a variety of other health issues at Eastern Health and may therefore mitigate the lack of awareness of clinical research.

Purpose and Objectives

The overall goal for this practicum project is to develop a communication strategy regarding research as a service at Eastern Health that may improve study enrollment rates. The following objectives were developed for this practicum project:

1. During the practicum, I will identify and describe the knowledge gap of research in patients and staff (Registered Nurses and physicians).
2. During the practicum, I will identify barriers and rationale as to why patients and staff are not aware of research as a service at Eastern Health.
3. During the practicum, I will develop a communication strategy to increase awareness of research.
4. By the end of the practicum, I will demonstrate advanced nursing practice competencies in relation to the development of a research communication strategy.

Overview of Methods

The methods for developing the communication strategy were selected to meet the objectives of the practicum project. To fulfill the first objective, an integrative literature review was conducted to demonstrate that there is evidence to support that a lack of awareness of clinical research in patients and healthcare professionals. In addition, a needs assessment was conducted as part of a consultation plan to identify a knowledge gap in clinical research in patients and healthcare professionals at Eastern Health. The second objective was accomplished in part by the literature review that identified barriers to research awareness in patients and healthcare providers. In addition, communication barriers were identified from consultations with key stakeholders at Eastern Health. The third objective of developing the communication strategy was informed by consultations with key stakeholders at Eastern Health and also by conducting an environmental scan of research communications at other health organizations, websites of health organizations, and clinical research recruitment websites. The fourth objective

was fulfilled by demonstrating advanced practice nursing competencies throughout the completion of the methods for this practicum project.

Summary of the Literature Review

An integrated literature review was conducted to discuss what is known about awareness of clinical research in patients, nurses, and physicians, and to identify strategies to increase it. In addition, the literature review also highlighted the importance of clinical research, provided arguments for the importance of increasing awareness of research, and supported the idea of creating a communication strategy for this practicum project. In addition, Adult Learning Theory (Sanchez & Cooknell, 2017) was identified as a guiding theory for this project. CINAHL, PubMed, and Cochrane Library databases were searched and articles were critically appraised using the Public Health Agency of Canada [PHAC] (2014) guidelines. The complete literature review can be found in Appendix A.

Awareness of Clinical Research and Participation Rates

Awareness and understanding of clinical research are associated with participation rates (Flood-Grady et al., 2019; Madsen et al., 2014). Having a lack of awareness or knowledge of research in a variety of patient populations impacted decision-making regarding enrollment into research studies in that it can negatively affect their willingness to participate (Chu, Kim, Jeong, & Park, 2015; Ellis, Dowsett, Butow, & Tattersall, 1999; Ellis et al., 2001). In addition, patients report lack of awareness as a reason for declining participation in clinical research (Tohid et al., 2016).

Patient awareness of and participation in clinical research may also be impacted by the awareness and knowledge that nurses have regarding research. Nurses comprise the largest group

of healthcare professionals and they play a significant role in caring for, and building relationships with, patients. Engaging nurses in clinical research may therefore improve patient awareness and participation in studies (Yanagawa et al., 2014; Kao, Hamilton, Lin, & Hu, 2019). Unfortunately, a lack of awareness or knowledge deficit has been noted in nurses working in a variety of settings. For example, many nurses are aware that clinical research exists, however, few nurses have an understanding of research aspects other than informed consent (Yanagawa et al., 2014). The literature indicates that there is a need for educating nurses about clinical research so that they may provide adequate information and support to their patients participating in clinical research.

Lack of awareness also exists in physicians and other primary healthcare providers (Madsen et al., 2014). In addition, physicians may have misconceptions about clinical trials which negatively influences their decision to discuss research as options for patients (Michaels et al., 2015). Like nurses, physicians also require education about clinical research as they have a key role in educating patients (Michaels et al., 2015).

Barriers to Awareness of Clinical Research

The review of the literature highlighted barriers to research awareness in patients, nurses, and physicians. These barriers include understanding of research, sociodemographic factors, and attitudes toward research.

Understanding of Research. Patient decisions to enroll in a study are influenced by difficulty understanding research concepts (Stead, Eadie, Gordon, & Angus, 2005; Massett et al., 2017; Meropol et al., 2016; Napoles, Cook, Ginossar, Knight, & Ford, 2017). Research information provided in clinical trial resources and communication from physicians often contain

information above the health literacy level for many patients (Friedman et al., 2014). Simplifying information presented to patients who are potential research participants might mitigate this barrier.

Sociodemographic Factors. Sociodemographic factors such as age, geographic location, socioeconomic status, and whether patients are of racial or ethnic minorities were also identified as barriers to clinical research awareness and participation in studies. Patients who are 65 or older (Cooke et al., 2010; Meropol et al., 2016; Michaels et al., 2015), who live in rural areas (Michaels et al., 2015), who are of low socioeconomic status (Meropol et al., 2016), or who are of a racial or ethnic minority (Meropol et al. 2016; Skinner et al., 2019) have low representation in clinical trials. Factors influencing the low representation include older persons not being offered the opportunity to participate in research (Kemeny et al., 2003) and geographic location placing an inconvenience on patients due to transportation access or financial burden (Meropol et al., 2016). In addition, those with higher education, higher yearly income, and greater internet use were significantly associated with having awareness of clinical research (Leiter, Diefenbach, Doucette, Oh, & Galsky, 2015), while non-white populations were significantly less likely to have heard of clinical research (Brown & Moyer, 2010). Addressing these sociodemographic factors is important when considering communication methods and content for patients and staff at Eastern Health so that the impact of these barriers to research awareness and enrollment might be lessened.

Attitudes. The integrated literature review also highlighted attitudes toward research as a barrier to clinical research awareness and participation. For example, feelings of uncertainty or fear may impact clinical research participation (Masset et al., 2017). Patients may worry that standard treatment is better than a clinical trial treatment (Du et. al, 2008), providers who are

associated with research (Friedman et al., 2014). The attitudes of healthcare providers also play a significant role in affecting awareness and participation of patients in research. For example, physicians interviewed noted feeling concerned that research would compromise their quality of care as they felt that trials are too time consuming, inappropriate for their practice, and are less effective than standard therapy (Masset et al., 2017; Michaels et al., 2015). Physician misconceptions about research influences their decisions to discuss research with patients or refer them to clinical research staff (Michaels et al., 2015). Communication with the public and healthcare providers about clinical research must consider these attitudes through the appropriate framing of messaging and ensuring adequate and accurate information is provided.

Strategies to Increase Awareness of Clinical Research

Strategies were identified in the literature to increase awareness of clinical research in patients, nurses, and physicians aim to address barriers to awareness of clinical research at Eastern Health. These include assessing the health literacy of communications, collaborating with stakeholders, use of technology, and targeting healthcare providers with education initiatives so that they may communicate about research with their patients.

Health Literacy. The health literacy of potential research participants is critical to consider when disseminating information about clinical research. To ensure that underrepresented populations receive and understand information, it is necessary to use appropriate content and readability. The literature indicates that clinical research resources often have a readability that exceeds the population average; for example, one analysis noted a mean readability of materials to be grade 11.7(Friedman et al., 2014). The readability of internet resources has also been determined to be challenging, and the websites are often not easily navigated to find relevant content (Abel et al, 2015). In addition, the content of many resources

do not include a specific call to action, meaning that potential participants were not provided with direction in terms of who to contact for more information about a study (Friedman et al., 2014).

Collaboration. Partnering with stakeholders such as other health organizations and pharmaceutical companies to develop communication resources to explain clinical research to the public has received positive feedback in the literature. Partners report satisfaction with their partnerships and the resources developed (Solomon et al., 2009). In addition, collaboration on a smaller scale within a multidisciplinary clinic has shown positive results (Madsen et al., 2014). Utilizing multiple platforms for education of patients about research such as posters around the clinic and education directly from team members has led to increased clinical research enrollment rates (Madsen et al.). A collaborative approach to communication at Eastern Health might improve awareness and participation rates by offering a variety of educational platforms.

Use of Technology. Technology is a valuable communication tool in today's society and is beneficial for dissemination of clinical research information. The majority of people who report awareness of clinical research have learned about research through mass media campaigns (Chu et al., 2015). In addition, the internet is the preferred source of information among many patients and their families (Flood-Grady et al., 2019). Web- based education tools (Flood-Grady et al., 2019) and interactive video programs (Meropol et al., 2016) have been effective in increasing patient knowledge (Flood-Grady et al., 2019; Meropol et al., 2016) and decreasing attitudinal barriers (Meropol et al., 2016) toward research participation. Technology that provides tools to increase access to clinical research information and offer an interactive component that might be beneficial within the Eastern Health large geographic region.

Targeting Healthcare Providers. Providing education to healthcare providers regarding clinical research is necessary to improve dissemination of research knowledge to their patients. Online self-learning modules containing clinical research information that can be accessed at any time have been positively received by nurses (Haugen, Gasber, Leonard, & Lander, 2015) and may be beneficial and convenient for the large number of front-line nurses working at Eastern Health. These nurses are valuable sources of information for patients and if they are knowledgeable about clinical research, they might be able to appropriately direct patients who are potentially interested in a trial (Kao et al., 2019). Primary care providers such as physicians are also valuable and trusted sources of information for their patients. Education targeting physicians may also encourage discussion about clinical research as options and therefore increase patient awareness and enrollment rates (Michaels et al., 2015). Education initiatives targeting healthcare providers have the potential to play a significant role in mitigating the lack of awareness of clinical research at Eastern Health.

Theoretical Framework

Communication regarding clinical research primarily includes education about it. With this in mind, and considering the target population for the communication strategy consisting of adults, Adult Learning Theory was selected as a guiding theory for communication initiatives (Sanchez & Cooknell, 2017). The key principles of Adult Learning Theory are that adults expect to receive useful knowledge; they are motivated by problems; their life experiences direct their learning; and they prefer a flexible learning environment and independence (Sanchez & Cooknell). These principles can be applied when educating both patients and healthcare providers such as nurses and physicians. Patient education utilizing Adult Learning Theory can strategically address multiple barriers to clinical research awareness. Effective patient education

in this manner will include sending clear messages that are to the point and use photos to account for health literacy, and will occur at multiple time points during a patient's time in the clinical setting (Sanchez & Cooknell). Brief education at multiple time points, or offering self-learning opportunities allows patients to learn at their own pace and possibly become more receptive to information in this way (Sanchez & Cooknell). Education for healthcare providers guided with Adult Learning Theory may also incorporate self-learning modules that are convenient for those with busy schedules and affected by the hard-to-reach nature of shiftwork.

Limitations and Implications

Critical appraisal of the literature within this review identified a need for more rigorous study designs to explore how communication strategies influence clinical research awareness and participation rates. Many of the studies included had descriptive study designs and self-reported outcomes that had potential for bias. However, these study designs were appropriate for answering questions about awareness and were appropriate for guiding the development of the communication strategy.

The barriers to clinical research identified within this review must be considered when developing the communication strategy. Potential strategies to increase clinical research awareness and participation rates were noted and many address the barriers identified. These strategies were further explored throughout the methods of this practicum project to determine if they were reflected in communications practices currently at Eastern Health and within other health organizations.

Summary of Consultations

Consulting with key stakeholders was a necessary aspect of developing the communication strategy for this practicum project to assess target audience needs, determine steps to take, and discuss potential methods for the strategy. The key objectives of the consultations were to discover how Eastern Health Corporate Communications currently implements communication strategies and the logistics behind this; to explore how learning resources are developed within the Learning and Development department; to learn how Human Resources engages employees; and to assess clinical research learning needs of patients, Registered Nurses, and physicians. The Consultations Report can be found in Appendix B.

Consultation interviews were conducted with one Communications Specialist, two Learning and Development staff members, and one Human Resources staff member. After each interview, a content analysis was performed on the data to identify themes using guidelines from Braun and Clarke (2006). The needs assessment included seven Registered Nurses, two patients, and four physicians who either worked on a unit participating in clinical research, or a unit that does not participate in clinical research. The nurses and physicians were approached on their units to answer a few questions regarding clinical research, and the patients were asked by their nurses whether or not they were aware of clinical research at Eastern Health.

Logistics

Consultation interviews provided important logistics for the communication strategy. The Communications Specialist provided templates as a guide for the development of the project, as well as information regarding the approval process for the strategy. In addition to the strategy itself, it was important to note that all communications content must be approved as well.

Learning and Development staff provided similar information regarding approvals of educational initiatives. It was also highlighted that this department may be consulted for development of educational materials for use as part of the communication strategy.

Themes from Eastern Health Staff Responses

Use of Technology. The use of technology was noted by all interviewed individuals as beneficial for communication and education of staff and the public. Eastern Health employees are all connected via email, Microsoft Teams, and the intranet. Other potential modes of communication include weekly newsletters that are sent via email by Corporate Communications called Pulse Plus, or a feature in the StoryLine blog. In addition, there is a digital signs network across Eastern Health facilities that might be used to display messaging to staff. This digital signs network may also be used for messaging to the public in public areas of the facilities. The public may also be reached via messaging on one of the many social media platforms that Eastern Health utilizes such as Facebook or Twitter. Using technology was described as a method to extend the reach of the communications so that staff and patients can be reached beyond the city hospitals, thus addressing the barrier of location regarding clinical research awareness.

Target Audience. All persons interviewed highlighted the importance of knowing your target audience and creating audience-tailored content. It was stated that conducting needs assessments, environmental scans, and consultations are important in developing individualized content for a particular group. The accessibility of content was also noted as important to ensure people of multiple reading levels can understand the messaging. In addition, barriers to communicating with a target audience were discussed and include geographic location, position held at Eastern Health, and learning style. They were also reflective of barriers noted within the

literature review and were important to consider when developing the strategy. For example, communications may differ whether targeting Leadership positions at Eastern Health, frontline staff, or the public, and it was important to ensure that the strategy would include learning opportunities for individuals outside of St. John's.

Providing Reasoning. The consultations indicated that providing reasoning for education and communication is important. Eastern Health staff and the public often express their desire to understand why they need to know something. In addition, this is consistent with Adult Learning Theory principles (Sanchez & Cooknell, 2017). It was suggested that evidence for clinical research benefits or testimonials from past participants be utilized as part of the strategy's messaging to healthcare providers and patients.

Inclusion. Including employees from the beginning in the development of any change or initiative at Eastern Health was described as important for employee engagement. Asking for input or feedback, and then acting on that feedback fosters a sense of trust with employees and also shows them that their opinions are valuable. Based on this information, ensuring that staff can have input in communication and education initiatives was an important factor to consider for this project.

Themes from Needs Assessment

The needs assessment indicated an overall lack of awareness of clinical research at Eastern Health in patients as well as healthcare providers. Registered Nurses working on units that participate in clinical trials and those that do not participate in clinical trials responded similarly. While Registered Nurses reported a general knowledge of clinical research, most were unsure of specifics regarding the research process, where the Clinical Research Division was

located, and who to contact if their patients were to request information regarding research. Physicians from both units were knowledgeable of clinical research taking place at Eastern Health; however, some were unsure of the location of the Clinical Research Division unless they were directly involved in clinical research. According to the nurses who spoke with a patient from their units, the patients assumed clinical research was taking place at Eastern Health, but were unaware of any specific details.

Important insight was obtained from this small needs assessment regarding the awareness of clinical research at Eastern Health. In the future, a larger scale and more robust assessment could be beneficial in gaining a more in-depth perspective of the needs of both the public and healthcare providers at Eastern Health in terms of clinical research knowledge.

Ethical Considerations

Approval from the Health Ethics Review Board and the institutional review board were not required for this project as it is classified as a quality improvement project as per the Health Research Ethics Authority Screening Tool found in the Consultation Report in Appendix B. Verbal consent to participate was obtained from each individual during initial contact, and participants were notified they were free to withdraw from the consultation at any time. Confidentiality of participants was maintained with the use of private interview rooms or private phone calls, and personal identifiers were not recorded during the interviews. Data was stored within a password protected folder on a password protected computer to maintain data security. In addition, no identifying information was stored with the data.

Summary of Environmental Scan

An environmental scan was completed as part of this practicum project to identify current communication practices regarding clinical research at Eastern Health and to explore communications at other Canadian health organizations. Health organizations with a known research presence, and health organizations that are similar to Eastern Health in terms of geographic location and size were targeted. Organizations were contacted via email and two organizations with a known research presence participated. Each organization was provided with a short questionnaire and responses were analyzed using content analysis (Braun & Clarke, 2006).

Websites for clinical research awareness campaigns, clinical trial search engines, and the websites of the organizations contacted for participation were examined for content themes. Data collected from the website scan were utilized to inform potential website development as part of the communication strategy. Themes identified from the websites were identified via content analysis as per Braun and Clarke (2006). The Environmental Scan Report can be found in Appendix C.

Eastern Health Current Practices

Representatives from the Clinical Research Division agreed to participate and describe current communication practices at Eastern Health. Responses indicated that there is currently no communication strategy regarding clinical research and there is no specific budget for communications. Current communication and recruitment methods of the department primarily include approaching potential participants in clinics and posters. The department has also participated in awareness campaigns and innovation fairs.

However, there are currently no ongoing and sustained communications about clinical research in general. Impeding factors to this process included a general lack of communication, the large geographical region of Eastern Health, and difficulty navigating the website.

This information indicated a need for sustained communication strategies to promote ongoing communication regarding clinical research at Eastern Health. In addition, the barriers described provided insight into considerations when developing the communication strategy.

Themes from Other Health Organizations

The participants from other health organizations provided valuable insight regarding communication methods that might benefit Eastern Health in increasing awareness of clinical research and improving study participation rates. While these individuals were not aware of specific communication strategies for clinical research within their organizations, both described their institutions as having a large research capacity that was promoted via multiple communication methods. Themes related to research communication were identified as the need for transparency about clinical research, targeting staff with education about clinical research, and providing understanding.

Both organizations were transparent that they were institutions that conducted research. For example, posters were placed at all entrances and throughout the hospitals to indicate to those entering into the facility that patients might be asked to participate in clinical research. These posters provided some assurance that patients would not be surprised if offered a chance to participate, and to ensure that they were aware that they were being cared for in a facility that conducts research. A similar initiative would be feasible at Eastern Health as there are many places to place signage via paper posters, or via the use of the digital signs network.

Participants also described targeting staff with clinical research education by providing learning opportunities, email newsletters, or website information. Staff were subsequently encouraged to disseminate this information to patients. In addition, public education modalities included the use of posters, the organization's website, or was provided by their healthcare provider.

In addition, there was a need to ensure that potential research participants have a clear understanding of research. For example, respondents described using clear messaging on posters and during other recruitment activities, and stated that this was a means to facilitate recruitment. In summary, these themes were used to inform the clear messaging and education initiatives as part of the communication strategy.

Themes from Clinical Research Websites

Websites associated with clinical research such as awareness campaigns, clinical trial search engines, and the websites of organizations invited to participate in the environmental scan were reviewed and the data analyzed for themes. The first theme noted was that website content appeared to have an appropriate literacy level with clear messaging. This is important in mitigating inequities in socioeconomic status and language that act as barriers to clinical research awareness and will be considered in the development of the clinical research portion of the Eastern Health website. Research information was also easy to locate on these websites, and was often accessible via a large tab on the landing page. This would also be beneficial for the Eastern Health website to mirror. In addition, there was a theme of altruism in the messaging directed at patients, and the use of testimonials from patients and their families was evident across the websites to facilitate feelings of personal connection with the target audience.

Ethical Considerations

Approval from the Health Ethics Research Authority and the institutional review board was not required for this project as it is classified as a quality improvement project as per the Health Research Ethics Authority Screening Tool (See Environmental Scan Report in Appendix C). Agreements to participate and share information were obtained from each individual during initial contact. Confidentiality was maintained using private interview rooms for any interviews or phone calls, and not recording personal identifiers during data collection. Participants were aware that they are free to withdraw at any time.

Security of data was maintained by storing it in a password protected folder on a password protected computer. No personal identifying information was stored with data.

Development of the Communication Strategy

Findings from the literature review, consultations, and environmental scan were integrated to create the communication strategy. Templates were provided by Corporate Communications at Eastern Health and were adapted for the purpose of this practicum project. Multiple drafts have been created for this course, however, the communication strategy must also meet organizational approvals from Eastern Health prior to its implementation. The communication strategy can be found in Appendix D.

Overview

The communication strategy is divided into sections as follows: a description of the issue; background information regarding the importance of clinical research; summaries of the literature review, consultations, and environmental scan key findings; target audiences; communications goals and objectives; internal and external stakeholders; a Strengths,

Weaknesses, Opportunities, and Threats (SWOT) analysis; key messages; a detailed description of communications activities including recommended tactics and an action plan chart; and a brief description of an evaluation of tactics plan.

This practicum report will describe key aspects of the strategy such as target audience; communications goals and objectives; key messages; and communications activities. The full strategy can be found in Appendix D.

Target Audience

Identifying a target audience has been described throughout the methods of this practicum project as an important piece for developing a communication strategy to increase awareness of clinical research. The primary target audience identified for this communication strategy are adult patients within the Eastern Health region who may benefit from clinical research. These patients are the primary target as the overall goal of increasing clinical research awareness at Eastern Health is to improve study enrollment rates; if adult patients are aware of clinical research and become more knowledgeable, it is speculated that enrollment rates might increase (Flood-Grady et al., 2019; Madsen et al., 2014).

Secondary target audiences identified for this strategy are employees of Eastern Health such as nurses, physicians, and other healthcare providers with direct contact with patients; stakeholders such as government organizations, community medical clinics, or pharmaceutical companies; and students of health professional schools, or graduate students in health related programs that are completing schooling or placements within Eastern Health. Healthcare providers will be targeted due to their lack of awareness of clinical research and also because targeting them with communication and education initiatives has shown success in the literature

review. In addition, targeting this group has been described as beneficial by Eastern Health staff and representatives at other health organizations in the environmental scan. Targeting students at Eastern Health ensures that these individuals will be aware of clinical research at the start of their career if they return to work at Eastern Health. Collaboration with stakeholders was described in the literature review as a strategy to increase awareness of clinical research (Solomon et al., 2009), thus providing rationale for targeting stakeholders as part of this strategy.

Communication Goals and Objectives

The goals of the communication strategy are: to communicate that research is a service offered at Eastern Health; to communicate what clinical research is, why it is important, and how people contribute to helping others when they participate; and to increase awareness of the Clinical Research Division at Eastern Health. These goals were developed based on knowledge gaps identified from the needs assessment.

The objectives of the communication strategy are: to expose patients to campaign messages for a sustained period of time; to expose Eastern Health staff to campaign messages for a sustained period of time; and to generate at least the average number of visits to the website noted during previous awareness campaigns in the first year of the campaign launch. These objectives are based on the objectives of previous communication strategies and will be modified to include numbers such as the number of exposed patients and number of website hits that are typical during similar campaigns.

These modifications will occur with continued consultation with Corporate Communications and will occur prior to approval and implementation of this strategy at Eastern Health.

Key Messages

The key messages for this communication campaign were created based on Adult Learning Theory principles such as adults require rationale for learning about a topic and they are expected to have life experiences that affect their learning (Sanchez & Cooknell, 2017). In addition, messaging was developed based on gaps in knowledge identified from the needs assessment, from messaging practices that are beneficial at other health organizations, and to ensure that barriers to clinical research awareness such as literacy level are taken into consideration.

The key messages of this strategy include:

1. Eastern Health conducts clinical research. You may be asked to participate in a research study.
2. What is clinical research and why is it important?
3. Who conducts clinical research?
4. How can I find out more about clinical research?

Communications throughout this campaign will pose these questions and also provide answers in messaging. These messages are simple with the idea that posing simple questions will provoke people to reach out for further details or specific questions.

Communication Activities

Activities for this communication strategy were identified based on the methods of this practicum project, previous methods utilized in communication strategies at Eastern Health, and consultations with the Clinical Research Division. The activities are classified within the

categories of branding, creation of collateral materials, use of technology, building capacity, and promotional activities.

Creating brand will ensure that the awareness campaign is identifiable through consistent messaging and aesthetic. The branding will be developed in consultation with Corporate Communications, the Clinical Research Division, and members of the target audiences. The brand will then be used for the development of collateral materials such as posters to promote the campaign. Collateral materials such as these will be placed in strategic locations to reach the maximum number of people in each target audience.

Targeting stakeholders such as health professionals, students at Eastern Health, and community partners with promotional materials will aim to influence behavior from multiple angles and build capacity in clinical research communications. For example, Registered Nurses as internal stakeholders will be offered the opportunity to participate in an online self-learning module about clinical research that will be developed in consultation with Learning and Development. Presentations and promotional materials about clinical research will be offered to Eastern Health students as well as community partners. All of these activities build capacity in the sense that these targeted individuals may then be utilized as additional sources of information regarding clinical research for patients at Eastern Health.

The use of technology was described within all methods of this practicum project as a beneficial tool to increase awareness of clinical research and it will be utilized in this communication strategy to extend the reach of the campaign's message. For example, the digital signs network will contain clinical research messaging and will reach patients and staff across Eastern Health. In addition, a social media campaign will also aid in reaching people across the

Eastern Health region. Education sessions might be offered via webinar as well to account for those individuals wishing to participate but are limited by transportation barriers.

The promotional activities for this strategy will begin with an official event launch. After this event, promotional activities will continue so that messaging is sustained at regular intervals via Eastern Health's communication platforms. This will address the current lack of sustained clinical research communications conducted by the Clinical Research Division.

All activities for this communication strategy will be developed in continuing consultation with the Clinical Research Division and Corporate Communications at Eastern Health after this practicum project is complete. The activities of the strategy will be implemented after final institutional approval of the communication strategy has occurred.

Advanced Nursing Practice Competencies

The Master of Nursing program at Memorial University provided a foundation for advanced nursing practice competencies that has supported the development of this practicum project. During this practicum project, the opportunity to demonstrate several of these competencies was provided including research competencies, optimizing health system competencies, consultation and collaboration competencies, and educational competencies, as specified by the Canadian Nurses Association [CNA] (2019) framework.

The research competency was demonstrated through the conducting of an integrated literature review which included critical appraisal of the literature. Advanced practice nurses formally appraise research in this manner to inform the development of new guidelines for practice (CNA, 2019), or in the case of this practicum project, to inform the development of a communication strategy. Data was collected in the process of conducting consultations with key

stakeholders and environmental scans. This information was analyzed looking for themes that incorporated research best practices and methods.

The CNA (2019) describes an aspect of the optimizing health systems competency as becoming involved and participating in strategic plan for the health-care service or department in which the advanced practice nurse is employed. This practicum project was completed for the Clinical Research Division and thus meets requirements for having demonstrated this competency.

Consultation and collaboration were continuing processes throughout the course of this practicum project. Stakeholders' input was greatly valued. For example, consulting with Eastern Health stakeholders and experts on the subject matter directly related to the development of this practicum project (CNA, 2019). In achieving this, I engaged in intra and interprofessional consultation that further enhanced my skill development in this area. This competency was further demonstrated through consulting stakeholders at other health institutions during the environmental scan, and through continued collaboration with the Clinical Research Division at Eastern Health.

Educational competencies were demonstrated in several areas including identifying learning needs of the public and staff at Eastern Health regarding clinical research, including educational initiatives within the communication strategy to address this learning need, and planning to educate target audiences about clinical research through the messaging and promotional activities planned for this communication strategy (CNA, 2019).

In addition, leadership competencies were demonstrated throughout the course of this project. Activities that reflect leadership included the evaluation of existing clinical research

communications and working to finding solutions that would improve research communications at Eastern Health. Identifying the issue of a lack of awareness of clinical research at Eastern Health and developing a plan to address this issue was also a leadership competency. (CAN, 2019)

Reflections and Next Steps

Reflection is a necessary part of learning and facilitates the identification of lessons learned, highlights the next steps to be taken, and allows for improvement in the completion of future projects.

Lessons Learned

Several lessons have been learned throughout the course of this practicum project. The literature review provided me with a clear understanding of the barriers to clinical research awareness that were not immediately obvious to me. For example, location as a barrier to awareness due to transportation difficulties was not something I had thought about; likely due to working in the largest health facility in the province where most research activity occurs. Location as a barrier was continuously echoed during the consultations with staff members who are responsible for the education of staff. These individuals made me cognizant of the challenges faced by rural employees participating in learning opportunities.

Timely communication during consultation was another lesson learned during this project. For example, the consultations took place during the summer, which is a challenging time of year for scheduling meetings. Many of the contacted individuals had limited availability thus it was difficult to obtain data within the time limits of the course. If I were to complete a

similar project in the future, I would consider logistics such as the time of year and determine whether I needed to adjust my timeline to account for similar challenges.

Collecting data during the environmental scan also provided a learning opportunity. As with the consultations, the environmental scan took place during the summer. It was difficult to contact organizations during this time and this might be due to individuals being on vacation, staffing changes, or incorrect contact information. As a result, the participation rate for the environmental scan was low and could be improved in the future by contacting more organizations than thought necessary. This could ensure a more accurate representation of clinical research communications from other Canadian health organizations in the future.

Next Steps

After the completion of this practicum project, the communication strategy will require continued collaboration with the Clinical Research Division and with Corporate Communications at Eastern Health prior to its institutional approval and implementation. As a result, the communication strategy found in Appendix D of this report may not be the final version and alterations may occur to meet additional requirements of Eastern Health. In addition, the development of the communication activities outlined within the communication strategy will occur with collaboration of the Clinical Research Division and Corporate Communications. Approval from Eastern Health of all materials developed must also occur prior to the implementation of this strategy.

Following the implementation of this strategy, an evaluation will take place to assess whether the communications goals and objectives, as well as the overall goal of the practicum project have been met. Evaluation activities will include evaluation of tactics such as using

backend analytics to assess website usage; monitoring social media success; sending out a post-launch survey to assess whether the target audience had heard of the campaign and if they had visited the website as a result; and assessing the uptake of the campaign by stakeholders within the organization and the community. In addition, the overall goal of increasing clinical research awareness and participation in clinical research will be evaluated by monitoring the number of new study enrollments after the launch of the campaign, monitoring the number of studies conducted at Eastern Health; monitoring the number of investigators conducting research; and monitoring how many people seek out information from the clinical research division about studies, whether or not they choose to enroll in one.

Conclusion

The Clinical Research Division identified a gap in knowledge and lack of awareness of clinical research at Eastern Health in patients, nurses, and physicians. This practicum project has completed a preliminary step in mitigating this lack of awareness. Evidence supporting the development of a communication strategy to increase awareness of clinical research at Eastern Health was obtained through a variety of methods throughout this practicum project. The literature review substantiated how lack of awareness is an issue that contributes to poor research participation rates that slows the progression toward new therapies and improved diagnoses. In addition, the barriers to clinical research awareness and potential strategies to increase awareness identified within the literature review informed guiding questions utilized during consultations and the environmental scan. Logistics for the communication strategy, approval of communication materials, and development of educational materials as part of the strategy were learned during the consultations. In addition, experiences in educating Eastern Health staff and patients was discussed to determine challenges and facilitators that might guide this project. Data

collected and analyzed from the consultations and environmental scan reflected the barriers and strategies identified within the literature review, as well as providing new insight to inform the development of the communication strategy. Critical analysis of the literature results and content analysis of the consultation and environmental scan data resulted in the development of an evidence- informed communication strategy. As a result of this strategy, there is potential for an increase in clinical research enrollment rates at Eastern Health. This could contribute to the advancement in the diagnosis and treatment of many health conditions, thus improving the quality of life for many individuals.

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Appendix A

Integrated Literature Review

Developing a Communication Strategy to Increase Awareness of Clinical Research at Eastern
Health: Integrated Literature Review

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Clinical trials and other forms of clinical research are offered as a service to patients by the Clinical Research Division at Eastern Health. An informal needs assessment interviewing patients, nurses, and physicians within Eastern Health as well as consultations with the manager and director of the Clinical Research Division highlighted a lack of awareness of research at Eastern Health. The purpose of this literature review is to discuss what is known about awareness of clinical trials and clinical research in patient, nurse, and physician populations and identify strategies to increase awareness of research. This literature review will also provide arguments for the importance of clinical research, the importance of increasing awareness of research, and how creating a communication strategy for this practicum project may be effective in meeting the practicum goal of increased research awareness. In addition, guiding theory for clinical research communication and education will be discussed. Articles included in the literature review will be critically appraised using the Public Health Agency of Canada [PHAC] (2014) guidelines to draw conclusions and assess evidence value for this practicum project.

Search Strategy

CINAHL, PubMed, and Cochrane Library databases were searched using search terms: “clinical trials”, “research”, “awareness”, “knowledge”, “barriers”, “strategies”, “patients”, “nurses”, “physicians”, “communication”, “education”, “attitudes”, “perceptions”, “nurse’s role”, “physician’s role”, “patient’s role”, “theory”, and “methods”. Search results were limited to academic journals, English language, and publication date within the last 10 years.

Background: Importance of Clinical Research

Clinical trials and other clinical research categories are important for advances in health care. Research works to improve the diagnosis, treatment, quality of life, and survival for patient populations (Madsen et al., 2014; Massett et al., 2017). Research progress is negatively impacted due to low rates of enrollment into studies (Madsen et al., 2014). Research studies that do not meet recruitment goals cannot answer their primary research questions (Masset et al., 2017). In addition, not reaching target recruitment results in study outcomes that are compromised, length of time to completion increases in an attempt to reach higher recruitment, and results may be biased due to lack of recruitment from “hard to reach” populations (Fenlon et al., 2013). Low participation rates into clinical research subsequently impacts the progression of advances in diagnosis and treatment of disease (Massett et al., 2017). Regulatory bodies now often require evidence from rigorous studies such as randomized controlled trials or meta-analyses prior to approving new therapies (Ellis, Butow, Tattersall, Dunn, & Houssami, 2001).

Clinical Research Awareness and Participation Rates

Awareness of clinical research is important for improving participation rates in clinical trials; lack of awareness and poor understanding is a significant barrier to clinical trial enrollment (Flood-Grady et al., 2019; Madsen et al., 2014) and affects a patient’s ability to make a decision about participating in research (Skinner, Fair, Holman, Boyer, & Wilkins, 2019). Issues with awareness and participation in clinical research extend beyond the patient population to include nurse and physician populations as well as they are often the gatekeepers to clinical research. Adequate participation from patients, plus nurses, and physicians may facilitate the progression of developments related to the diagnosis and treatment of disease as well as improvements in quality of life.

Patient awareness and knowledge of clinical research is associated with decisions to participate in clinical research in a variety of populations. Women attending a breast cancer screening clinic were surveyed using a cross-sectional study design to determine their knowledge of, attitudes toward, and willingness to participate in clinical trials.

Inclusion criteria included women who were being screened, who were newly diagnosed with breast cancer, or who were undergoing treatment for early-stage breast cancer (Ellis et al., 2001). Thirty three percent would consider participation in a clinical trial if they had breast cancer, while women already diagnosed with breast cancer were significantly more likely to decline enrollment into a study than those undergoing screening (Ellis et al., 2001). In addition, women who reported they would consider participating in a trial were more knowledgeable about these, were younger, and preferred active decision making in their treatment (Ellis et al., 2001). Other studies of patients with cancer also highlight a lack of knowledge contributing to willingness to participate in clinical trials (Ellis, Dowsett, Butow, & Tattersall, 1999), with only 58% stating they are aware of clinical research (Bazarbashi, Hassan, Eldin, Soudy, & Hussain, 2015). Awareness and positive perceptions of clinical trials are significantly associated with participants stating they would consider participating in clinical trials (Chu, Kim, Jeong, & Park, 2015), and a lack of awareness is cited as a reason that people decline participation in clinical research (Tohid et al., 2016). Of the participants who were aware of clinical trials in the study by Chu et al. (2015), most had heard of them through mass media campaigns. In another cross-sectional study of persons with epilepsy, knowledge and awareness of clinical trial procedures was associated with factors such as ability to work and age at onset of epilepsy (Reijula et al., 2015). The authors did not directly hypothesize reasoning for this association. However, they did

discuss how low education levels lead to misconceptions about clinical trials and education level may be associated with ability to work and having epilepsy from a young age.

Literature reporting on awareness of the patient population of clinical research is largely descriptive in nature. The studies discussed are all cross-sectional designs that are categorized as weak study designs as per PHAC (2014). However, the quality of the evidence in each of these studies is medium to high as per PHAC (2014), and a cross-sectional study design is appropriate for exploring the outcome of clinical trial awareness in patient populations. Although the study designs are weak, the quality of evidence is sufficient to argue that awareness, clinical trial knowledge, and positive perceptions are associated with willingness to participate in clinical research (Chu et al., 2015; Ellis et al., 2001; Reijula et al., 2015).

Awareness of clinical research is also essential in the nursing population as nurses play a significant role in caring for and building relationships with patients. Engaging nurses in clinical research may be beneficial to improving patient awareness and participation; nursing is the largest group of health professionals and is therefore appropriately positioned to disseminate information regarding clinical research (Yanagawa et al., 2014; Kao, Hamilton, Lin, & Hu, 2019). A survey of nurses working in a Japanese university hospital was conducted to examine awareness, knowledge, and experiences with registration trials and clinical research. While 90% of nurses reported being aware of research, 40% did not know the difference between clinical research and registration trials (Yanagawa et al., 2014). In addition, less than 50% were aware of aspects associated with research (other than informed consent) such as ethics committees, institutional review boards, and Good Clinical Practice (Yanagawa et al., 2014). Ward nurses in Taiwan were surveyed to assess awareness, knowledge, and experiences with clinical research in a similar study (Kao et al., 2019). The results indicate that while many (80%) nurses had

experience caring for patients enrolled in clinical trials, their clinical trial knowledge mean score was 4.5 out of 10, indicating a knowledge deficit in this population (Kao et al., 2019).

This literature discussing nurse awareness of research is rated as medium quality (PHAC, 2014), with weak study designs as they both utilized surveys as their methodology (PHAC, 2014). Although response rates were sufficient and survey tools were developed based on literature, there is always the risk of self-report bias and desirable response bias when administering a survey. Sampling was not random but statistical analysis was appropriate for study design to explore correlational relationships. This medium level quality of evidence has utility for this literature review in supporting the argument that a lack of clinical research awareness exists within the nursing population. This conclusion indicates a need for education regarding research so that nurses are equipped to care for patients participating in trials, as well as acting as a source of information about research for patients who lack awareness.

Lack of awareness of clinical research in the physician population was also noted within the literature and viewed as a barrier to patient awareness (Madsen et al., 2014); however, the amount of available literature on this topic is not substantial. Physicians and other primary care providers are key in educating patients about clinical research and the opportunity to receive treatments through clinical trials (Michaels et al., 2015).

Qualitative focus groups and interviews with primary care providers of oncology patients indicated that there are misconceptions about clinical trials within this population which impacts whether they discuss research with patients as potential treatment options (Michaels et al., 2015). These results indicate that physicians and primary care providers have a need for targeted education regarding clinical research and highlights the importance of educating their patients of these options (Michaels et al., 2015). Increasing patients' awareness of research requires that

their care providers are also knowledgeable about research. While the findings by Michaels et al. (2015) adds value to what is known on the topic, further quantitative research is required to strengthen the level of evidence for the argument that lack of physician awareness of clinical research is an issue.

Barriers to Clinical Trial Awareness and Participation

There are barriers noted in the literature that influence awareness of and participation in clinical research for patients, nurses, and physicians. Recruitment is noted to be particularly difficult among minority and underserved populations (Friedman et al., 2014).

Understanding of Research

Difficulty understanding the meaning and purpose of concepts within clinical research may negatively impact a potential participant's decision to enroll in a study (Stead, Eadie, Gordon, & Angus, 2005; Massett et al., 2017; Meropol et al., 2016; Napoles, Cook, Ginossar, Knight, & Ford, 2017). Concepts such as randomization and double blinding may be difficult to comprehend for many potential participants (Stead et al., 2005). Clinical trial resources and communication from physicians includes technical dialogue that overestimates the health literacy of many patients. This further impedes understanding of clinical research for patients and presents a barrier to enrollment in studies (Friedman et al., 2014).

Reports of the dearth of clinical trials knowledge as a barrier to participation come from studies that are descriptive in nature with data gathered through surveys. Surveys provide the most feasible option for answering research questions pertaining to these concerns. While the study designs, including surveys, are weak as per PHAC (2014) guidelines, the results stating

that one's lack of understanding of clinical trials is a concern are still beneficial to consider when developing a communication strategy for this practicum project.

Sociodemographic Factors

Age. Patients who are 65 or older are noted to have low representation in clinical trials (Meropol et al., 2016; Michaels et al., 2015). In contrast, being of a younger age is associated with greater awareness and knowledge of research and higher rates of participation (Skinner et al., 2019). Age as a barrier to clinical trial participation has been explored throughout the literature. For example, cross-sectional analysis of screening logs from three multicentered, randomized, controlled acute lung injury trials assessed for demographic differences in patients that were enrolled versus not enrolled (Cooke et al., 2010). The results of this study further substantiate the argument that older patients are less likely to be enrolled; however older women were more likely to be enrolled than older men (Cooke et al., 2010). The underrepresentation of older persons might be attributed to factors such as older patients not being offered the opportunity to participate in clinical trials, or older patients refusing to participate. A study by Kemeny et al. (2003) specifically addressed the concern of whether older patients are being offered clinical trials as treatment options. The authors targeted patients with breast cancer as nearly half of breast cancer patients are 65 years of age or older. However, they noted that this age group remains underrepresented in breast cancer clinical trials (Kemeny et al., 2003). The results of this retrospective case-control study indicate that there was no significant difference in enrollment rates between younger and older patients that were offered clinical trials. In addition, 68% of younger persons were offered a trial compared to 34% of older patients. The authors controlled for physical functioning and comorbidities, and disease stage and age remained significant predictors of being offered a trial (Kemeny et al., 2003). Age was also significantly

inversely associated with clinical trial enrollment in a cross-sectional population-based analysis of participants in a National Cancer Institute clinical trial cooperative group that included trials targeting many different cancers (Murthy, Krumholz, & Gross, 2004). In addition, older persons were less likely to be enrolled in a cancer clinical trial while also controlling for ethnicity and race (Murthy et al., 2004). Overall, the literature indicates that persons of older age are less likely to be offered a clinical trial in the first place, and they are also less likely to participate in trials. Age is therefore a significant barrier to clinical trial participation and is a factor to consider when developing a communication strategy for this practicum project.

Location. The location of clinical trials may be inconvenient for patients who would have a lack of transportation, thus impeding access to participation (Meropol et al., 2016). The literature suggests that participation from those who live in rural areas is lower (Michaels et al., 2015). In addition, geographical location may place a financial burden on patients who would have to travel to participate in clinical trials, creating a further barrier to clinical trial participation. Many patients highlight that the cost of care and their worry that insurance would not cover the cost of a trial are reasons for not participating in clinical trials (Wong et al., 2016). The Eastern Health Health Authority spans a large geographical region that includes many rural communities. The location of trials is likely a significant barrier for patients residing in communities within Eastern Health. Therefore, the requirement to travel for participation and the costs associated with this must be acknowledged when communicating about clinical research for this population.

Socioeconomic status. Populations with low socioeconomic status have low representation in clinical trials (Meropol et al., 2016). A national trends survey was analyzed for sociodemographic factors associated with clinical trial awareness. The authors indicated that

higher socioeconomic status factors such as higher education, higher yearly income, and increased internet use were significantly associated with clinical trial awareness (Leiter, Diefenbach, Doucette, Oh, & Galsky, 2015). A retrospective analysis of pre-existing large datasets of health information surveys also reported lower socioeconomic status factors, such as low income and low education levels, were associated with being less likely to have heard of clinical trials (Brown & Moyer, 2010). Concerns about insurance coverage (Du, Mood, Gadgeel, & Simon, 2008; Meropol et al., 2016) and overall cost of participation are also barriers for those with low socioeconomic status. Clinical research communication must take into account factors associated with low socioeconomic status to be effective in targeting those with lower education levels and lower yearly income.

Ethnic and racial minorities. Racial and ethnic minorities tend to have poor representation in clinical trials (Meropol et al., 2016; Skinner et al., 2019). Being of a Hispanic background was significantly associated with decreased awareness in one survey analysis (Leiter et al., 2015), while non-white population survey respondents, in general, also were significantly less likely to have heard of clinical trials (Brown & Moyer, 2010). In cancer clinical trials, racial and ethnic minorities were less likely to be enrolled than Caucasian individuals, even while the analysis showed an increase in overall enrollment over a span of two years (Murthy et al., 2004). While these studies took place in the United States, however, the results may be appropriate for this practicum project when considering minorities within Newfoundland and Labrador.

According to the literature, sociodemographic factors such as age, location, ethnicity, and socioeconomic status impact awareness and participation in clinical research. As with most of the literature reviewed thus far, survey study designs and analysis of previous survey data produced the reports regarding sociodemographic barriers. PHAC (2014) rates descriptive study

designs as weak, while critical appraisal of specific components provides insight into the quality of evidence provided. Neither of these survey studies had any significant weaknesses where the validity and reliability were impacted; statistical analyses were appropriate, and they all had clear, focused research questions. Random sampling was not utilized in many studies due to convenience which introduces the possibility of bias. In addition, survey studies always pose risk of self-report bias and desirable response bias. The overall rating of the majority of these survey studies was medium for quality as per PHAC (2014) when considering the overall strengths and limitations. Therefore, sociodemographic factors may be a barrier to consider when developing strategies to increase awareness of clinical research.

Attitudes

Attitudes toward clinical research play a significant role in decision making regarding participation in many populations (Meropol et al., 2016). It is associated with many barriers to participation, including awareness. Brown and Moyer (2010) note that awareness of clinical trials is a predictor of having a positive attitude about research.

They also report that black people and those with low education levels tend to feel significantly less positive about using medical information for research than Caucasian individuals. Further examination of feelings toward research revealed feelings of uncertainty or fear which have been identified as barriers to clinical trial participation (Masset et al, 2017). More specifically, people may fear they will get a placebo or they will be treated as a “guinea pig”. Some are also concerned that the standard treatment is better than a clinical trial treatment (Du et al., 2008). In addition, some populations report a distrust of researchers and care providers associated with research (Friedman et al., 2014).

Not only are the attitudes of potential participants of interest here. The attitudes of physicians and care providers play a role in affecting the awareness and participation of patients in clinical research. Interviews with physicians highlighted feelings that trials were too time consuming, inappropriate for their practice, are less effective than standard therapy thus they worry that quality of care will be compromised (Masset et al., 2017; Michaels et al., 2015). Misconceptions about the quality of care patients would receive by participating in trials impacts physician decisions to discuss and refer clinical trials as treatment options (Michaels et al., 2015). Additional barriers impacting decision to refer patients to specialists that discuss clinical trials as treatment include patients' insurance coverage, the strength of the physician-patient relationship, and location and proximity to treatment facilities (Michaels et al., 2015). Physicians have described concerns about how patients would react to the suggestion of participating in research, and have experienced having limited confidence or experience explaining trials to patients (Masset et al., 2017). The reviewed studies took place in the United States, thus concerns of physicians practicing within that healthcare system may differ from Canadian physicians. For example, Canadian physicians may not place as much concern on insurance coverage for their patients depending on the nature of the research. However, it is reasonable to assume that the other concerns expressed by physicians in this review may be reflected in Canadian physicians.

While patients' attitudes toward clinical trials were assessed by weakly designed studies using survey instruments, the quality of the research is high (PHAC, 2014) due to large representative sample sizes obtained by oversampling those within typically underrepresented populations (Brown & Moyer, 2010). In addition to the survey instruments, physicians were interviewed to discover themes in terms of their perceptions and beliefs toward research (Masset

et al., 2017; Michaels et al., 2015) indicating that the study designs also include qualitative research. A qualitative study design is useful for exploring beliefs in a population, and thus was an appropriate choice for these research questions.

Attitudes of the public toward research must be taken into consideration when deciding how to frame educational messages as part of the communication strategy to increase awareness of clinical trials. Considering physician attitudes as a barrier may help alleviate fear and feelings of mistrust of the public toward research and care providers associated with research. It must also be considered with the development of this practicum project as physicians may be adverse towards research, thus impacting the information received by patients from these providers. Addressing barriers such as these may assist in reaching the practicum project goal of increasing awareness of clinical research.

Strategies to Increase Awareness and Participation

Providing clinical research education to the public, nurses, and physicians while addressing the barriers to clinical research awareness and participation may meet the practicum project goal of increasing awareness of research as a service at Eastern Health. The literature reviewed provides arguments for communication strategies, who should be communicating about clinical research, and what materials and methods of communication may be most effective.

Current Education About Clinical Trials

Clinical research studies distribute educational materials to potential participants, thus an exploration of literature examining current resources is necessary. Friedman et al. (2014) conducted a retrospective descriptive analysis to examine the content and readability of resources within one US state. Major academic medical centres were contacted for copies of materials

from the last 5-10 years. The results noted there was a specific call to action found in only 30% of resources and the mean readability overall was grade 11.7 (Friedman et al., 2014). Analytic tools used within this study were previously tested for reliability and two independent researchers completed coding to ensure agreement of results. Limitations include using convenience sampling, and a lack of acknowledgement that there may be other factors impacting a person's understanding of clinical trials other than readability. This study is critically appraised as high quality although the study design is weak as it was descriptive in nature (PHAC, 2014).

Therefore these results may be interpreted as an indication that development of future resources needs to address the usage of technical terms so that readability is at a lower level. A lower level of reading will assist in reaching underrepresented populations such as those with low socioeconomic status or of marginalized ethnic or racial minorities, thus mitigating barriers to awareness and participation in research. In addition, content should include a specific call to action so that potential research participants have clearly outlined directions for contacting appropriate personnel that will provide them with further information about a research study. Research recruitment materials are often the first information received by potential participants, thus they may have great impact on participation decisions (Friedman et al., 2014).

Patients frequently use the internet to find health information to educate themselves, and internet usage is associated with higher levels of clinical research awareness (Abel, Cronin, Earles, & Gray, 2015). The quality of information available on the internet regarding clinical research was examined by two independent coders that simulated a naive cancer patient without clinical trial knowledge (Abel et al., 2015). After screening 120 websites found through popular search engines and analyzing 40 of these, it was determined that readability was poor overall. Clinical trials were mentioned on 68% of the landing pages, and only 44% offered interactive

interfaces to allow patients to customize their search results and find a trial that was potentially specific to them (Abel et al., 2015). The authors suggest that clinical trial information be more readily accessible via the internet by lowering the literacy level and creating more easy to navigate websites that offer interactive components so that patients are able to find trials more personalized to them (Abel et al., 2015). While this study has a weak descriptive design, the quality of evidence is medium (PHAC, 2014), indicating it may have utility toward the development of a communication strategy for this practicum project.

Collaboration

The National Cancer Institute (NCI) partnered with other organizations such as pharmaceutical companies, advocacy groups, and other cancer organizations to raise awareness and address barriers related to clinical research enrollment (Solomon et al., 2009). The Clinical Trials Education Program (CTEP) was developed to explain what clinical trials are, why they are important, and how they are conducted (Solomon et al., 2009). An evaluation of this program through surveys and focus groups indicated that partners were satisfied with the program resources, and with their partnership, used the resources, and disseminated them to the public. This evaluation used mixed methods with the use of feedback surveys and focus groups with people employed by partner organizations. The study design is weak (PHAC, 2014), and the authors do not provide much detail regarding the rigor of the evaluation survey thus the overall quality is medium (PHAC, 2014). The most valuable information from this study is the potential for increasing awareness of clinical research by developing partnerships with other organizations to ensure a widespread dissemination of information to the public, including those that are typically underrepresented in clinical research. A similar approach could be taken for this practicum project on a smaller scale; partnering with groups outside of the Patient Research

Centre, but still within Eastern Health, may aid in building capacity to provide education about clinical research to the public and hospital staff.

Clinical trial initiatives that aim to increase enrollment through education provide evidence for developing a communication strategy. Madsen et al. (2014) assessed how clinical trial understanding and enrollment was impacted by a clinical trial initiative in a multidisciplinary prostate cancer clinic. They utilized multiple platforms for providing education including posting trial specific information in clinics, providing educational information directly to patients that is trial specific, and including trial information as part of treatment option discussions. The frequency of men with new prostate cancer diagnoses enrolled in clinical trials increased from 39% to 84% from pre the initiative introduction to post (Madsen et al., 2014). The PHAC (2014) guidelines were used to rate these results as medium quality, thus rendering the conclusion that a clinical trial initiative involving multiple educational platforms may achieve increased enrollment in clinical trials. However, there was no randomization of participants. In addition, it is not known how many trials each participant that enrolled in a trial was offered, nor is it known as to why the participants chose to enroll. The mitigation of clinical trial participation barriers may have influenced the increased enrollment such as physicians being more aware of trials due to the presence of information in their clinics, and the researchers minimized the inconveniences for trial participants by combining blood collections in single visits wherever they could. While this study does provide valuable insight for the current practicum project, more rigorous research is required to conclude that this clinical trial initiative was effective.

Use of Technology

The literature notes that many people who are aware of clinical research report hearing about research through mass media campaigns (Chu et al., 2015). Given how advances in technological information delivery platforms have improved accessibility of health information, many studies aimed to determine the benefit of various methods of clinical research education using technology. The internet is used as a preferred source of information among patients with cancer and survivors, and it is known that web-based decision tools increase patient knowledge and positively influence their decision making satisfaction (Flood-Grady et al., 2019). For example, a pilot study evaluated knowledge gained using a cancer research website that was developed as an educational tool for patients and their caregivers. In addition, qualitative analysis was completed to examine the perceptions of patients and caregivers across domains of credibility, attractiveness, effectiveness, and clarity (Flood-Grady et al., 2019). This study was of high quality as per PHAC (2014), due to strengths such as expert created content ensuring accuracy and readability, appropriate statistical analysis, and accounting for bias such as health literacy with the use of eHealth literacy testing. The results indicate that both patients and caregivers perceived the website as attractive, credible, easy to understand, and moderately effective in assisting with decision making about clinical trials (Flood-Grady et al., 2019). These perceptive domains are important for consideration with the development of a communication strategy for this practicum project.

A theory-guided, web-based, interactive computer program was developed by the NCI to deliver tailored video educational content to patients. The aim of this video series was to aid decision making about clinical trial participation by preparing patients with adequate knowledge (Meropol et al., 2016). This high quality study (PHAC, 2014) randomized a large sample size of

patient to either a control group or intervention group, where the control group received standard clinical info by NCI in a text format. While both groups had improved knowledge and attitudes post-intervention compared with baseline, the intervention group had a significantly greater increase in knowledge and a significantly greater decrease in attitudinal barriers. In addition, the intervention group had an increase in preparedness to consider clinical trials. These results indicate that tailoring video delivery to patients according to their identified barriers and attitudes in an interactive manner may be effective in raising awareness of research and willingness to participate. Another video intervention, however, did not produce significant results in another study using control and video intervention groups with oncology patients (Skinner et al., 2019). The results indicated no differences in knowledge increases between control and video intervention groups. However, the sample size was too small to draw a confident conclusion (Skinner et al., 2019). Interesting to note, however, was that minority participants reported significantly more negative beliefs and barriers to research participation than white participants (Skinner et al., 2019). This knowledge may be valuable when considering how to effectively reach underrepresented populations with this practicum project. For example, a video intervention that presented views and perspectives on trials from patients with diverse ethnic backgrounds was used in an educational intervention with lung cancer patients (Du et al., 2008). The results of this intervention indicated that a video such as this may positively impact attitudes of lung cancer patients from many diverse backgrounds toward participation in clinical trials as enrollment rates were higher post video group intervention (Du et al., 2008). Although enrollment rates were higher, it was not statistically significant, indicating that further research is required with larger sample sizes. Again, use of videos as educational tools may be effective as

indicated by these medium quality (PHAC, 2014) studies by Skinner et al. (2019) and Du et al. (2008).

Providing education to healthcare professionals such as nurses is necessary in a communication strategy to increase awareness of research at Eastern Health. Learning modules of clinical trial information that contain videos that can be accessed at any time and paused may be convenient for the nursing population (Haugen, Gasber, Leonard, & Lander, 2015). A descriptive exploratory study that examined usage of learning modules with nurses (Haugen et al., 2015) found that 57% were aware of the modules, while 51% had viewed at least one of the modules. Ninety percent of those who had viewed the modules were satisfied or very satisfied with their viewing experience. This study was high quality as per PHAC (2014) as the development of modules was based on expert opinion and previous work, survey tools are assumed reliable and valid due to the involvement of experts, and there was a clear, focused research question. The nurses' satisfaction levels in this study indicate that similar methods may be useful in future research or as part of this practicum project.

Who Should be Communicating about Clinical Trials?

Healthcare providers may contribute to low awareness and enrollment into clinical research due to limited awareness themselves or lack of communication with their patients about research (Friedman et al., 2014). Targeting healthcare providers such as nurses and physicians with education initiatives (so that they may disseminate clinical trial information to their patients) may mitigate the concerns with a lack of awareness in the patient population in subsequently increase research participation.

Madsen et al. (2014) enlisted an advanced practice nurse to facilitate the education of patients regarding treatment options that included a list of clinical trials. This study saw an increase in trial enrollment rates, thus indicating that the involvement of the advanced practice nurse may have a beneficial effect (Madsen et al., 2014). Nurses working on inpatient wards are also valuable sources of information for patients.

Targeting this large population of nurses will ensure that they are aware of and knowledgeable about clinical research so that they may competently care for those participating in trials, and that they may properly direct patients who may be potentially interested in clinical research (Kao et al., 2019). Clinical research specific nurses are also noted to play a key role in recruitment increases (Fenlon et al., 2013). A large study in the United Kingdom chose nursing staff for the focus of the recruitment engagement process. The authors did this because they believed nurses are the most appropriate health provider to establish an effective relationship with this population as they often engage with patients during cancer clinical trial recruitment to promote recovery and psychosocial well-being (Fenlon et al., 2013).

Primary care providers such as physicians are also in a position to provide knowledge and guidance with regard to clinical research. Physicians are well known and trusted sources of information for their patients. Therefore, targeted education initiatives for physicians about clinical trials may encourage them to discuss research with patients (Michaels et al., 2015). A study of primary care providers indicates that they have concerns about clinical trials that negatively impact them referring patients to specialists who offer clinical trials as treatment options (Michaels et al., 2015). This study concluded that primary care providers require education that addresses these concerns and enhances their communication skills so that they are more likely to refer patients to specialists involved in clinical trials (Michaels et al., 2015).

Guiding Theory for Clinical Trials Communication and Education

Theory is useful for providing guidance in the development of strategies to increase awareness and participation in clinical research. Education initiatives have been identified in the literature as having potential benefits on increasing awareness of research in patients, nurses, and physicians. The target population of this practicum project is comprised of adult patients, nurses, and physicians, thus the principles of Adult Learning Theory will be considered when developing the communication strategy. Key principles of Adult Learning Theory are that adults are assumed to have life experiences that affect and direct their learning; they are motivated by problems; they expect to obtain useful knowledge; and they are independent and prefer a flexible learning environment (Sanchez & Cooknell, 2017). Adult learning theory may be utilized for patient education as a means of empowering patients to improve self-knowledge (Sanchez & Cooknell, 2017). Providing effective patient education includes a number of factors such as: considering learning styles and literacy level; having an individualized multimedia approach; sending clear messages that include use of photos to account for health literacy; considering language and culture; and knowing that education should occur at multiple time points during a patient's time in hospital (Sanchez & Cooknell, 2017). The principles of Adult Learning theory account for a number of barriers to awareness of clinical research in the patient population such as literacy, ethnic and racial minorities, and time constraints. If patients are provided with brief education at multiple time points, or if they are provided with self-learning activities that they may choose to partake in at their own pace, they may be more receptive to information about clinical trials. Adult Learning Theory may be used to guide education for healthcare professionals (such as nurses and physicians) who prefer a self-learning approach that is at their own pace so that they may fit it within their schedule. Self-guided learning modules

may be satisfactory modes of education for staff as discussed in the study by Haugen et al. (2015). Nurses and physicians at Eastern Health might increase their awareness of clinical research with the introduction of learning modules that they can complete at their own pace. This mode of education will be further explored throughout the practicum project in consultations to determine if it may be appropriate as part of the communication strategy.

Conclusion

Participation in clinical research is necessary to continue the advancement of therapies, improve diagnosis of disease, and improve the quality of life for many. Lack of awareness of clinical research is a significant issue that impacts enrollment rates. Barriers have been identified in the literature, such as sociodemographic factors and attitudes toward research, that negatively impact awareness of clinical research and participation rates. Strategies to increase awareness and participation that target patients, nurses, and physicians, and that address the barriers to awareness may be effective. A communication strategy to educate patients, nurses, and physicians should be collaborative, address underrepresented populations, contain simple content to account for health literacy, and use multimedia platforms that are easily accessible and appropriate for self-learning.

Much of the available literature concerning awareness are comprised of descriptive study designs which is appropriate for exploring awareness in populations, however further research involving rigorous study designs such as randomized controlled trials would be beneficial to guide future communication strategies.

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Appendix A

Table 1 Literature Summary Table

Name, Author, Date, Study Objective	Sample/Groups (Size, Setting, Characteristics)	Design and Methodology	Key Results/Findings	Strengths/Limitations	Conclusion and Rating
<p>The impact of an educational video on clinical trial enrollment and knowledge in ethnic minorities: A randomized control trial, (Skinner et al., 2019)</p> <p>Objective: Determine if an educational video intervention will increase clinical trial awareness, knowledge, attitudes and subsequent enrollment.</p>	<p>63 oncology patients without previous history of clinical trial participation.</p> <p>Patients recruited from urology, hematology, and breast cancer clinics at Vanderbilt Ingram Cancer Centre.</p> <p>Prospective participants were oversampled to ensure sufficient inclusion of racial/ethnic minorities at a ratio of 2:1.</p> <p>Participants received recruitment letter in the mail followed</p>	<p>Randomized Control Trial</p> <p>Participant s randomly assigned to intervention of watching a clinical trial educational video or to control group without watching the video.</p> <p>Clinical trial knowledge survey given before intervention and 1 week post intervention.</p> <p>Trials participation assessed one year</p>	<p>At 1 year post-intervention there were 3 participants enrolled in clinical trials from the intervention group and 2 from the control group. These results were not statistically significant.</p> <p>The clinical trial knowledge survey indicated that the video did change attitudes, knowledge or barriers; minority participants reported significantly more negative barriers and beliefs than white participants.</p>	<p>Strengths: study design randomized control trial; approved by Vanderbilt University Medical Center Institutional Review Board; power calculation used to determine appropriate sample size; clear inclusion and exclusion criteria; groups similar at baseline</p> <p>Limitations: results not statistically significant; did not stratify by ethnicity in sample size calculation to account for minority oversampling; random sampling not used but also not</p>	<p>This trial stated null effect of educational video intervention on clinical trial knowledge or enrollment, however not statistically significant.</p> <p>Design: Strong as per PHAC (2014)</p> <p>Quality: Medium as per PHAC (2014)</p>

				feasible for this study; assessors not blinded	
<p>Harnessing technology to enhance delivery of clinical trials education for nurses: A report from the children's oncology group, (Haugen et al., 2015)</p> <p>Objective: To assess awareness and user experience of multimedia modules regarding pediatric oncology clinical trials for</p>	<p>106 nurses participated in the survey</p> <p>Majority worked in the United States (91%)</p> <p>Age: 31.7 % were <40; 48.1% were 40-54; 20.2% were 55+</p> <p>Most had their masters (51%) or bachelors degree (33.7%)</p> <p>Nursing role: staff nurse (16.3%); advance practice nurse (42.3%); clinical research assistant</p>	<p>Cross- sectional survey study</p> <p>Survey administered to Clinical Oncology Group (COG) nurses attending COG meeting to determine level of awareness of modules and experience with the modules</p>	<p>57% nurses aware of the modules and 51% had viewed at least one module - 90% of nurses that had viewed the modules were satisfied or very satisfied with viewing experience, content satisfaction (73%), relevance (70%) - younger nurses (under 40) were 4 times more likely to be unaware of the modules than older nurses, nurses with masters degrees more likely to be aware</p>	<p>Strengths: 90% surveys returned; clear, focused research question; ethically approved</p> <p>Limitations: potential bias from recruiting at conference; self-assessment bias from survey completion;</p>	<p>40% of the nurses remained unaware of modules even though they were posted on website/emails/newsletters, and may need to use a novel approach to ensure younger nurses are aware (>40)</p> <p>Study design: Weak as per PHAC (2014) Quality: High as per PHAC (2014).</p>

nurses.					
<p>How are we communicating about clinical trials? An assessment of the content and readability of recruitment resources, (Friedman et al., 2014.)</p> <p>Objective: to examine content and readability of clinical trial recruitment resources.</p>	<p>127 materials collected for analysis.</p> <p>Contacted major academic medical centres to ask for copies of materials for recruitment and promotion from last 5-10 years.</p> <p>Materials included: web pages, electronic or hard copy newsletters, hospital public relations magazines, posters, flyers, and videos. They also searched the five centres' websites for relevant material.</p> <p>37.8% print, 62.2% web materials.</p>	<p>Retrospective Descriptive Analysis</p> <p>Convenience sampling to collect clinical trial recruitment education resources from one state in the United States</p> <p>Codebook developed from previous analysis and themes from focus groups regarding clinical trials.</p> <p>Code analysis covered domains of source, format, design, content, frames, and readability level.</p>	<p>Most content was treatment- related clinical trials (60.6%);</p> <p>Described the most were inclusion criteria related to specific disease conditions and age</p> <p>Specific call to action found only in 30% of resources.</p> <p>Mean readability overall was Grade 11.7.</p> <p>Higher reading level significantly more likely in web-based resources compared to print.</p> <p>Readability varied significantly depending on creator, clinical trial type, presence or absence of</p>	<p>Strengths: analysis based on previous content analysis methodology to strengthen validity and reliability; coding completed by two independent researcher team members to ensure agreement; appropriate statistical analysis; analysis tools tested for reliability.</p> <p>Limitations: convenience sample; other factors may impact a person's understanding of clinical trials thus readability may not be the most appropriate measure on its own.</p>	<p>Insight provided regarding readability of content in recruitment materials for clinical trials; recommendations provided for developing clinical trial recruitment resources.</p> <p>Study Design: Weak as per PHAC (2014)</p> <p>Quality: High as per PHAC (2014)</p>

			inclusion criteria, and call to action.		
Impact of clinical trial initiative on clinical trial enrollment in a multi-disciplinary prostate cancer clinic. (Madsen et al., 2014) Objective: To determine the impact of a clinical trial initiative on enrollment in a clinical oncology trial.	1370 male participants. Median age of 64 years. Low risk disease patients = 32%; Intermediate risk = 49%; High risk disease in 19% of participants.	Design: Uncontrolled before and after study Posting trial specific information in clinics, providing educational information for patients that is trial specific, and providing education about clinical trials when discussing treatment options. Evaluated frequency of new prostate cancer diagnosed men enrolling in clinical trials from 2004-2008 and used logistic regression to determine the impact of the clinical trial initiative and patient characteristics on enrollment	74% enrolled in at least one trial while 29% enrolled in multiple trials. Trial enrollment increased from 39% to 84% from before the initiative to after the initiative. Younger men were more likely to enroll in trials.	Strengths: clear, focused research question; appropriate statistical analysis; large sample size Limitations: were not able to document number of trials offered to patients throughout the initiative although they knew the number accepted by patients - number of trials offered similar though before and after the initiative; they did not account for why the patients chose to enroll; no random sampling	Enrollment rates increased after the clinical trial initiative, and the enrollment at the study clinic was higher than seen in adult cancer patients on a national level Study design: Medium as per PHAC (2014) Quality: Medium as per PHAC (2014)
Randomize trial of a web-based intervention to address barriers to clinical	1255 oncology patients.	Prospective randomized clinical trial	PRE-ACT and control group both had improved knowledge and	Strengths: Clear research question; clear inclusion/exclusion criteria; study tools based on	Patient education prior to first oncology consultation improves

<p>trials, (Meropol et al., 2016)</p> <p>Objective: to examine how a web- based intervention would impact knowledge, attitudes, and preparation for decision making about clinical trials.</p>	<p>Intervention (PRE-ACT) group n=623.</p> <p>Control group n=632.</p> <p>Control and PRE-ACT groups similar characteristics at baseline and post-intervention.</p>	<p>Two groups compared: control group receiving general clinical trial information versus intervention group receiving PRE-ACT.</p> <p>PRE-ACT consisted of: assessment of clinical trials knowledge and attitude barriers,</p>	<p>attitudes compared to baseline.</p> <p>PRE-ACT group had significantly greater increase in knowledge and significantly greater decrease in attitudinal barriers.</p> <p>Both control and PRE-ACT groups significantly increased their preparedness to consider clinical trials.</p> <p>Values assessment with clarification back to patients, and videos tailored to individual patients' barriers.</p> <p>Patients randomized to each group and instructed to complete baseline survey prior to education, post-education survey, and post-consultation survey 2 weeks following consult.</p>	<p>previous work and literature; adequate sample size and power calculations; treatment groups had similar baseline characteristics;</p> <p>Limitations: programming error that provided incorrect videos to 4.1% and omitted video assignments for 5.3%; participants may have been biased toward more educated people due to requirement of high speed internet access</p> <p>PRE-ACT group was favored in preparedness to consider clinical trials.</p> <p>PRE-ACT associated with greater patient satisfaction.</p>	<p>knowledge, attitudes, and preparation for decision making.</p> <p>Tailored video delivery effective in improving responses to knowledge questions.</p> <p>Design strength: Strong</p> <p>Quality: High as per PHAC (2014)</p>
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			Outcomes were knowledge and attitudes, and preparation for decision making about clinical trials		
Age-, sex-, and race- based differences among patients enrolled versus not enrolled in acute lung injury trials.. (Cooke et al., 2010) Objective: to explore the representation of ethnic minorities, women, and elderly in acute lung injury clinical trials and determine reasons for non-enrollment.	n=2452 44 Academic hospitals participating in 3 multi- centered, randomized, controlled trials. The studies analyzed took place from 1996-2005.	Cross- sectional study design. Cross- sectional analysis of screening logs from three multicentered, randomized, controlled trials for acute lung injuries. Assessed enrollment for age, sex, racial groups, and presence of exclusion criteria by age, sex, and race. Adjusted for demographics, lung injury risk factor, study, and study center.	Older patients less likely to be enrolled. Older women more likely to be enrolled than older men. No differences in enrollment among racial/ethnic groups.	Strengths: large sample size; clear, focused research question; appropriate statistical analysis; Limitations: screening not standardized across each trial site; over 24% of screened patient population excluded because local Institutional Review Board did not allow release of data for non- enrolled patients;	There is under-representation of older patients in clinical trials of acute lung injuries. Study design: Weak as per PHAC (2014) Study quality: High as per PHAC (2014)

<p>Randomized clinical trials in oncology: Understanding and attitudes predict willingness to participate. (Ellis et al., 2001)</p> <p>Objective: to explore the effect of anxiety, knowledge, and attitudes on women's willingness to participate in research at different time points during the course of breast cancer care.</p>	<p>Women attending Medical Benefits Fund Sydney Square Breast Clinic for screening of mammogram or diagnostic assessment over a 4 week period, or women having treatment for early stage breast-cancer were eligible.</p> <p>545 participants.</p>	<p>Cross-sectional Survey</p> <p>Questionnaire covered demographic data, The Hospital Anxiety and Depression Scale, preferences for amount of info they want to receive from doctor and level of involvement in decision making, knowledge about need for clinical trials, attitudes toward clinical trials, willingness to participate, and reasons for considering a trial or not.</p>	<p>545 participants completed the survey (75% response rate)</p> <p>33% would consider participation in a trial if they had breast cancer.</p> <p>Women already diagnosed with breast cancer significantly more likely to decline participation than women having screening or diagnostic assessment.</p> <p>Women that considered participation were more knowledgeable about trials, were younger, and preferred active decision making.</p>	<p>Strengths: study tools developed based on previous research and pilot tested; appropriate statistics; clear, focused research question; 75% participation rate.</p> <p>Limitations: no mention of random sampling; sampling from one clinic; self-report bias; desirable response bias; no evidence of blinding in data collection.</p>	<p>Women with more knowledge of trials are more likely to consider taking part and have more positive attitudes about trials.</p> <p>Design Strength: Weak</p> <p>As per PHAC (2014)</p> <p>Quality: High as per PHAC (2014).</p>
<p>Factors associated with willingness to participate in clinical trials: a</p>	<p>n= 1515 of the general Korean population.</p>	<p>Cross-sectional survey.</p> <p>Systematic random sampling method.</p>	<p>75% were aware of clinical trials and awareness was significantly associated</p>	<p>Strengths: stratified and systematic random sampling; large sample size; study tools tested for</p>	<p>Awareness, perceptions, and favourable feelings associated with</p>

<p>nationwide survey study. (Chu et al, 2015)</p> <p>Objective: to examine awareness of, perceptions about, necessity of, and safety of clinical trials and factors associated with willingness to participate.</p>		<p>Questionnaire examined demographic data, experience with clinical trial participation, awareness of clinical trials, where they heard of clinical trials, perceptions about, necessity of, and safety of clinical trials and factors associated with willingness to participate.</p>	<p>with males that were educated.</p> <p>25% were willing to participate in clinical trials.</p> <p>Awareness, perception of benefits, favourable feelings, and safety were significant predictors of willingness to participate.</p> <p>Most people that were aware of clinical trials had heard of them through mass media campaigns.</p>	<p>reliability and validity;</p> <p>Limitations: willingness to participate does not reflect actual participation in studies; desirable response bias; self-report bias;</p>	<p>willingness to participate in clinical trials.</p> <p>Design Strength: Weak As per PHAC (2014)</p> <p>Quality: High as per PHAC (2014)</p>
<p>Therapeutic misconception correlates with willingness to participate in clinical drug trials among patients with epilepsy: Need for better counseling.</p>	<p>Questionnaire mailed to random sample of Finnish Epilepsy Association.</p> <p>Age 18 years and older.</p> <p>342 questionnaires returned with 325 included in analysis after exclusion.</p>	<p>Cross- sectional survey.</p> <p>Survey collected demographic data, socioeconomic issues, and clinical aspects of epilepsy and treatment.</p>	<p>Most participants viewed participation in trials as valuable.</p> <p>Inadequate knowledge of clinical trials was associated with retired respondents and people who developed epilepsy young.</p>	<p>Strengths: questionnaire based on previous research and literature; appropriate statistical analysis</p> <p>Limitations: low response rate of 18%; self-report bias; favourable response bias; survey not</p>	<p>Attitudes were generally positive toward clinical trials in an epilepsy population.</p> <p>However, adequate information must be given to those with epilepsy</p>

<p>(Reijula et al., 2015)</p> <p>Objective: to assess attitudes toward and knowledge of clinical trials and factors associated with participation in clinical trials in epilepsy patients</p>		<p>Survey also assessed knowledge of and attitudes toward clinical trials, willingness to participate, and experiences of participation in trials.</p>	<p>Education level and number of antiepileptic drugs were significant predictors for not understanding clinical research (therapeutic misconception).</p>	<p>validated with people who have epilepsy</p>	<p>during recruitment of clinical trials.</p> <p>Design Strength: Weak As per PHAC (2014)</p> <p>Quality: Medium as per PHAC (2014)</p>
<p>Nurse awareness of clinical research: A survey in a Japanese university hospital. (Yanagawa et al., 2014)</p> <p>Objective: to assess nurses' awareness of research at a university hospital.</p>	<p>453 nurses at Tokushima University Hospital</p> <p>95.4% females.</p> <p>79.5% worked on wards, 19.9% worked in outpatient clinics, and 0.6% provided no info on work area.</p>	<p>Cross-sectional survey</p> <p>Assessed nurses' awareness of health research including registration trials and clinical research</p> <p>Relationship between awareness and experiences also analyzed.</p>	<p>90% of nurses aware of registration trials and clinical research.</p> <p>40% of nurses aware of research did not know the difference between registration trials and clinical research.</p> <p>Most aware of informed consent but less than 50% aware of ethical guidelines, Good Clinical Practice, ethics committees,</p>	<p>Strengths: pre-tested questionnaire; 75.9% response rate;</p> <p>Limitations: self-report bias; desirable response bias;</p>	<p>Nurses may be aware of research but knowledge about research is limited. Necessary to make nurses aware of specific issues related to research in order to expand research team.</p>

			institutional review boards.		Design Strength: Weak As per PHAC (2014) Quality: Medium as per PHAC (2014)
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Appendix B

Consultation Report

Developing a Communication Strategy to Increase Awareness of Clinical Research at Eastern
Health: Consultation Report

Kari Jenkins

Memorial University of Newfoundland

Lack of awareness of clinical research at Eastern Health has been noted by the Clinical Research Division in patients, nurses, and physicians. It negatively impacts participation in clinical research, thus a communication strategy developed through this practicum project will aim to increase the awareness of clinical research at Eastern Health, Newfoundland and Labrador (NL). Consulting with key stakeholders is a necessary aspect of developing a communication strategy to assess the needs of the target audience, determine appropriate steps to take, and discuss potential methods to use. The objectives of the consultation were: to discover how Eastern Health currently implements public and employee communication strategies including describing the logistics regarding approval of content; to discover how staff and clinical educators within the Learning and Development department develop educational resources and sessions for staff about clinical research; to discover how Human Resources performs employee engagement related to research; and to assess the learning needs of patients, nurses, and physicians regarding clinical research. The purpose of this consultation report is to provide background and context for the consultations and practicum project, and to discuss findings from the consultation process that will be used to inform the development of the communication strategy.

Background

Clinical research is an important service to patients worldwide. Research improves the quality of life for patients through advances in the diagnosis and treatment of many health conditions (Madsen et al, 2014). A review of the literature indicates that low participation rates in clinical research negatively impacts advancements in treatments and therapies. This is due to potential biased results from the inability to recruit underrepresented populations and increasing the study duration to reach recruitment goals, thus potentially compromising the study outcomes

(Fenlon et al, 2013). In addition, rigorous research is now often required by regulatory bodies as evidence for the approval of new therapies (Ellis, Butow, Tattersall, Dunn, & Houssami, 2001).

A lack of awareness of clinical research is present within patient, nurse, and physician populations. Communication and educational efforts targeting patients (Du, Mood, Gadgeel, & Simon, 2008; Flood-Grady et al., 2019; Madsen et al., 2014; Meropol et al., 2016) and health care providers (Haugen, Gasber, Leonard, & Lander, 2015) have shown an increase in clinical research knowledge immediately post-intervention and increased participation over periods of 6 months to four years. A review of the literature noted sociodemographic factors as limitations to clinical research awareness such as older age (Meropol et al., 2016; Michaels et al., 2015) and living in a rural community (Meropol et al., 2016; Michaels et al., 2015; Wong et al., 2016). These barriers are relevant to the aging population of NL, and the widespread geographic region of Eastern Health that includes many rural communities. Additional barriers to clinical research awareness, knowledge, and participation include negative attitudes of patients (Du et al., 2008; Massett et al., 2017) and healthcare providers (Masset et al., 2017; Michaels et al., 2015). The literature notes many misconceptions and fear toward clinical research participation which might be reflected at Eastern Health.

A review of materials and methods of increasing awareness of clinical research in the literature suggests that engaging healthcare providers as champions (Madsen et al., 2014) to facilitate patient education about research results in increased participation. In addition, collaboration with other organizations (Solomon et al., 2009) and the use of technology (Flood-Grady et al., 2019; Haugen et al., 2015) to spread awareness and facilitate education initiatives are effective in raising awareness of clinical research in patients and healthcare professionals.

Consultations

Consultations with key stakeholders can provide important insight regarding the potential barriers in the development of a communication strategy, and assess the utility of methods identified in the literature review for communication about clinical research. Key stakeholders such as communications specialists, education specialists, human resources, and representatives from patient, nurse, and physician populations will provide information to guide the development of communication and educational efforts for this practicum project.

Sample

Potential participants were targeted from several departments within Eastern Health: communications; learning and development; an inpatient unit that participates in clinical research; and an inpatient unit that does not participate in clinical research. The Communications Specialist was contacted as they are an expert in communication strategy development. They are responsible for all communications at Eastern Health and would assist in fulfilling objective #1 of the consultation process. Objective #2 was fulfilled by contacting a clinical educator as they are responsible for educating nursing staff and are therefore familiar with adult education methods. An additional education specialist was identified from the Learning and Development department to enrich this data. For objective #3, two Human Resources staff members who lead employees in professional development workshops and are responsible for leadership and engagement of employees were identified and targeted to explore employee engagement strategies. In an informal needs assessment, the Patient Care Coordinator, senior nurses, novice nurses, and a physician were targeted from an inpatient unit that participates in clinical research, and from an inpatient unit that does not participate in clinical research to meet objective #4. In

addition, nursing staff were asked to informally consult with two patients on their units for objective #4 as they are within the circle of care for these patients.

Data Collection

The Communication Specialist, the two Human Resources personnel, the Clinical Educator, and education specialist from Learning and Development were initially contacted via email to request a face-to-face interview or phone conversation. Responses were received from each of these personnel with the exception of one of the Human Resources employees. Of those who responded, all agreed to participate in an interview. Due to time and office location restraints, all interviews were conducted via telephone with the exception of the Clinical Educator. All phone calls and face-to-face interview took place in private offices to ensure privacy was maintained.

The nurses and physicians on the inpatient units were approached in-person so that I may identify myself, explain the purpose of my practicum project, and invite them to participate in an informal needs assessment. Three senior nurses, one novice nurse, the Patient Care Coordinator, and two physicians on an inpatient unit that does not participate in clinical research agreed to participate. On an inpatient unit that does participate in clinical research, two senior nurses and two physicians agreed to participate. In addition, nursing staff approached a patient from each unit asking them to participate in an informal conversation. All informal interviews took place in private offices to ensure that privacy and confidentiality were maintained.

A list of guiding questions were developed for each department so that there were tailored questions addressing communications, education, and employee engagement.

The needs assessment questionnaire was the same for all participants from the inpatient units to ensure consistency. These questions are attached in Appendix A. While I used the guiding questions during the interviews, I added some questions based on the conversation's direction. I took handwritten notes and asked for confirmation of responses to ensure accuracy. Stakeholder meetings were no longer than 45 minutes in length and meetings with healthcare staff on inpatient units were no longer than 15 minutes due to time constraints.

Data Management and Analysis

Data collected from stakeholders were entered and organized into a table in Excel and analyzed with content analysis. This was based on guidelines from Braun and Clarke (2006) to facilitate the identification of themes and patterns from the interviews. Data was stored on a personal computer that was password locked and within a password protected folder. In addition, all data was stored without identifying factors to ensure anonymity of participants. Appendix C presents responses from inpatient unit participants that have been analyzed for common themes. Information pertinent to this practicum project was summarized from each interview, and common themes were identified across all interviews. Another content analysis will take place after additional interviews occur to add another Education Specialist and another Human Resources staff member.

Interview response summary. Consultation with a staff member on the communications team was essential for this project as it is responsible for all communications strategies at Eastern Health. This individual provided valuable information regarding the logistics of developing a communication strategy. For example, they highlighted how there are existing templates for communication strategies that are used at Eastern Health, and all communication strategies must go through their department, followed by the executive level for approval prior to

implementation. For each strategy, the template typically includes a background, description of target audience, and objectives to be achieved. This individual highlighted the importance of knowing your target audience, and that communication for staff versus patients often differs.

The Human Resources staff member discussed the benefits of generalized employee engagement in depth. They noted that engaged employees result in increased productivity and creativity, and have decreased sick time. In addition, employee engagement results in healthy work environments that improve the psychological and physical health of employees. Employees who feel they are engaged in the organization might be more likely to facilitate communication and education about clinical research.

The Clinical Educator and Learning and Development staff member provided insight into education strategies for Registered Nurses. All education materials need to be approved by the organization prior to implementation. A working group typically works on approval which includes members from professional practice, the policy committee, and a quality and safety officer. In addition, the Clinical Educator noted that the Learning and Development department may be able to assist with the development of materials for this communication strategy. The Learning and Development staff member provided further insight by discussing how an educational request is required to enlist the help of their department in developing educational materials.

Themes

Use of technology. All individuals consulted noted that the use of technology is beneficial for communicating and educating staff and the public. Eastern Health has a digital signs network that is overseen by the communications department, and was cited by the Communications

Specialist as a potentially effective means to display simple messages to both staff and the public. In addition, the use of PowerPoint presentations was noted as effective in providing education to staff by both the Human Resources staff member and the Clinical Educator. Eastern Health staff are also all connected now with Microsoft Teams, the intranet, and through email. The Communications Specialist discussed how the CEO has held meetings open to all staff members using Microsoft Teams which allows for important information to reach many staff members while also providing opportunity for discussion for all. The intranet provides weekly newsletters for staff about important new information, and may offer a platform for posting about clinical research. In addition, weekly emails are sent to all staff members to provide updates from the organization from the communications department called pulse plus.

The thoughts and opinions of employees can also be assessed by the use of technology with a new tool called “Thought Exchange”. Employees can anonymously post their thoughts about issues such as potential barriers to attending workshops. Once a response is posted, employees have the opportunity to rate each response; responses with more ratings allow for the identification of major themes. Using this tool may be beneficial to assess issues with communication about clinical research.

Employees are able to access an increasing amount of education online via LEAP which is Eastern Health’s eLearning program. According to the Learning and Development staff member, the online learning condenses content of education sessions to include only what people need to know and is thus modeled after Adult Learning Theory. The use of technology for providing education with programs such as LEAP may be beneficial for this communication strategy as most staff prefer self-learning as per the discussion with Learning and Development.

Using technology was also noted as a method for reaching the public with communication and education initiatives. For example, most people are connected through social media and often view news on these platforms. Social media was noted as a potential platform for communicating about clinical research for the public. However, caution must be taken as there is potential for public backlash. In addition, contacting the media may be an option to communicate with the public with the use of a spokesperson.

Target audience. The importance of knowing your target audience was emphasized by all persons interviewed. The Communications Specialist stated that identifying the target audience is a key step in the development of all communication strategies. The Human Resources staff member, the Clinical Educator, and the Learning and Development staff member provide staff education, and discussed how education methods should be based on the target audience. Conducting needs assessments, environmental scans, and consultations via phone interviews were highlighted as important in developing individualized content depending on the group. Needs assessments of staff can be completed by directly approaching staff members, or through managers who assess their staff learning needs. Content of educational materials and information in communication strategies must also be kept simple and at a low reading level so that it is accessible by all. In addition, barriers to reaching the target audience were discussed as important to consider such as geographic location, position held at Eastern Health, and learning style.

The wide geographic region that Eastern Health encompasses was noted as a barrier on multiple occasions during the interviews. For example, many professional development opportunities are offered in St. John's, and may be viewed as a waste of time for someone who has to drive three hours to attend a one hour session. It is therefore important that education be

made equally accessible for all employees. Considering location is also applicable for communicating with and educating the public. Public messages would have to extend beyond St. John's city hospitals if they were to inform all Eastern Health's patients about clinical research.

The majority of Eastern Health's employees are frontline staff. Frontline staff do not typically check emails or the intranet for news from the organization according to backend analysis, and it was noted in interviews with the education specialists that staff, generally, do not like to participate in educational sessions outside of work that would not be compensated. Although technology has been noted as a useful tool for communicating to staff, the communications department still considers it a struggle to reach frontline staff in this way. Some methods of overcoming this are to go to the staff directly via drop-offs of written, hard-copy information at nursing stations, or by relying on managers to pass along information. Relying on managers, however, was described as not always being successful because the managers would have to stay during shift change to reach all of their staff, and this is not always feasible. If managers do not communicate to staff face-to-face, they often post information on bulletin boards that may not be seen by all staff. In addition, the education specialists and Human Resources staff member noted that they adapt education so that they provide frontline staff such as nurses with information in the most efficient way possible to avoid "wasting time" of those with busy schedules.

Targeting people in leadership positions at Eastern Health may include considering factors relevant to them such as budgeting and pressure from their directors, according to the consultation interviews. In contrast to frontline employees, email communication may be effective in reaching this population. Targeting leadership may be beneficial as it provides opportunity for education of employees from the top down.

The target population of staff and the public for those who were interviewed are primarily adults. The education specialists and Human Resources staff member noted the importance of providing adults with limited theory, including movement and hands-on activities where possible, providing scenario based learning to maximize experience, and allowing adequate time for coffee breaks and checking emails during education sessions. In addition, interviews highlighted the importance of providing objectives for education sessions, including a summary of key points at the end, and offering opportunity for feedback.

Providing reasoning. Another major theme that emerged from the content analysis of the interview data was the importance of providing reasoning behind new information. Participants discussed how the staff and public often express that they need to know why something is beneficial for them or why they need to know something. In addition, they may also want to know the risks of not participating in something. Those who were interviewed stated that providing evidence often helps illustrate reasoning, thus providing statistics about clinical research may help with this practicum project.

Testimonials from participants in clinical research were also highlighted as beneficial as many people relate to real-life stories and remember information that comes from them.

Inclusion. The theme of needing to be included was evident throughout the consultation data. Including employees in the process of any change or initiative at Eastern Health was viewed as important. Employees need to feel that their opinions are valued, and are more receptive to change and new ideas if they contribute to the development of these initiatives. In addition, if an initiative does not work, employees will take ownership of this if they had been involved in the process, instead of blaming leadership. Including employees, providing

opportunity for feedback and then acting on this feedback facilitates the development of trusting relationships.

Needs Assessment. Content analysis was completed on data collected during the needs assessment of Registered Nurses, physicians, and patients of inpatient units. This content analysis resulted in common themes from these informal interviews and questionnaires.

Registered Nurse responses. The responses from Registered Nurses on both research and non-research unit indicate a lack of awareness of clinical research at Eastern Health. While most knew that research exists at Eastern Health, none of the nurses were aware of specific studies, and none of them reported knowing where to direct patients if they were asking about clinical trials. In addition, only two of the nurses were aware of the Clinical Research Division and its location. Interestingly, a nurse working on a unit who participates in research did not think that research was taking place on their unit.

All nurses were able to list some benefits of clinical research for patients with themes of finding a treatment that works, advancing treatments, patients having a sense of hope, and patients feeling altruistic about participating. In addition, all nurses felt that patients on their units could benefit from clinical research if offered.

Physician responses. Physicians from research and non-research units were all aware of research at Eastern Health and the Clinical Research Division. However, they did not all know of its location. In addition, only physicians directly involved in clinical research reported knowing where to direct patients if they had questions about a trial. The other Physicians stated they would consult with their colleagues who participate in research.

Patient responses. The patients who were informally interviewed were aware that there is research ongoing at Eastern Health. They were not aware, however, of the Clinical Research Division, nor where it is located. In addition, they reported some knowledge of benefits of clinical research such as treatment and diagnosis of disease, and finding cures.

Summary. Overall, the needs assessment results indicate that there is a lack of awareness of the specifics of clinical research at Eastern Health in patients, nurses, and physicians. This provides important insight regarding how to direct the content of communications in this strategy. Furthermore, all participants were aware that there are benefits of clinical research to patients, thus indicating that they might be receptive to educational information about clinical research with the development of this communication strategy.

Ethical Considerations

As per the ethics review checklist, approval from the Health Ethics Review Board and the institutional review board were not required for this project as it is classified as a quality improvement project (see completed checklist in Appendix D). Consultation agreements were obtained from each individual during initial contact. Participant confidentiality was maintained with the use of private interview rooms and not recording any personal identifiers during data collection. Participants were notified that they are free to withdraw their participation at any time. Data security was maintained by storing data within a password protected folder on a password protected computer. Any identifying information was not stored with the data.

Conclusion

Consultations with individuals from the Communications, Human Resources, and Learning and Development departments at Eastern Health provided valuable information that will aid the development of a communication strategy to increase awareness of Eastern Health. Each interview provided insight into the logistical aspects of developing the strategy and providing educational materials to patients and the staff within Eastern Health. The themes of assessing the target audience, using technology for communication, providing reasoning for the information and education, and inclusion emerged during content analysis of data from the interviews with participants. These themes will serve to inform this practicum project through consideration of the target audience, assessing the use of technology to provide information, and ensuring that people understand why clinical research is important and that they should be aware of it. In addition, it will ensure that the public and staff feel a sense of inclusion in education about clinical research in order to feel more ownership in the research process, increase awareness of clinical research, and improve participation rates.

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Appendix A

Invitation Letters and Guiding Questions

Human Resources Invitation Letter

Hello,

My name is Kari Jenkins and I am a Masters of Nursing student at Memorial University. I am currently completing the final practicum project for this program. I am developing a communication strategy regarding clinical research at Eastern Health for my project. The purpose of this project is to increase awareness of clinical research in patient, nurse, and physician populations. Engaging employees in the communication strategy may assist in increased awareness of clinical research. Increased awareness may improve participation rates in clinical research which leads to advancement in the diagnosis and treatment of disease.

I am in the process of conducting consultations to inform the development of the communication strategy and I am inviting you to participate. I have attached a list of guiding questions and would like to set up a meeting to discuss these. The information you provide will help determine what strategies are currently used to engage employees. If you volunteer to participate, you are free to withdraw participation at any time. If you have any questions, feel free to reach me by phone at (709)-777-5229 or email at kari.jenkins@easternhealth.ca.

Regards,

Kari Jenkins, BSc (Hons), BN RN

Hospital Staff and Patient Invitation Letter

Hello,

My name is Kari Jenkins and I am a Masters of Nursing student at Memorial University. I am currently completing the final practicum project for this program. I am developing a communication strategy about clinical research at Eastern Health for my project. The purpose of this project is to increase awareness of clinical research in patient, nurse, and physician populations. Increased awareness of clinical research may improve participation rates in clinical research which leads to advancement in the diagnosis and treatment of disease. Learning about current awareness of clinical research from patients, nurses, and physicians at Eastern Health will help me develop an effective strategy.

I am in the process of conducting consultations to inform the development of the communication strategy and I am inviting you to participate. I have attached a list of guiding questions and would like to set up a meeting to discuss these. The information you provide will help determine what is known about clinical research at Eastern Health. If you volunteer to participate, you are free to withdraw participation at any time. If you have any questions, feel free to reach me by phone at (709)-777-5229 or email at kari.jenkins@easternhealth.ca.

Regards,

Kari Jenkins, BSc (Hons), BN RN

Education Specialist Invitation Letter

Hello,

My name is Kari Jenkins and I am a Masters of Nursing student at Memorial University. I am currently completing the final practicum project for this program. I am developing a communication strategy regarding clinical research at Eastern Health for my project. The purpose of this project is to increase awareness of clinical research in patient, nurse, and physician populations. Increased awareness of clinical research may improve participation rates in clinical research which leads to advancement in the diagnosis and treatment of disease. Effective education of staff may improve awareness among nurses and physicians, and improve the education of patients about clinical research.

I am in the process of conducting consultations to inform the development of the communication strategy and I am inviting you to participate. I have attached a list of guiding questions and would like to set up a meeting to discuss these. The information you provide will help determine what strategies are currently used to raise awareness of clinical research at Eastern Health. If you volunteer to participate, you are free to withdraw participation at any time. If you have any questions, feel free to reach me by phone at (709)-777-5229 or email at kari.jenkins@easternhealth.ca.

Regards,

Kari Jenkins, BSc (Hons), BN RN

Communication Specialist Invitation Letter

Hello,

My name is Kari Jenkins and I am a Masters of Nursing student at Memorial University. I am currently completing the final practicum project for this program. I am developing a communication strategy regarding clinical research at Eastern Health for my project. The purpose of this project is to increase awareness of clinical research in patient, nurse, and physician populations. Increased awareness of clinical research may improve participation rates in clinical research which leads to advancement in the diagnosis and treatment of disease.

I am in the process of conducting consultations to inform the development of the communication strategy and I am inviting you to participate. I have attached a list of guiding questions and would like to set up a meeting to discuss these. The information you provide will help determine what communication strategies are currently used Eastern Health. If you volunteer to participate, you are free to withdraw participation at any time. If you have any questions, feel free to reach me by phone at (709)-777-5229 or email at kari.jenkins@easternhealth.ca.

Regards,

Kari Jenkins, BSc (Hons), BN RN

Interview Guiding Questions

Education Specialists

1. What educational materials/methods would you use for an adult population?
2. Do you think patients, nurses, and physicians require different education methods?
3. What are some key points to consider when developing educational materials?
4. What is your experience with self-learning modules? What is your opinion on using self-learning modules for staff at Eastern Health?
5. Are there any organizational approvals required when providing education materials to the staff or public at Eastern Health? If so, what is the process for this?
6. What are some facilitators/restrictions to this process?

Communication Specialists

1. What communication strategies or awareness campaigns exist at Eastern Health?
2. What are some key steps in developing a communication strategy?
3. Can you describe some current methods of communication for the public and staff at Eastern Health?
4. Which communication methods have been most effective in your experience?

Which methods have been least effective?

1. Are there any formalities/approvals to consider when communicating at Eastern Health?

Human Resources

1. Tell me a little about your position at Eastern Health.
2. What are the benefits of employee engagement?
3. What strategies do you use to engage employees during presentations and workshops?
4. How have employees responded to engagement strategies at Eastern Health?
5. What are some important factors to consider when developing employee engagement plans?

6. Which level of staff (frontline vs. management vs. executive leadership) should be targeted to result in overall improved employee engagement?
7. Do your strategies differ when targeting each level of staff?
8. Do you think employee engagement strategies could be beneficial for a campaign to increase research awareness?

Needs Assessment Questionnaire for Patients, Nurses, and Physicians

1. What do you know about research at Eastern Health?
2. Are you aware of the Clinical Research Division?
3. Do you know where the Clinical Research Division is located?
4. Does your unit participate in clinical trials?
5. If a patient were to ask you about a clinical trial, would you know where to direct them?
6. What do you think the benefits of clinical trials are for patients?
7. Can/do patients on your unit benefit from clinical trials?
8. What do people (patients, physicians, nurses etc) ask about clinical research?

Appendix B Consultation Data Summary

Questions	Communication Specialist Response Summary Themes
What communication strategies or awareness campaigns exist at Eastern Health?	
What are some key steps in developing a communication strategy?	Set objectives for plan Know your target audience Rewrite
Can you describe some current methods of communication for the public and staff at Eastern Health?	Face-to-face communication is best from managers to employees Use of technology: digital signs good for patients and staff; intranet and emails should be used by staff Struggle to reach staff Staff have no time for reading/listening to messages
Which communication methods have been most effective in your experience? Which methods have been least effective?	Take caution when communicating to the public due to social media and potential backlash
How do you evaluate the effectiveness of communication strategies at Eastern Health?	
Are there any formalities/approvals to consider when communicating at Eastern Health?	
Additional comments: potential communication methods for clinical research	

Questions	Clinical Educator and Staff Educator Themes
What educational materials/methods would you use for an adult population?	Technology Multiple methods for different learners
How has your target audience responded to these methods?	Opportunity for feedback is important People prefer multiple methods but online learning has been well- received
Do you think patients, nurses, and physicians require different education methods?	Different methods for different target audiences
What are some key points to consider when developing educational materials?	Efficient teaching for nurses Target Audience Do objectives match with EH strategic plan
What is your experience with self-learning modules? What is your opinion on using self-learning modules for staff at Eastern Health?	Feedback varied regarding self-learning modules due to differences in learning style
Are there any organizational approvals required when providing education materials to the staff or public at Eastern Health? If so, what is the process for this?	
What are some facilitators/restrictions to this process?	

Questions	Human Resources Themes
What are the benefits of employee engagement?	Engaged employees result in healthier workplace

<p>What strategies do you use to engage employees during presentations and workshops?</p>	<p>“What’s in it for me?”</p> <p>Inclusion</p> <p>Evidence</p> <p>Respect</p> <p>Open to opinions</p> <p>Value opinions and act on them</p> <p>Trust</p>
<p>How have employees responded to engagement strategies at Eastern Health?</p>	
<p>What are some important factors to consider when developing employee engagement plans?</p>	<p>“What’s in it for me?”</p> <p>Value opinions</p> <p>Involve employees</p> <p>Provide reasoning</p> <p>Why it’s worthwhile Evidence</p> <p>Testimonials and real stories</p>
<p>Do you think employee engagement strategies could be beneficial for a campaign to increase research awareness?</p>	
<p>What educational materials/methods would you use for an adult population?</p>	<p>“What’s in it for me?”</p> <p>Include multiple teaching methods to account for learning style preferences</p>
<p>Do you think patients, nurses, and physicians require different education methods?</p>	<p>Assess target audience</p>

What are some key points to consider when developing educational materials?	
Are there any organizational approvals required when providing education materials to the staff or public at Eastern Health? If so, what is the process for this?	
Additional comments:	

Appendix C

Needs Assessment Data Summary

Table 2
Registered Nurse Responses

Questions	Registered Nurses						
	research unit	research unit	non research unit	non research unit	non research unit	non research unit	non research unit (Patient Care Coordinator)
What do you know about research at Eastern Health?	not much	I know it exists	Not a lot	I am aware that Eastern Health has research departments for areas such as genetics, cardiology, rheumatology, and oncology but am not aware of any specific research efforts (trials / studies).	I know that there are research positions for individuals interested in working in research, but I don't know much about research studies or how the different floors are involved in research.	Not a lot.	I know there is research taking place but I don't know specifics.
Are you aware of the Clinical Research Division?	no	no	no	no	No.	Yes.	Yes.
Do you know where the Clinical Research	no	no	no	no	No.	Health Science Centre?	HSC.

Division is located?							
Does your unit participate in clinical trials?	no	I know there is some research going on but I don't know specifics.	no	Not that I'm aware of.	I don't think my unit participate in clinical trial, but I think it would be beneficial in improving patient care delivery.	No. But periodically we may have a patient on a drug who is participating in one, not related to our unit.	No.
If a patient were to ask you about a clinical trial, would you know where to direct them?	no	I would ask the charge nurse or educator.	no	no	I would ask my colleagues nurses on the unit regarding clinical trials, if they don't know where patients can get more information, I would ask the charge nurse or my manager.	No, but the PCC could direct me.	No, but I would consult with the unit manager or clinical educator.
What do you think the benefits of clinical trials	It would benefit the patient to see what works and what	Advances in treatment and get to try new treatment.	Possible new forms of treatment, support from	Greater potential treatment options, keeps patients	Patient will be able to access treatments that are not available/	A cure? Relief of symptoms? More knowledge	Patients can benefit by potentially having a new drug that works for their

are for patients?	doesn't work in a clinical trial, beneficial for Improving patient care and outcome of future patients		peers dealing with the same medical issue, furthering/enhancing the treatment of patients in the future.	hopeful, keeps patients involved in and knowledgeable about their own care.	offered yet, clinical trials can give hope to patients regarding finding a cure for different diseases. Most of the time, clinical trials are free or low cost, this can alleviate some of the stress regarding affording specific drugs or procedures.	of disease? Sense of pride/ Inclusion in finding a cure?	condition; perhaps they had run out of options and the clinical trial would give them hope for a drug that works.
Can/do patients on your unit benefit from clinical trials?	Absolutely	Yes	They could certainly benefit from clinical trials	I believe they could if clinical trials were offered!	Yes, for sure! Some of our patients are diagnosed with inoperable conditions such as brain tumors, clinical trials where new surgical procedures could be	I'm sure they could if a trial was targeted for them.	They could if they were offered.

					tested can be beneficial to research and future treatment options.		
What do people (patients, physicians, nurses, etc.) ask about clinical research?	I have never been asked about clinical research.	I haven't been asked this.	I have never been approached for any clinical research.	No, I can't remember being asked about clinical research in my worksite.	Nobody so far asked me anything regarding clinical research.	No.	No.
Additional comments							Charge nurses could participate by identifying potential research candidates.

Table 3
Physician Responses

Questions	Physicians			
	Research Unit	Research unit	Non Research Unit	Non Research Unit
What do you know about research at Eastern Health?	There are many studies taking place in a variety of disciplines. Many clinicians are also	Research takes place at Eastern Health but not every unit participates in clinical trials. Services without	I know there are many studies taking place on other units.	There is research taking place as this is a teaching hospital.

	principal investigators within research studies.	residency programs do not participate; most services have a head of research.		
Are you aware of the Clinical Research Division?	yes	yes	yes	yes
Do you know where the Clinical Research Division is located?	yes	no	no	no
Does your unit participate in clinical trials?	yes	yes	no	no
If a patient were to ask you about a clinical trial, would you know where to direct them?	Yes.	I would consult with my colleagues.	I would consult with colleagues.	No but I would ask the appropriate personnel.
Can/do patients on your unit benefit from clinical trials?	yes	yes	They could if offered	Yes if available.

Table 4
Patient Responses

Questions	Patients	
	Research unit	Non Research Unit
What do you know about research at Eastern Health?	I know of research because I used to work in it.	Nothing but I assume there is some.
Are you aware of the Clinical Research Division Patient Research Centre?	No.	No.
Do you know where the Clinical Research Division is located?	No.	No.
What do you think the benefits of clinical trials are for patients?	<ul style="list-style-type: none"> - Treatment of disease and diagnosis - People don't know about it but they need to know about it, especially genetics since Newfoundland is such a great place to study genetics. 	<ul style="list-style-type: none"> - Finding cures.

Appendix D

Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review	<input type="checkbox"/>	x
.	Are there any local policies which require this project to undergo review by a Research Ethics Board?	<input type="checkbox"/>	x
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.	<input type="checkbox"/>	<input type="checkbox"/>
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?	<input type="checkbox"/>	x
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?	<input type="checkbox"/>	x
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?	<input type="checkbox"/>	x
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	<input type="checkbox"/>	x
.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?	<input type="checkbox"/>	x
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		0	

	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	<input type="checkbox"/>	x
9.	Is the project intended to define a best practice within your organization or practice?	x	<input type="checkbox"/>
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	x	<input type="checkbox"/>
1.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	x	<input type="checkbox"/>
2.	Is the current project part of a continuous process of gathering or monitoring data within an organization?		x
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		3	
SUMMARY See Interpretation Below			

Appendix C
Environmental Scan Report

Developing a Communication Strategy to Increase Awareness of Clinical Research at Eastern
Health: Environmental Scan Report

Kari Jenkins

Memorial University of Newfoundland

The Clinical Research division at the Health Sciences Centre functions to coordinate and conduct clinical research as a service to patients at Eastern Health. A lack of awareness of clinical research within the public and Eastern Health staff has been reported by leadership at the Clinical Research Division as well as research staff. This lack of awareness results in low participation rates in research studies which slows clinical knowledge advancement.

Communication and education about clinical research have been shown to increase awareness of clinical research and improve study recruitment rates. The overall goal of this practicum project is to create a communication strategy that will increase awareness of clinical research at Eastern Health. An environmental scan was completed to determine current communication practices of the Clinical Research Division at Eastern Health, and to explore what communication strategies other Canadian health organizations have for clinical research to inform the strategy for this practicum project. In addition, examination of website content of clinical research search engines and awareness campaigns will provide insight for creation of communication materials. The purpose of this report is to provide background for this environmental scan, describe the collection, management, and analysis of data, and to discuss results and how they are relevant to this practicum project.

Background

Clinical research is important for advancing the diagnosis and treatment of disease (Madsen et al., 2014). Lack of awareness of research has been reported in patient, nurse, and physician populations. The lack of awareness leads to low patient participation rates in clinical research which negatively impacts the advancements in treatment and diagnosis of disease. Low participation can result in biased findings due to inability to reach recruitment targets, and increases the duration of the study (Fenlon et al., 2013).

Strategies to increase awareness of clinical research in the literature include communication and education utilizing a variety of methods such as collaborating with outside organizations (Solomon et al., 2009), utilizing multiple educational platforms (Madsen et al., 2014) and technology (Chu et al., 2015; Du et al., 2008; Flood-Grady et al., 2019; Meropol et al., 2016), and targeting healthcare professionals as champions of research education initiatives (Haugen et al., 2015; Kao et al., 2019; Madsen et al., 2015). Educational materials for clinical research studies have been noted as having a reading level that was too high for the general public (Friedman et al., 2014; Abel et al., 2015).

Patients often access the internet to find health information, thus it is important that clinical research information online is of high quality. Analysis of clinical research websites to determine their strengths and weaknesses may help develop a quality web presence for the Clinical Research Division.

The literature highlights a variety of other communication methods that may increase awareness and participation in clinical research such as displaying information in clinics (Madsen et al., 2014), providing interactive computer programs to potential participants (Meropol et al., 2016), and educating nurses about clinical trials through self-learning modules (Haugen et al., 2015). Exploring communication methods from other institutions in Canada may reflect the methods identified within the literature, or there may be additional methods identified that can be adapted to Eastern Health.

Sources of Information

Organizations similar to Eastern Health within Atlantic Canada were contacted via email to gather information about clinical research awareness and whether they have communication

strategies for clinical research within their organizations. These organizations have been chosen as they are comparable in terms of size and geographical location to Eastern Health. In addition, organizations that have a known research presence were contacted via email to gather information about clinical research awareness and whether they have communication strategies at their institutions. Please see Appendix A for copies of letters for these organizations.

Websites for clinical research awareness campaigns were examined for content such as It Starts with Me, the Health Canada Clinical Trials Database, and Patients at Heart. These websites provide examples of both government and pharmaceutical company funded campaigns.

Data Collection

Data for the environmental scan were collected by viewing websites associated with locating clinical trials in Canada and raising awareness of clinical research, and contacting Canadian organizations both comparable to Eastern Health and those that have a known, strong research presence. A list of guiding questions and note taking were used to compile data for analysis from these websites. A separate list of guiding questions was provided via email to representatives from Eastern Health and from comparable organizations and those that have a strong research presence and the answers will be recorded to examine if clinical research awareness strategies exist within their organization. In addition, the websites of these organizations were examined to determine if they identify a research presence and what strategies, if any, they have in place to raise awareness of clinical research. See Appendix A for guiding questions for the organizations and website analysis. Questions were the same for each organization to ensure consistency is maintained.

Data Management and Analysis

Data was entered and organized into a table in Excel and analyzed with content analysis. The content analysis was based on guidelines from Braun and Clarke (2006) to facilitate the identification of themes and patterns from the interviews and answers from questionnaires. Data from websites was organized into a table in Excel and analyzed using a content analysis approach. Data was stored on a personal computer that was password locked and within a password locked folder. In addition, all data was stored without identifying factors to ensure anonymity of participants. See Appendix B for a data analysis summary.

Responses were received from representatives from Eastern Health, one organization similar to Eastern Health, and two organizations with a known research presence. The names of these organizations are omitted to ensure anonymity of participants. Questionnaires have been answered by all of these organizations with the exception of the one most similar to Eastern Health which withdrew participation due to difficulty finding time to complete the questionnaire.

Eastern Health Response Summary and Themes

A representative from the Clinical Research Division agreed to participate in this environmental scan to determine current communication practices at Eastern Health. The department employs about 11 Research Registered Nurse Coordinators that are each responsible for coordinating about 6 to 7 studies on average, and funding for research primarily comes from research grants. There is currently no specific communication strategy to increase awareness of clinical research, and there is no budget specifically for communication about research as noted by the representative. However, current recruitment and communication methods of the department include posters, screening clinics, and approaching potential participants in clinics.

The department has also participated in awareness campaigns such as Clinical Trial Awareness week which included setting up a booth at the Health Science Centre for people to approach and have the opportunity to ask questions about clinical trials. There has also been representation of the department at the Innovation fair for Eastern Health, and there is information available on the intranet for staff, and on the Eastern Health website for the public.

Current challenges related to research communication and recruitment described in the data include the large geographical region that Eastern Health covers, circle of care policy, lack of communication, and difficulty navigating the website.

Overall, the research capacity at Eastern Health is currently modest due to a small research department, however, this is likely appropriate for the population that the organization serves. From this data provided by the Clinical Research Division, it is evident that there are barriers to increasing awareness of clinical research. The geographical region is large within Eastern Health, thus making it difficult to reach all patients and facilities within the regional health authority. In addition, Research Coordinators only screen patients within their circle of care and the provision of information about research is often limited to individuals identified from screening initiatives. The communication strategy must take into consideration the large geographic area to ensure that all patients are reached with information. In addition, information about research must be made more readily available to the public so that it is being provided beyond patients that have been screened as potential participants. There is evidence that the department participates in some awareness campaigns, however, the campaigns described occur only at specific timepoints during the year. It may be beneficial to ensure the department is involved in awareness campaigns more frequently as part of the communication strategy.

Information from organizations outside of Eastern Health will help provide different perspectives on communication about research and inform the communication strategy as well.

Organizations with Known Research Presence Response Summaries and Themes

Insight from two organizations with a known research presence has provided additional information that will be valuable in the development of the communication strategy. The feasibility of their communication strategies will be assessed for adaptation within Eastern Health. To ensure anonymity, these organizations will be called Organization A and Organization B for the purpose of this report.

Organization A. A representative from Organization A who acts as a primary investigator and co-investigator on clinical research studies agreed to participate in this environmental scan, and confirmed the extensive involvement of Organization A in clinical research. Within this individual's specialty there are 5 principal investigators, 8 research volunteers who aid with recruitment and data mining, and 2 paid research coordinators. The research presence at Organization A is so large that this person was unaware of how many individuals were involved in research in general. However, they did highlight that there is a research tower separate from the main hospital that houses scientists, clinicians, and researchers. The research department at Eastern Health is modest in comparison; it has one floor of the hostel building with a few small satellite sites in other buildings.

The Organization A representative noted that intervention or clinical trial studies were not common within their specialty. They discussed how their department typically maintains clinical databases for a variety of conditions or diseases, and they do this by collecting data longitudinally in every clinic. Organization A receives funding from research grants much like

Eastern Health does, however, Organization A also has a foundation and receives a lot of donations as per their representative. In addition, the representative stated that they are unsure specifics regarding a specific budget for communication about research but they felt confident that there is an entire team within the research tower whose job is to communicate about research.

The research volunteers facilitate the recruitment and consent of patients into studies as per the Organization A representative. The greatest challenges with recruitment noted by this individual was that recruitment of children requires parental consent, and they occasionally have personnel who forget to ask families if they would like to participate in the research.

Organization A is so well-known for its involvement in research that many people expect to be approached about it according to the Organization A representative. The communication about research was described as being a facilitator of recruitment into clinical research. For example, the representative highlighted how there are commercials on television about how important research is at Organization A, there are signs everywhere throughout the building about research, and the organization also utilizes social media to communicate about research. At every entry point of the building and near the elevator in the parking garage there are signs that say, “you may be asked to participate in research”. The representative was unsure if there was a specific communication strategy developed, but they mentioned that there is a quality improvement project happening now that includes a needs assessment of patients’ knowledge of clinical research taking place at Organization A. In addition, education about clinical research can be found on the hospital’s website and there are newsletters. It was reported that staff do not ask anything specific about clinical research, while patients usually ask about what the researchers do with the data and results.

Organization B. Organization B is another organization that is well-known for conducting research. A representative that conducts research as a primary investigator agreed to participate in this environmental scan. This organization is a large centre, much like Organization A, and the individual that participated in this environmental scan is part of a subspecialty within the research department. Within this individual's subspecialty, there are 2 to 4 research assistants available, 3 volunteers, 10 surgeons that are primary investigators, and one nurse practitioner that is a primary investigator. The subspecialty has 2 to 3 active studies as well as 2 prospective databases that they are responsible for at any given time. There are no Research Coordinators that are nurses; they only have research assistants that are responsible for the studies. Funding was noted as coming from the hospital's research office for internal funding, and external funding comes from entities such as professional associations and the Canadian Institute for Health Research (CIHR).

Strategies to communicate about research and recruit potential participants come from the research office. These strategies were listed as posters that describe eligibility criteria and purpose of the study, education of clinicians that would be seeing potential patients, and providing laminated sheets to clinicians to remind them to screen their patients for eligibility. In addition, the organization also has a research poster day across the organization, emails are sent to staff about research, there is information on the website for the staff and public, there are lunch and learn sessions for staff, and there are some workshops that take place throughout the year that focus on aspects of clinical research. The representative stated some facilitators for recruitment into clinical research include thank you gifts, parking passes, and families having a clear understanding of the benefits of research and of the study. Challenges noted for recruiting

into clinical research included the cost of parking and additional visits to the centre beyond appointments with their health care provider.

Overall, the data from organizations with a strong research presence such as Organization A and Organization B had a variety of themes emerge such as research capacity; provide understanding; transparency; and targeted education. The themes and initiatives noted within these organizations may be compared with Eastern Health to determine if they might be beneficial and feasible at Eastern Health.

Both organizations have large research capacities as evidenced by a dedicated research tower for Organization A, and research office at Organization B. The individuals interviewed were only aware of their small subspecialties within the vast clinical research operations at their respective organizations. Those who work in the research department at Eastern Health by comparison are able to recall each member of the small team. In addition, it appears that there is a large amount of funding that contributes to their research capacity through organizational foundations, donations, and grants. Eastern Health also relies on funding from grants, however, there is no research foundation. It is likely not possible that Eastern Health could reach the research capacity of these other organizations, however, communication methods utilized at these organizations might be adapted on a smaller scale for the research department at Eastern Health.

The organizations demonstrated transparency with regard to their conducting of clinical research. The data indicated that each hospital had posters throughout their buildings, and Organization A had posters that ensure patients are aware that they may be asked to participate in clinical research. An initiative at Eastern Health that mirrors this would be feasible. There are already many areas throughout the hospitals that display posters, and there is a digital screen

network that could inform the public that they may be asked to participate in research. Posters such as these may prompt patients to ask questions and thus increase their knowledge and awareness of clinical research at Eastern Health.

Targeted education was also noted as a theme within the data. Education about clinical research was provided to patients and staff at these organizations. For staff, research education targeted clinicians who may assist in screening patients for studies, there are workshops or sessions that staff can attend about research, there is email communication about research, and the website offers information. Public education is provided through posters, from healthcare providers, and from the organizations' websites. Within this theme, the theme of ensuring people have a clear understanding of research emerged. For example, posters reflected eligibility criteria and purposes of studies, and one representative cited that a clear understanding of research was a facilitator of recruitment. Educational initiatives are feasible at Eastern Health, thus the targeted education and providing understanding themes will be utilized to inform the communication strategy.

Website Analysis

The Clinical Research Division noted that there will be revision of the research department section on Eastern Health's website. Analyzing the websites of clinical research associated websites such as clinical trial search engines, awareness campaigns, and the websites of the organizations included within this environmental scan will inform the revision of research department website and development of communication methods within the strategy.

Clinical trial search engines. The clinical trial search engines analyzed for this environmental scan include Canadian Cancer Trials, Canadian Cancer Trials Group, and the

Health Canada Clinical Trials Database. The target audiences for these websites were patients, families, or healthcare professionals seeking clinical trials or specifically, cancer clinical trials. Funding of these websites was provided from organizations such as the Canadian Partnership Against Cancer, the Canadian Cancer Trials Group, the Canadian Cancer Society, Queen's University, and the Government of Canada. Each of these websites allows users to search for clinical trials either in general, or by filtering by province. Education is provided briefly in the form of Frequently Asked Questions (FAQ) (Canadian Cancer Trials Group, 2019), images describing aspects of clinical trials, and links to additional resources (Canadian Partnership Against Cancer, 2019). The Health Canada (2019) search engine does not provide education about clinical research. All of the search engine websites provide contact information for individuals that can answer questions about clinical research.

The clinical trial search engine websites appear to be user-friendly overall and provide an easy method to locate clinical trials. The clinical trial information can be found on the landing page of the websites, or by following minimal links. The creation of a search engine on the clinical research portion of the Eastern Health website may assist the public in finding relevant studies.

Awareness campaigns. The awareness campaign websites analyzed in this environmental scan were Patients at Heart (Abbvie, 2019) and It Starts with Me (Network of Networks [N2], 2019). These websites targeted Canadians participating in clinical trials, or those who were considering participation in clinical trials. The Patients at Heart website is funded by Abbvie which is a pharmaceutical company (Abbvie, 2019), whereas the It Starts with Me website is funded by a CIHR grant awarded to N2 (N2, 2019). Both of these websites were easy to navigate, and they contained simple information that was easy to understand. In addition,

users can search for clinical trials using these websites. There are short videos explaining the benefits of clinical trials (N2, 2019), testimonials from patients and families (Abbvie, 2019; N2, 2019), and detailed information about clinical trials aiming to educate the public (Abbvie, 2019; N2, 2019).

The awareness campaign websites overall were very user friendly and appealing. They used color, images, and videos to attract the attention of users. Navigation of the websites was easy and the flow of information from each link was logical. The development of website and other communication materials for clinical research within this communication strategy will ensure that users can navigate with ease and they are visually appealing. In addition, the use of testimonials as a source of information may add a personal touch that patients might appreciate when receiving information about clinical research.

A theme of altruism was evident from the awareness campaign websites. Many of the phrases and messages used the word “help” or “helping” with reference to participating in research to help yourself, help others, and help advance research (N2, 2019). In addition, the awareness campaigns have a theme of focusing on the patient as evidenced by describing clinical trials with the patient at heart (Abbvie, 2019), and displaying personable messages such as “your actions may improve lives”, “tested by people like you”, and “are you ready to see if there’s a clinical trial for you?” (N2, 2019). Tailoring messages in the communication strategy so that they are perceived as personable by the public may interest them in learning about clinical research.

Websites of Organizations. The websites of Eastern Health, Organization A, Organization B, Organization C, Organization D, and the Organization E were analyzed. Each of these websites were funded and created by the organizations themselves. There were no options for searching for clinical trials on these websites, and only the Organization A, Organization C,

and Organization E websites provided education about clinical research although minimal in some cases. Although there were no clinical trial search engines on these websites, the Organization D website stated that patients could submit a form indicating which types of trials they would be interested in, their name would be entered into a secure database, and they would be contacted if a matching trial came up. In addition, there was a list of cancer clinical trials on the Organization E website.

Contact information is provided on most of the websites; however, these contacts are not specific to clinical research on each website. All websites except the Eastern Health and Organization E websites had research links located on their landing pages that were easy to locate. Clinical research information was very difficult to find and limited on both the Eastern Health and Organization E websites, and the clinical trials at Organization E was found by chance during this environmental scan while assessing a third-party clinical trial search website. Education about clinical research was provided on the Organization A, Organization C, and Organization E websites, however, the information on the Organization A website appeared to target primarily staff. In comparison, the Organization C and Organization E website education targets the public as well.

A scan of organization websites has provided insight into ways that might improve the Eastern Health website for clinical research. For example, many of the sites had a “Research” link that was easily located on the landing page. These research links direct users to a Research landing page that includes information about the research currently conducted within the organization. In addition, information about what clinical research is and how people can become involved was provided. Improving the website for Eastern Health so that research

information is easily located is a feasible goal as part of the development of the communication strategy to increase awareness of clinical research.

Ethical Considerations

As per the ethics review checklist, approval from the Health Ethics Review Board and the institutional review board was not required for this project as it is classified as a quality improvement project (see completed checklist in Appendix C). Agreements to share information were obtained from each individual during initial contact. Participant confidentiality was maintained with the use of private interview rooms for in-person interviews or phone calls, and not recording any personal identifiers during data collection from these interviews or from returned questionnaires. Participants were notified that they are free to withdraw their participation at any time. Data security was maintained by storing data within a password protected folder on a password protected computer. No personal identifying information was stored with data.

Conclusion

An environmental scan of organizations including Eastern Health, Organization A, and Organization B has provided valuable insight regarding current communication practices about clinical research at Eastern Health compared to what is occurring within larger organizations. In addition, examination of websites of these health organizations, clinical trial search engines, and clinical trial awareness campaigns will help inform the development of communication methods for this practicum project. Although Organization A and Organization B operate with a greater budget and research capacity, themes and practices identified in the data may be adapted within Eastern Health. These include maintaining organizational transparency about clinical research

and providing targeted education to the public and staff. The themes of altruism and focusing on patients identified from the awareness campaigns can also be incorporated into content within the communication strategy. In addition, improvement of the Eastern Health website to ensure that research information is easily accessible may be modeled after organizational websites and clinical trial search engines.

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Appendix A

Environmental Scan Invitation Letter

Hello,

My name is Kari Jenkins and I am a Masters of Nursing student at Memorial University. I am currently completing the final practicum project for this program. I am developing a communication strategy regarding clinical research at Eastern Health in St. John's, Newfoundland and Labrador for my project. The purpose of this project is to increase awareness of clinical research in patient, nurse, and physician populations.

Increased awareness of clinical research may improve participation rates in clinical research which leads to advancement in the diagnosis and treatment of disease.

I am in the process of conducting an environmental scan to inform the development of the communication strategy and I am inviting you to participate. I am requesting information regarding how your organization communicates about clinical research. I have attached a list of guiding questions to facilitate this. The information you provide will help determine what communication strategies are currently used within Canada for clinical research awareness. In addition, the information gathered will be compared with Eastern Health to determine how to enhance our research program. Data collected will be destroyed once the project is completed.

Submitting information will indicate agreeing to participate as a consultant and that you understand the contents of this letter. If you have any questions, feel free to reach me by phone at (709)-777-5229 or email at kari.jenkins@easternhealth.ca.

Regards,

Kari Jenkins, BSc (Hons), BN, RN

Environmental Scan Guiding Questions

Organizations

1. Does your organization participate in research?
2. What is your role in research within the organization?
3. What is the size of your clinical research department? e.g. how many research coordinators primary investigators, research assistants, etc. do you have?
4. How many studies does your research department conduct at any given time?
5. How many studies is one research coordinator responsible for?
6. From where does your organization receive funding for research? What kind of budget does your organization have for communication about research?
7. What strategies do you use for recruitment into clinical research?
8. What challenges does your organization have regarding recruitment into clinical research?
9. What facilitates recruitment into clinical research at your organization?
10. Does your research program have a communication strategy to raise awareness of clinical research?
11. Who at your organization facilitates communication about clinical research?
12. What materials and methods does your organization utilize to communicate about research?

13. Does your organization provide education to patients, nurses, and physicians regarding clinical research?
14. What kinds of questions does your department get from patients and staff regarding research?

Website Analysis

1. Who is the target audience?
2. Who funds this website?
3. Who created this website?
4. When was this website established?
5. Is this an awareness campaign?
6. Can you search for clinical trials on this website?
7. Is education provided about clinical research? e.g. explanations about what clinical trials are, informed consent, study procedures, why clinical research is important etc.
8. Is contact information provided for questions regarding clinical research?

Appendix B
Data Summary

Table 1.

Responses from organizations

Question	Institution		
	Eastern Health	Organization A	Organization B
Does your organization participate in research?	Yes.	Yes. Extensively.	Yes.
What is the size of your clinical research department? e.g. how many research coordinators, primary investigators, research assistants etc do you have?	11 Research Registered Nurse coordinators	Within my division I have 8 research volunteers to provide coverage in clinic for recruiting patients, mining data etc. There are 2 paid research coordinators. We have 5 principal investigators. Within Organization A I have no idea. There is research tower across the street that is filled with scientists, clinicians and researchers.	0 specific to nursing For Pediatric Surgery which we are not able to access without paying for: 2 – 4 research assistants, 3 volunteers, all the surgeons would be primary investigators around 10 No other NP has been a primary investigator at the children’s hospital other than me
How many studies does your research department conduct at any given time?	It varies	Varies. We maintain clinical databases for a variety of conditions where data is collected longitudinally in every clinic. Intervention studies/trials are not that common. We have 5 fellows all	Our division has 2-3 active studies at any given time, in addition to prospective databases (2)

		with various projects of their own. For each conference for our specialty we try to send at least 8-10 abstracts	
How many studies is one research coordinator responsible for?	6-7 studies	Again, this varies. See above. There are 2 coordinators for the division.	n/a, only have research assistants. They are responsible for all the studies in our division
From where does your organization receive funding for research? What kind of budget does your organization have for communication about research?	Grants. There is no specific budget for communication about research.	Grants mostly. I think other funding comes from the foundation. Others from donors. Same for "communication about research". Organization A has a foundation responsible for marketing everything, including research.	Internal funding (hospital research office), external funding (professional associations, CIHR)
What strategies do you use for recruitment into clinical research?	Posters, screening clinics, approaching people in clinics.	Clinic volunteers handle consent. Relevant studies are introduced by one and another will obtain consent if they agree.	Posters with eligibility criteria and purpose of study, education for any clinician seeing pts, laminated sheets to remind clinician to screen for eligibility for possible study patients

<p>What challenges does your organization have regarding recruitment into clinical research?</p>	<p>Eastern Health has a large geographic region, lack of communication, circle of care policy.</p>	<p>As in all areas of pediatrics, recruitment is challenging due to the fact that we are trying to enroll children which requires parental consent. it is a well-documented challenge in the literature about recruitment of children. Other challenges are if people forget to ask the families or forget about the projects. We are a trainee heavy environment so sometimes kids could get missed.</p>	<p>Typical: cost of parking, additional visits.</p>
<p>What facilitates recruitment into clinical research at your organization?</p>	<p>Giving information, screening clinics.</p>	<p>Maybe people expect to be approached because it is Organization A. There are commercials on TV about how important research is here. There are signs everywhere. When you park your car in the parking garage, there is a sign at the elevator saying "you may be asked to participate in research". Also at each entry point.</p>	<p>Some type of thank you gift (gift card), parking pass, families having clear understanding of the benefits of research and the particular study.</p>

Does your research program have a communication strategy to raise awareness of clinical research?	No.	There is a QI project right now I think where someone is surveying our patients about this. What they know. How they know etc. We have signs around our work area about specific projects.	Research poster day across the organization, emails about funding
Who at your organization facilitates communication about clinical research?	Clinical Research Division.	Not sure exactly. There is always mention on the hospital twitter page. As I said there are infomercials. I'm sure there is a department at the tower full of people whose job it is to disseminate info about research.	Research office
What materials and methods does your organization utilize to communicate about research?	Posters, participating in clinical trials week, had a table at the innovation fair, participating in awareness campaigns.	Social media. TV. in hospital signage	Emails, posters, website
Does your organization provide education to patients, nurses, and physicians regarding clinical research?	Yes to those involved in studies.	There are newsletters. A website for the hospital. Each study will have literature. Not sure about research education in general though.	Lunch and learn sessions, some workshops throughout the year

What questions does your department receive from patients and staff regarding research?	Questions about the studies.	From patients it is usually about what we do with the data. Results. etc. From staff not really anything specific.	Nothing specific.
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Table 2.

Website Analysis: Clinical trial awareness campaigns and search engines

Questions	Website (Campaigns and Search Engines)				
	https://patientsatheart.com/	https://itstartswithme.ca/	http://www.canadiancancertrials.ca/	https://www.cctg.queensu.ca/	https://health-products.canada.ca/ctdbdec/index-eng.jsp
Title	Patients at Heart	It Starts with Me	Canadian Cancer Trials	Canadian Cancer Trials Group: a national academic-led cooperative group conducting cancer clinical trials and testing innovative treatments	Health Canada Clinical Trials Database
Who is the target audience?	Canadians thinking about participating in clinical trials or who are currently participating in clinical trials	Canadians considering participation in clinical trials	Patients with Cancer in Canada	Patients/families and healthcare professionals	Persons seeking clinical trials in Canada
Who funds this website?	Abbvie	CIHR Grant awarded to N2	Canadian Partnership Against Cancer	Canadian cancer trials group; Canadian cancer society; queen's university; ... likely grants?	Government of Canada

Who created this website?	Abbvie	Network of Networks (N2)	Canadian Partnership Against Cancer	Queen's university: Canadian cancer trials group	Government of Canada
When was this website last updated?	2019	2019	2019	2019	2018
Is this an awareness campaign?	Yes	Yes	No - it's a website to search for cancer clinical trials	No - it is a place to search for cancer clinical trials	No
Can you search for clinical trials on this website?	Yes	Yes	Yes - cancer clinical trials in each province and it tells you the number of trials that are recruiting in each participating province	Yes - there is a list of current cancer clinical trials that are participating	Yes
Is education provided about clinical research?	Yes	Yes	Yes - there is brief info in the FAQ section of the website that explains what clinical trials are	Yes - there is some brief information provided on the website, and there are links to additional resources for information the current website has some visuals about how to participate in a clinical trial, and what informed consent is	No

Is contact information provided for questions regarding clinical research?	Yes	Yes	Yes - there is contact info provided for each recruiting site of a particular trial	to visit the it starts with m	Yes there is a link for contacting support.
Additional Notes			Patients advised to print trial information and bring to a doctor to get a referral to a clinical trial.		
			EH noted as clinical trial partner		

Appendix C

Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review	<input type="checkbox"/>	x
.	Are there any local policies which require this project to undergo review by a Research Ethics Board?	<input type="checkbox"/>	x
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.	<input type="checkbox"/>	<input type="checkbox"/>
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?	<input type="checkbox"/>	x
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?	<input type="checkbox"/>	x
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?	<input type="checkbox"/>	x
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	<input type="checkbox"/>	x
.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?	<input type="checkbox"/>	x
	LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)	0	
.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	<input type="checkbox"/>	x

9.	Is the project intended to define a best practice within your organization or practice?	x	<input type="checkbox"/>
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	x	<input type="checkbox"/>
1.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	x	<input type="checkbox"/>
2.	Is the current project part of a continuous process of gathering or monitoring data within an organization?		x
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		3	
SUMMARY See Interpretation Below			

Interpretation:

- If the sum of Line A is greater than Line B, the most probable purpose is research. The project should be submitted to an REB.
- If the sum of Line B is greater than Line A, the most probable purpose is quality/evaluation. Proceed with locally relevant process for ethics review (may not necessarily involve an REB).
- If the sums are equal, seek a second opinion to further explore whether the project should be classified as Research or as Quality and Evaluation.

These guidelines are used at Memorial University of Newfoundland and were adapted from ALBERTA RESEARCH ETHICS COMMUNITY CONSENSUS

INITIATIVE (ARECCI). Further information can be found at: <http://www.hrea.ca/Ethics-Review-Required.aspx>.

Appendix D

Communication Strategy

Developing a Communication Strategy to Increase Awareness of Clinical Research at Eastern
Health: Communication Strategy

Kari Jenkins

Memorial University of Newfoundland

Developed by: Kari Jenkins	Date Drafted: Nov. 21, 2019
In consultation with: Clinical Research Division of Research and Innovation Department	
Approved by:	Final Approval:

Issue

Clinical research is important for advances in the diagnosis and treatment of disease, and improvement in the quality of life for patients. The Clinical Research Division at Eastern Health has identified a lack of awareness of clinical research in patients and staff. Increasing awareness of clinical research has become a priority of the Clinical Research Division.

In support of this priority, as an employee of the Clinical Research Division, and as a Masters of Nursing student at Memorial University, I have developed a communication strategy to increase awareness of clinical research at Eastern Health as my practicum project. The Patient Research Centre will work with the Communications Department to launch an awareness campaign for clinical research.

Background

A lack of awareness of clinical research in patients, nurses, and physicians leads to poor recruitment into research studies. As a result, research studies often do not meet target recruitment goals and studies take longer to complete. As a result, advances in the diagnosis and treatment of disease can be slowed due to regulatory bodies requiring evidence from rigorous research prior to approval of new therapies.

A needs assessment at Eastern Health identified a lack of awareness of clinical research in Registered Nurses, physicians, and patients. This lack of awareness was evident on units that participate in research and units that do not participate in research. A communication strategy was identified by the Clinical Research Division as a preliminary method aiming to increase awareness of clinical research at Eastern Health for patients and staff.

A literature review, consultations with key stakeholders, and an environmental scan were completed as part of this practicum project to inform the development of the communication strategy; The results of which are summarized below.

Literature Review

A literature review was conducted to discuss what is known about awareness of clinical research in patients, nurses, and physicians. The importance of clinical research awareness, strategies to increase awareness, and the rationale for developing a communication strategy were also discussed in the review. In addition, Adult Learning Theory (Sanchez & Cooknell, 2017) was discussed as a guide for communicating and educating about clinical research.

The literature review provided support for the argument that there is a lack of awareness of clinical research in patients (Bazarbashi, Hassan, Eldin, Soudy, & Hussain, 2015; Ellis et al., 1999; Tohid et al., 2016), nurses (Kao et al., 2019; Yanagawa et al., 2014), and physicians (Madsen et al., 2014; Michaels et al., 2015) and it highlighted existing barriers to awareness. These barriers include:

1. Understanding of research (Stead, Eadie, Gordon, & Angus, 2005; Massett et al., 2017; Meropol et al., 2016; Napoles, Cook, Ginossar, Knight, & Ford, 2017).

2. Sociodemographic factors such as age (Meropol et al., 2016; Michaels et al., 2015), location (Meropol et al., 2016; Michaels et al., 2015; Wong et al., 2016), socioeconomic status (Brown & Moyer, 2010; Leiter et al., 2015; Meropol et al., 2016), and being of ethnic or racial minority (Leiter, Diefenbach, Doucette, Oh, & Galsky, 2015; Meropol et al., 2016; Skinner et al., 2019).

3. Attitudes of patients (Brown & Moyer, 2010; Massett et al., 2017) and staff (Masset et al., 2017; Michaels et al., 2015) toward clinical research.

Consideration was given to these barriers in the strategies identified to increase awareness of clinical research. Strategies identified to increase awareness of clinical research include:

1. Education of patients and staff (Haugen, Gasber, Leonard & Lander, 2015; Madsen et al., 2014; Michaels et al., 2015)

2. Targeting nurses and primary care providers to communicate with patients about clinical research (Kao et al., 2019; Madsen et al., 2014; Michaels et al., 2015).

3. Collaboration with stakeholders (Solomon et al., 2009)

4. Use of technology for communication and education (Chu et al., 2015; Meropol et al., 2016)

Other important considerations highlighted in the literature for communication and education about clinical research included ensuring materials are an appropriate reading level (Abel et al., 2015; Friedman et al., 2014) and that learning methods are interactive (Abel et al., 2015).

Consultations

Consultations with Eastern Health staff from Corporate Communications, Learning and Development, and Human Resources were completed. The purpose of the consultations was to learn the logistics of developing a communication strategy and to explore expert opinion regarding communication, education, and the importance of engaging staff and the public. Themes were identified from the consultation interviews that would help inform the development of this strategy. These include:

1. Use of technology to increase access to information as Eastern Health has a wide geographic region
2. Tailor content depending on target audience (Different content for staff versus the public)
3. Provide reasoning for education (People want to know why they are learning something)
4. Include staff in development and evaluation of education and communication initiatives

Environmental Scan

An environmental scan was conducted to determine current research communication methods at Eastern Health and explore existing communications at other institutions. Two health organizations with an established research presence agreed to participate. While Eastern Health does not have a current communication strategy, however, the Clinical Research Division does

communicate about research using methods such as participating in awareness campaigns, posters, innovation fairs, and speaking directly with study participants.

Themes regarding clinical research communication that were identified from other institutions include:

1. Transparency about clinical research within the organization
2. Target staff with clinical research education so that they can discuss research with their patients

Websites of clinical trial search engines, awareness campaigns, and health organizations invited to participate in the environmental scan were analyzed. Themes identified in this review might help in developing a website for Eastern Health. They include:

1. Research information easy to locate on the front page
2. Information with appropriate literacy level
3. Visually appealing
4. Target patients with altruism.
5. Include testimonials from patients

Target Audience

Primary

- Adult patients within the Eastern Health region who may benefit from clinical research

Secondary

- Employees of Eastern Health (Nurses, Physicians, and other healthcare providers who have direct contact with patients)
- Stakeholders (e.g. Government, community medical clinics, pharmaceutical companies)
- Students (e.g. health professional schools, graduate students in health related programs).

Communications Goal

- To communicate that research is a service offered at Eastern Health.
- To communicate what clinical research is, why it is important, and how people contribute to helping others when they participate.
- To increase awareness of the Clinical Research Division at Eastern Health.

Communications Objectives

- To expose the patients to campaign messages for a sustained period of time.
- To expose Eastern Health staff to campaign messages for a sustained period of time.
- To generate at least the average number of visits noted in previous awareness campaigns to the website in the first year of the campaign launch.

Stakeholders

Internal

- Research Registered Nurse Coordinators, Primary Investigators, Research and Innovation staff, Clinical Research Division, Research Proposals Approval Committee (RPAC), Corporate Communications.

External

- Patients participating in clinical research within Eastern Health.
- Patients who are potential participants in clinical research at Eastern Health.
- Family members of patients participating or potential participants in clinical research.
- Sponsors of clinical research (Industry and Academic).
- Private medical clinics participating in research within the Eastern region.
- Family medicine clinics within the Eastern region
- Health Research Ethics Authority
- Government of Newfoundland and Labrador
- Media

Strategic Considerations (SWOT Analysis)

Threats

- Not everyone is eligible for a clinical research study and there may be some backlash from people seeking treatment options.
- In the literature, negative attitudes toward clinical research are noted in patients as well as healthcare professionals and may impact initial reception of campaign messages.
- Eastern Health has a large geographic region and it may be hard to reach people outside of St. John's.

- Registered Nurses comprise the majority of Eastern Health employees and they are often difficult to reach with communications due to the nature of shift work.

Opportunities

- There has not been a previous awareness campaign specific to increasing awareness of clinical research at Eastern Health.
- This campaign provides the opportunity to educate patients and staff about the importance of clinical research.
- Increasing awareness of clinical research may increase research participation which helps achieve research study goals and may provide more funding opportunities.
- Increasing participation in research may result in improved quality of life for a greater number of Eastern Health's patients.
- Providing recognition for research achievements at Eastern Health may result in positive views toward the organization.

Strengths

- There are many qualified health professionals who can become champions for the clinical research awareness strategy within Eastern Health as it is the largest regional health authority.
- This campaign will provide opportunity for other research campaigns.
- This campaign aligns with Eastern Health having teaching hospitals and clinics.

- External partners and organizations may be open to supporting or promoting the campaign as Eastern Health is a credible organization.

Weaknesses

- The research and innovation department is small, potentially limiting the capacity of campaign promoters who are directly involved in research.
- The Eastern Health website is not mobile friendly which limits reaching individuals who use mobile devices for information.

Key Messages

Campaign Tag Lines

- Research: A Health Service
- Clinical Research: For you. For your family. For the future.

Main Key Messages

- Eastern Health conducts clinical research. You may be asked to participate in a research study.

O Eastern Health has teaching hospitals and clinics due to collaborative arrangements with schools such as Memorial University.

O Teaching hospitals conduct clinical research. Health professionals are often recruiting patients to participate in various research studies.

- What is clinical research and why is it important?

O Clinical research is healthcare research carried out on humans to test the safety and effectiveness of new treatments.

O Clinical research is a service offered by Eastern Health to its patients.

O Clinical research is important to advance the treatment and diagnosis of health conditions for you and your family.

O Clinical research offers treatment options that would otherwise be unavailable.

• Who conducts clinical research?

O Research teams of healthcare professionals and associates conduct research in many different specialty areas throughout Eastern Health.

O Research teams may include: Primary Investigators, Research Coordinators, and Research Assistants.

O The Clinical Research Division at the Health Sciences Centre in St. John's employs Research Coordinators who coordinate research studies for the Primary Investigators.

• How can I find out more about clinical research?

O By contacting the Clinical Research Division at Eastern Health.

O By accessing the Research and Innovation website.

O By participating in learning opportunities.

Communications Activities

Activities within this communication strategy will be recommended based on results from the methods of this practicum project and consultations with the Clinical Research Division and Corporate Communications. Activities will include branding, creation of collateral materials, use of technology, building capacity, and promotional activities.

A brand will be created so that the awareness campaign is identifiable by a common aesthetic and consistent messaging. The target audience will be surveyed about the campaign's brand to inform the development of the brand. Collateral materials such as banners and posters will be created based on branding and used to promote the campaign. Additional posters and signage will be created that states that Eastern Health conducts clinical research and patients may be asked to participate. All collateral materials will be distributed to strategic locations with high traffic to reach maximum number of people. In addition, these materials will also be available online on Eastern Health's established communication platforms.

Stakeholders such as trusted health professionals, health professional students, and community partners will be targeted with key messages from the campaign with the aim to influence behaviour from multiple angles. For example, internal stakeholders such as Registered Nurses will be targeted with promotional materials and the opportunity to participate in an online self-learning module regarding clinical research. This module will be developed in consultation with Learning and Development. Registered Nurses will then be able to act as sources of information for this awareness campaign. Health professional students will be targeted with information sessions and in-class presentations so that they are aware of clinical research at Eastern Health upon graduation. In addition, community partners such as medical clinics will

receive promotional materials to increase the number of people reached with campaign messages.

Technology will be used to expand the reach of this campaign's messages. For example, a social media campaign will target an extensive group of the public and employees. In addition, the digital signs network that spans across Eastern health will be utilized to display key messages in areas that are accessed by both employees and the public.

An official event launch will publicly introduce the awareness campaign and will be carried out by the Clinical Research Division in consultation with Corporate Communications. This event will be an interactive information session where research information will be shared. After the official event launch, promotional activities will continue to sustain the message of the campaign via social media and traditional Eastern Health communication platforms.

Budget

The Research and Innovation department will assume the costs associated with the project including advertising, printing, and distribution costs.

Recommended Tactics

Collateral Materials

Branding. This campaign will be developed with a consistent look and feel that will be created in consultation with the Clinical Research Division and Corporate Communications. Branding will include consistent colours and graphic elements.

Posters. The posters will communicate that Eastern Health conducts research and that people may be asked to participate in a study. The posters will also contain campaign slogans and will direct people to the website or Clinical Research Division for more information.

Banner Bugs. Branded display banners will contain campaign messages and be placed in facilities or at events as needed. The banners will direct people to the website or Patient Research Centre for more information.

Digital Signage. Content will be developed for the digital signs network that will contain key messages for this campaign. These signs will be displayed at Eastern Health to reach both staff and public.

Promotional Items

Buttons. Employees will receive buttons that are branded with key messages that prompt the public and other employees to ask them about clinical research. Employees who do not work within the Research and Innovation department will receive these buttons after they have completed learning modules about clinical research at Eastern Health.

Online Promotion

Website. A web-in-web website will be developed under Eastern Health's web framework and will be accessible via an easy to locate link on Eastern Health's landing page. Content will communicate information about clinical research studies taking place at Eastern Health, explain the research process, provide resources related to clinical research, provide contact information for study coordinators and the research department, and explain what clinical research is, and why it is important.

Website Promotion. The awareness campaign will be promoted via banner ads and hyperlinks on the Eastern Health website.

Social Media Campaign. Key messages from the clinical research awareness campaign will be promoted using Eastern Health’s social media platforms such as Facebook and Twitter.

StoryLine Story. A story will be written for Eastern Health’s StoryLine Blog featuring the clinical research awareness campaign. This story will highlight key messages from the campaign and will be shared via social media platforms.

Paid Online Promotion

Online Advertising. Local media organizations will be contacted to purchase online ad packages so that the campaign is promoted via their websites.

EH Social Media Advertising. Banner ads will be created for Facebook that link to the research site on the Eastern Health website.

Amplifying the Reach

Electronic partnership package (for external stakeholders). External stakeholders such as medical clinics, and the schools of medicine, nursing, and pharmacy will be provided with electronic packages containing an e-letter, campaign poster links, and website buttons or banners to share on their websites or other communication platforms.

Email signature (staff). All Research and Innovation staff will be encouraged to add a common clinical research message or link to their Outlook email signatures.

Public Announcement/Launch

News Release and Media Relations. Corporate Communications will be asked to provide a news release to launch the clinical research awareness campaign to provide the goals and purpose of the campaign to the media and Eastern Health email users.

Event Launch. The Research and Innovation department will work with Corporate Communications to host an event that will publicly launch the clinical research awareness campaign. This will be an interactive event where research staff will be available for questions about the clinical research taking place at Eastern Health. In addition, guest speakers will be invited to provide short presentations about research or their experiences with research.

Building Capacity

(Internal) In-house training for Health Professionals. Learning and Development will be consulted to aid in the development of an online self-learning module that Eastern Health employees can complete via LEAP to enhance their knowledge of clinical research. Short lunch-and-learn sessions may also be provided for staff to promote the key messages of the campaign.

(External) Presentations to Students. The Research and Innovation department will work with schools such as Nursing, Medical, Pharmacy, Kinesiology to provide presentations to students about clinical research and the opportunities to participate in or work in the field of clinical research at Eastern Health. Paid Promotion

Educational Videos. Short educational videos will be developed with key messages and available via the Eastern Health website and Eastern Health's social media.

Table 1. Action Plan Chart

Tactic	Description/Vehicle	Responsibility	Target Group	Approximate Budget
Campaign Development				
Branding	Create the look and feel of the campaign and the signature images.	Clinical Research Division/ Corporate Communications	Public & Staff	TBD
Banner bugs	Branded banner bugs (x 1 design) to be used throughout campaign.	Clinical Research Division/ Corporate Communications	Public & Staff	TBD
Give-aways: Buttons	Buttons asking people to ask about clinical research will be distributed to all research staff. Staff that complete clinical research learning modules will also receive buttons. Communications to develop graphics. Patient Research Centre to seek out quotes and arrange for production and delivery.	Clinical Research Division/ Corporate Communications	Public & Staff	TBD

<p>Poster (11x17")</p>	<p>Posters will be developed to indicate that patients may be asked to participate in clinical research. These will be placed inside all clinic waiting rooms and inside all entrances to the building.</p> <p>Additional posters will be created with key campaign messages and placed throughout Eastern Health's buildings.</p> <p>A portion of the posters will be distributed to external stakeholders such as the nursing schools, medical school, and pharmacy school.</p>	<p>Clinical Research Division/ Corporate Communications</p>	<p>Public & Staff</p>	<p>TBD</p>
<p>Website</p>	<p>A web-in-web site will be developed using Eastern Health's web framework. A link will be on the landing page of the Eastern Health website.</p> <p>Content will include: information about clinical trials, current research studies, and how to find out more information.</p>	<p>Clinical Research Division/Corporate Communications</p>	<p>Public & Staff</p>	<p>TBD</p>
<p>Digital signage</p>	<p>Develop digitals signs imagery based on the campaign brand and key messages. The campaign</p>	<p>Clinical Research Division/Corporate Communications</p>	<p>Public & Staff.</p>	<p>TBD</p>

	<p>will be promoted on Eastern Health’s digital signage network, which includes signs that reach both employees and public (via the Foundation signs). The TVs are located in the following EH sites:</p> <ul style="list-style-type: none"> - Health Science Centre - St. Clare’s Mercy Hospital - Janeway - Waterford Hospital - Miller Centre, Veteran’s Pavilion - Cancer Care Centre - Placentia Health Care Centre (Placentia) - Dr. G.B. Cross Hospital (Clareville) - Central Laundry 		<p>Patients, residents, clients, families, visitors, volunteers and students who visit these sites.</p>	
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	- Burin Peninsula Health Care Centre			
Prepping and Launch				
Electronic letter/package to stakeholders (stakeholder outreach)	External stakeholders such as medical clinics, and the schools of medicine, nursing, and pharmacy, will be provided with electronic packages containing an e-letter, campaign poster links, and website buttons or banners to share on their websites or other communication platforms. Resource packages will include: <ul style="list-style-type: none"> • Short description of campaign • Call-to Action • Links to images and logos • Link to website • An electronic version of the 11x17 poster • Website buttons • Email signatures 	Clinical Research Division/ Corporate Communications	Stakeholders Memorial University schools of Nursing, Medicine, & Pharmacy; Medical clinics (TBD).	TBD

Eastern Health's online ad campaign	Eastern Health's Facebook and Twitter.	Corporate Communications	Public & Staff.	TBD
Online advertising	Local media organizations will be contacted to purchase online ad packages so that the campaign is promoted via their websites. Banner ads will be created for facebook that link to the research site on the Eastern Health website.	Corporate Communications	Public & Staff.	TBD
Launch (Phase 1)				
News release	A news release announcing the launch of the campaign and outlining the details of the launch event will be issued. This will provide media, as well as all Eastern Health email users, with the vision and purpose of the campaign. The news release will be sent out through the Eastern Health's media relations distribution list. Communications will draft and prepare the release for distribution.	Corporate Communications	Media Government External Stakeholders Eastern Health employees General public.	TBD

Event launch	<p>The Research Department will work with Corporate Communications to host an event that will publicly launch the clinical research awareness campaign. This will be an interactive event where research staff will be available for questions about the clinical research taking place at Eastern Health. In addition, guest speakers will be invited to provide short presentations about research or their experiences with research.</p> <p>Research Department will identify and coordinate event, in consultation with Corporate Communications.</p>	Clinical Research Division/ Corporate Communications	Public and Staff Stakeholders	TBD
Website promotion	The awareness campaign will be promoted via banner ads and hyperlinks on the Eastern Health website.	Corporate Communications	Eastern Health employees and clients.	TBD
Social media campaign	<p>Key messages from the clinical research awareness campaign will be promoted using Eastern Health’s social media platforms such as Facebook and Twitter. This will hyperlink back to the website for detailed information.</p> <p>Clinical Research Division will draft social media campaign. Corporate</p>	Clinical Research Division/ Corporate Communications	Parents Stakeholders Media Eastern Health employees	TBD

	Communications will review, edit and prepare content for publishing.			
Article on StoryLine	<p>A story will be written for Eastern Health’s StoryLine Blog featuring the clinical research awareness campaign. This story will highlight key messages from the campaign and will be shared via social media platforms.</p> <p>Clinical Research Division will stories and send to Corporate Communications for review, editing and preparation of content for publishing.</p>	Clinical Research Division	Eastern Health employees, StoryLine’s followers.	TBD
Online advertising	Local media organizations will be contacted to purchase online ad packages so that the campaign is promoted via their websites.	Clinical Research Division	Patients and Staff	TBD
Post-Launch/Sustaining the Message)				
Email signatures	All Research and Innovation staff will be encouraged to add a common clinical research message or link to	Corporate Communications /Clinical Research Division	Eastern Health employees Community partners	TBD

	their Outlook email signatures.			
StoryLine articles	<p>Post-launch: Continue to develop a series of stories related to healthy eating and highlighting one or more key messages from the campaign throughout the year.</p> <p>Clinical Research Division will write or coordinate stories with other writers. Communications will review, edit and prepare content for publishing.</p>	Clinical Research Division	Eastern Health employees, StoryLine's followers.	TBD
Social media campaign	<p>Launch and post- launch: Begin with high frequency posts in initial weeks, then continue with less frequency but maintain consistency in posting.</p> <p>Clinical Research Division will draft social media campaign and consult with Communications for review prior to publishing.</p>	Clinical Research Division/ Corporate Communications	Public Staff Stakeholders Media	TBD

Evaluation of Tactics

- Use backend analytics to monitor website usage as per Corporate Communications
- Monitor social media success of posts
- Monitor media by assessing how many media sources discuss the campaign after its launch
- Monitor the program by assessing how many people seek out information about clinical research to the Research Department and how many people enroll in research studies.
- Send out a post-launch survey to assess if the target group saw the campaign and visited the clinical research website as a result.
- Assess the uptake of the campaign by stakeholders in the community such as health professional schools, the government, and community medical clinics. Key indicators:
 - Number of website visits
 - User engagement on social media such as number of comments and shares
 - Number of times campaign is discussed in the news
 - Number of positive, neutral, or negative comments on social media and news media
 - Number of times the StoryLine stories are viewed and shared
 - Number of partners and stakeholders that use the promotional tools and campaign links on their websites

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Approved by:

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