Integrating Care into Clinical Research

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This culminating project will not be submitted for publication and it does not involve vulnerable populations as part of the data collection or intervention.

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Abstract

Decreasing errors will further support patient-centered care and improve outcomes. Errors within this healthcare setting are very disruptive to the quality and standard of care that is provided to clinical trial patients. Staff experience, training, as well as workplace stressors all contribute to procurement errors. 75 clinical staff were distributed questionnaires in order to gauge area of concern and in need of improvement. This led to the implementation of a finely tuned resource document for staff to rely on, as well as integrated within the department. The decreased rate of error and increased quality of care is evident.

Keywords: errors, clinical, patients, trial, care, quality, staff, training, PDSA

Literature Review

The impact of staff burnout and wellbeing is significantly associated with higher rates of patient safety and quality of care errors (Hall et al., 2016). In order to deliver and sustain a high caliber of care, the organization must provide a work environment that fosters staff wellbeing, provides adequate training, and protects staff against burnout (Hall et al., 2016). Further to maintain this high caliber of care, staff must be adequately trained. Errors and interruptions within a healthcare setting can be highly disruptive in maintaining a high standard of care for clinical trials patients who are a very frail patient population (Grundgeiger et al., 2009). Clinical trials are typically offered and run because none of the standard and approved methods of treatment work, or side effects are not tolerable. Clinical trials provide another option when standard therapy has failed. All clinical trials have guidelines and eligibility criteria that outline who can participate. The criteria are based off of age, sex, type and stage of disease, and previous treatments. Therefore, it is important that not everyone who applies or wants to be on a clinical trial will be accepted (FDA, 2018).

Furthermore, because of the complexity of clinical trials patients' care there are many fields dedicated to the extent of interruptions leading to adverse events within the patient's care (Grundgeiger et al., 2009). Therefore, routine, precisely scheduled blood draws at repeated intervals are crucial to both patient safety, drug research and tolerability. The importance of this testing helps determine drug metabolism and elimination, and how patient characteristics such as sex, age, and genetics play a role in drug development (Panetta et al., 2003). These new and novel therapies throughout phase 1 clinical trials are increasingly requiring mandatory blood collection samples which may be a potential barrier to trial participation if the strict guidelines aren't met (Charles et al., 2015).

Barriers to patient accrual in cancer clinical trials must be identified and overcome to increase patient participation. Barriers to cancer clinical trial accrual in this particular case are largely due to enrollment blood draws not occurring in window and rendered un-usable, therefore the patient cannot enroll onto the clinical trial of their choice (Primo et al., 2001). If clinical trials were better executed by thorough staff training and elimination of common barriers- the hypothesis would support the reduction of staff errors.

Clinical Trial Barriers

The issue of clinical trial enrollment is at the foundation of cancer clinical trial endeavors. Less than 5% of all adult cancer patients participate in clinical trials, in contrast to 70% of pediatric cancer patients. This low enrollment has significant consequences to the study as a whole, causing delays in new therapies, premature closure of study, as well as increased costs to conduct the study (Basnet et al., 2017). Cancer clinical trials are crucial for improving patient outcomes; however, with such low patient enrollment to begin with, it is important to address any potential barriers (Primo et al., 2001). With only 3% of new patients diagnosed with cancer participating in clinical trials, the room for error on behalf of the health care provider is non-existent (Primo et al., 2001). A clinical trial system that enrolls patients at a faster rate will get corresponding improvements in cancer population outcomes (Unger et al., 2016). Some of the common barriers are the lack of knowing about the availability of clinical trials (CT) in the institution, CTs never discussed with their primary care providers, and never receiving brochures about CTs. Furthermore, there is a distrust in research from pharmaceutical companies, as well as family disapproval also being huge barriers to cross (Basnet et al., (2017). The fewer barriers to trial participation would enable the trials to be completed more quickly and is crucial to providing patients the opportunity to receive the

newest treatments (Unger et al., 2016).

Administrative Barriers

Administrative barriers can be broken up into the following three types: procedural, structural, and infrastructural (Dilts et al, 2006). Procedural barriers are steps necessary to activate or perform a study or trial. Structural barriers are created by the design of the institution- how blood draws are performed and where they are performed (Dilts et al, 2006). The structural barrier is created when different participating groups in the overall process have different steps and rules to follow leading to errors, screen failures, as well as increased patient anxiety (Dilts et al, 2006). Lastly, an infrastructural barrier is the design of the underlying system and connection between all the aspects within the system. A screen fail in the clinical trial setting is when a patient does not get enrolled onto the study due to declining health or when blood samples needed for trial entry were not done in time or at all (Dilts et al, 2006). Increasing administrative education amongst staff, knowledge of research methods and clinical practice skills will help facilitate easier workflow across patient care (Bostrom et al., 2002).

Challenges

There is evidence supporting the effectiveness of an empathy training program for hospital staff nurses, especially those who work in clinical trials. Nurses trained in empathy skills are more in sync with the patients' needs and concerns, as well as more self-aware, leading to overall better quality of care (Herbek et al., 1999). Though not an exclusive reason for errors in clinical trial procurement, empathy fatigue is responsible to making healthcare professionals more susceptible to errors as well as making training and guidance more difficult. Empathy fatigue occurs when a healthcare professional no longer has the energy or

motivation to care for a patient that they once had (Coetzee et al., 2010). Extensive research indicates that individuals in helping professions such as nursing must be empathic (Herbek et al., 1999). Managing staff empathy fatigue is proportional to the quality of care and minimizing mistakes in screening patients, specifically pertaining to patients' blood draws (Herbek et al., 1999). O'Rourke (1995) looked into training programs' success by evaluating changes in quality of care from the staff as measured by patient satisfaction, patient management, as well as successful patient enrollment onto treatment or clinical trials. As comprehensive training increased it was found that waiting time between admission and treatment was drastically reduced for patients (O'Rourke et al., 1995).

Given the tight schedules and long hours that many of these frontline staff work, List et al., (2019) looked at an option for telehealth training with lecture style presentations in a role transition course. Self-reported confidence in learned material from telehealth indicated there was a positive change in care and improvement in the current system overall (List et al., 2019). In a field that primarily deals with face-to-face contact on a daily basis, communicating effectively is key. In particular, it would be beneficial to have open communication on both sides of care in order to screen the patient successfully and obtain the blood draws in the allotted window. In most healthcare institutions, the patient does not have a sole provider when doing blood draws and other study related procedures (Alrubaiee et al., 2011). Due to the constant flow of different staff obtaining blood samples for clinical trials- techniques and styles may vary which causes errors and disrupts the flow of communication (Alrubaiee et al., 2011).

Amongst the many challenges to improving the current situation- the main one is organizational. Compassion fatigue is a huge emotional challenge that many frontline staff

deal with on a daily basis and can hinder workflow and quality of care (Bush et al., 2009). It is a term that is coined by Joinson (1992) to describe the unique stressors that affect people in caregiving professions. It is an expanded form of burnout which negatively affects hospital staff as well as the ability to meet patients' needs (Bush et al., 2009). Providing a resource will help alleviate some of the workplace stressors and therefore reduce rates of errors (Bush et al., 2009). Communication and patient provider interactions are a key component in decreasing rates of error, the reference document will help guide both the provider into providing better comprehensive care as well as relaying this information to the patient (Epstein et al., 2012).

Effective communication skills enable healthcare staff to improve patient adherence to treatment regimens, in this case blood draw scheduling, as well as use time and timelines efficiently and increase professional fulfilment (Back et al., 2009). The common communication errors include lecturing the patient, staff that are dependent on a routine, as well as staff prematurely reassuring the patient prior to knowing the critical facts pertaining to patient's health (Back et al., 2009). Shared decision making not only helps mitigate patient risk but helps balance and minimize variation of care within the practice (Stiggelbout et al., 2011). Interestingly, the framework the majority of healthcare teamwork and communication techniques are drawn from is the aviation industry. The frequency of unintended harm to patients' quality of care has focused the attention on the importance of training, teamwork, and communication amongst frontline staff (McCulloch et al., 2011).

Statement of Problem

Anything that can be done to increase the patient's experience, quality of care, as well as successful enrollment onto trials at this institution is welcomed. The problem is that there is

low enrolment in clinical trials and there is evidence that empathy training will help improve this problem. Addressing both clinical trial errors as well as empathy fatigue will prove to be an effective direction to take against healthcare staff through creating a reference document for employees new and old to train, use and rely on. It is evident that staff experience, training, as well as workplace stressors all contribute to blood draw errors (Fogolino et al., 2016).

Decreasing errors will further support patient-centered care and improve outcomes (Grundgeiger et al., 2009). Errors within this healthcare setting are very disruptive to the quality and standard of care that is provided to clinical trial patients (Grundgeiger et al., 2009). Clinical trial patients are very complex to manage and treat; therefore, it is crucial to minimize any errors or inconveniences due to any barriers or lack of training. Increasing the quality of care and interactions between patients and staff is proven to show positive disease outcomes and overall quality of life in clinical trial patients (Epstein et al., 2012).

Research Question and Hypothesis

The research question was:

Will there be greater staff engagement as well as reduced blood draw errors after this training document has been implemented into staff training? With the development of this reference document to help guide staff through the processes, rate of procurement errors should decrease in proportion to the level of training obtained. This will benefit the patient, staff, and study as a whole with strict adherence to study protocol.

The research hypothesis was:

There will be greater staff engagement and fewer counterbalance errors in day to day clinical trial duties, specifically resulting in reduced blood draw errors, when a new training document has been implemented into staff training.

Methods

Overview

The Princess Margaret Cancer Centre (PMCC) is part of the University Health Network in Toronto, ON, Canada and is a Federally Qualified Health Centre (FQHC (C2)). The PMCC is able to see and treat over 1000 patients per day, and has the capacity to deliver, treat, and follow-up with close to 200,000 patients per year. The services provided in the past year were 6,031 cancer surgeries, as well as 37,754 system therapy visits, 91,517 radiation visits, and 428 stem cell transplants (PMCC, 2019). The primary focus of a phase 1 clinical trial within this institution is to determine the safety, tolerability, and pharmacokinetics (PK) of a compound. Therefore, routine precisely scheduled blood draws at repeated intervals are crucial to both patient safety, drug research and tolerability. Phase 1 trial was selected as this is the most intensive type of clinical trial for both staff and patients. As the phase 2 and 3 trials still are ongoing at the institution- the rate of errors drastically drops as the drug gets closer to approval.

Furthermore, there are 12 site groups within PMCC with over 3000 staff making it one of the largest comprehensive treatment facilities in the world. There are around 311 physicians on site, 25 behavioral health staff, 1100 nurses, and 600 students. They are responsible for 135 beds on-site with 432 beds at our sister site. This site is responsible for over 600 clinical trials, with every 1 in 6 new patients being enrolled onto a trial. In the next decade, the cancer centre hopes to double the number of patients being enrolled onto trials; therefore, this system is crucial to both the expansion of research within the institution as well as patient care.

Participants

New staff as well as experienced nursing staff with issues or concerns in terms of workflow were identified and referred directly by the nurse manager as well as PMCC

education. Staff had self-identified or were referred to by their direct reports or collaborating colleagues from other departments. Staff who weren't identified would only be included if they completed the survey which is anonymous; the link was sent out to an email list consisting of all research nurse staff, therefore there would be no methods to distinguish one staff member from the next. For that reason, it helps with anonymity when the survey was completed on the staff's part as they are more comfortable discussing information with no identity attached.

Materials

There are approximately 75 responses and feedback documented from all the clinical trials nursing staff given their availability. The survey is a 4 question, 5-point Likert scale survey, the theme of the survey primarily revolves around the importance of training in this field, and the perceived usability of this new training document. The data was collected and analyzed through the Survey Monkey site using the pro account tools for analysis as well as evaluation. The data was already de-identified as there is no data or information linking the results to any participating individual. The data was organized into tables, charts, and graphs that will help display and compare pre and post reference document rate of error amongst staff. Furthermore, the data is being kept on file online for as long as the project is in progress- Survey Monkey has an option for deleting all data and study responses. With the email used to create the account, the person is considered the sole owner and is accountable for all information created and collected in the system-including the destruction of this information.

Design

Data security as well as participant recruitment was all done in-house as per hospital standard operating procedures. Furthermore, in order to implement and adjust there was multiple PDSA cycles weekly-bi-weekly in order to ensure accurate improvement and

feedback is obtained and tweaked accordingly. The team had also developed a 5-question online survey (see appendix) distributed to nursing email list in order to get feedback as well as data pre-implementation. The feedback consisted of staff issues, issues pertaining to blood draw errors, as well as how important these blood draws were to the staff in the overall scope of the trial. The survey touched upon the importance of the work the department does as well as the importance of proper training and downstream effects. Their responses via meetings, and Survey Monkey are all documented digitally and stored in an encrypted computer system.

Procedures

The researcher as well as the departments management team has access to the data as read only with edit access granted to the researcher. The statistical analysis of the data was conducted by this researcher using the data obtained from all methods of collection. Furthermore, the survey reached out to staff to ask what they would like to see incorporated into this training document- concepts or techniques that are crucial but often missed out. The plan is to create a similar survey to analyze improvements post implementation as well as feedback from weekly team meetings. We have identified nurse education, nurse managers, as well as eLearning at an institutional level for support in both developing and implementing this training document across the board and making it into an eLearning module to be completed online as well for new employee orientation. The organization and reason for the topic of concern was because of the crucial bottleneck it causes when not done properly. Leading up to clinical blood draws, the process is fairly straight forward- during the blood draw is when errors seem to arise, and after the blood draw is when these errors begin to create a domino effect onto other areas of patient care. Minimizing errors at this pivotal step will be beneficial to both staff and patients in the overall duration of care.

Results

The proposed idea of creating a training manual for new staff, specifically new nurses working in clinical trials was accepted positively across the board. This acceptance was partially due to the fact that the implementation of this document for nurse training could help decrease corrective and preventative action plans (CAPA) pertaining to blood draws. This support for this document coincided with the original research question of whether there would be greater staff engagement, as well as reduced errors after this document has been implemented into staff training.

Quality control meetings that occurred prior to the start of the internship easily identified areas of concern which often involved CAPAs related to blood draws, patient care and clinical trial enrollment errors. The meetings occurred prior to the start of the internship, pinpointing and analyzing areas of concern was accomplished in a more streamlined fashion. These CAPA's often involve common staff errors involving patient care clinical trial enrollment. The most common errors involving CAPA's are blood draws outside of window per protocol, meaning the blood sample was not obtained during the designated draw time period and it cannot be obtained later.

The current protocol is a set of instructions provided to the department detailing how to run and organize the clinical trial. Unfortunately, with the number of trials and trial-specific instructions, the protocol can be confusing to follow due to use an umbrella method which covers hundreds of trials, hence the high rate of error. The department has attended various weekly nursing staff meetings, as well as created brainstorming groups in order to narrow down areas of interest as well as areas of improvement. These meetings have been occurring for a few years as a measure to increase quality control institution wide. In order to keep all

invested parties interested and engaged throughout the process, there are bi-weekly update meetings to discuss next steps and issues that have arisen, as well as ongoing email threads to provide consistent feedback.

The first hypothesis was that there would be greater staff engagement post-implementation. As seen in figure 1, there is some overlap between the orange line (post-implementation) and the blue line (pre-implementation). However, over such a short time span the engagement of employees is quite noticeable amongst the frontline staff and displays that the implementation of the training document helped out within the early stages quite considerably.

Figure 1.

The comparison of staff engagement pre/post-implementation.

Furthermore, the second hypothesis is further complimented with the reduction of errors as a by-product of increased staff engagement in their day-to-day duties. This reduction is observed in figure 2, which displays a quite substantial change in errors and workflow since the implementation of the training document. As the weeks progress the rate of error decreases quite drastically.

Figure 2.

The comparison of staff errors pre/post-implementation.

Interestingly, upon completing the pre and post process capability analysis as outlined in the A3 report, even the highest rate of errors in the post analysis which was 15% was still 5% lower than the lowest point in the pre analysis and implementation. There were two weeks (week 8 and 9) where there were no errors at all. This is highly suggestive of both buy-in across all participating healthcare professionals as well as increased staff morale and engagement.

With these two time points in both weeks 8 and 9, both the primary and secondary hypothesized outcomes combined to be true. They are inversely proportional to each other, with the increase in engagement, there is a decrease in errors and vice-versa. In line with what was hypothesized, there was a drastic decrease week-per-week in the rate of errors in trial related procedures, which is emphasized by increased engagement in daily duties. This is a combination of increased training and resources, increased engagement, as well as a better overall understanding across the healthcare team of what is involved and required from both

ends of the care spectrum. Moreover, both of these major points of improvement improve the patient experience and quality of care, as well as line up with the triple aim healthcare institutions strive to achieve.

Table 1

Timeline of events

Define	Feb 18 th , 2019: begin meeting various teams we collaborate with, roll out survey
Measure	Mar 4 th , 2019: begin to define and measure impacted individuals as well as downstream impact and potential benefit
Analyze	Mar 18 th , 2019: Rough draft of research tool guide, incorporating feedback and survey results
Improve	June 2019: multiple PDSA cycles in order to fine tune the tool
Control	Dec 2019: print and roll out to institution, eLearning module, in-class training (optional).

Process Outcomes

New staff as well as experienced nursing staff with workflow issues or concerns were identified and referred directly by the nurse manager as well as PMCC education. Staff self-identified or were referred to by their direct reports or collaborating colleagues from other departments. Staff who were not identified were only included if they completed the anonymous survey. The survey link was emailed to all research nurse staff, therefore there is no way to distinguish one staff member from the next. This anonymity increased staff's comfort level in completing the survey. There are approximately 75 responses and feedback documented to date. The goal is to obtain approximately 85-100 responses from all the clinical trials nursing staff. The survey is a 4 question, 5-point Likert scale survey, the themes of the survey are the importance of training in this field, and the perceived usability of the new training document. This training document is a new measure created for this study- the content is primarily driven by the feedback from staff and patients alike.

Figure 3.

Phases of Reference Document Implementation

Figure 4.

Expectations of Nursing Staff

Contextual Elements

It is evident that the nature of healthcare is becoming more complex and it is necessary for teams and individuals to ensure effective and efficient operations within the organization. The current ratio of patients to staff is quite high. With enrolment levels becoming more competitive than ever, PCPs are extremely overwhelmed with patients and the clinical “homework” that comes along with them. This cancer center is the second biggest in the world which also makes it one of the top recruiters of patients across the province, country, and world. Rhetoric within the field indicate that healthcare team training is robust and inclusive, training strategies, and the characteristics of the work environment- specifically team training programs that involve feedback. The goal of this training document was to expand the use of team training and identify and rectify areas of improvement to optimize nurse effectiveness within clinical trial healthcare settings. Specifically, this documents focus is to help mitigate repeated blood draws for patients also known as multiple “pokes” per visit.

Unintended Consequences

Improving training, facilitating a more streamlined workflow, better organization, and the development of specialized tools to do so will allow nurses and clinical staff to do what they do best. Improved training reduces staff errors, increases patient satisfaction and quality of care. As shown in figure 2, it is obvious that the majority of respondents are aware of a problem that is in dire need of a solution. It is evident that this document will serve as a transitional tool to change the clinical trial landscape within the institution. Moreover, it also cannot be a sole reason for change as the dynamic and rhetoric across the institution must change in order to have integrated care throughout. This document is one of many to come, and serves as a starting point and benchmark for quality of care across the institution.

Missing Data

New staff that were not identified or self-identified were not given the questionnaire due to personal as well as professional reasons. There is approximately 5-10 new staff during the duration of this questionnaire, therefore the overall population of respondents + ~5-10 participants is the total number of nurses overall. This can be accounted for when analyzing the data. The decision to not include everyone was made by nursing education as well as nurse manager.

Discussion

Summary

Anything that can be done to improve the patients' experience, quality of care, as well as, successful enrollment onto trials at this institution is welcomed. The problem is that there is low enrolment in clinical trials and there is evidence that empathy training will help improve this problem. Addressing both clinical trial errors as well as empathy fatigue will prove to be an effective direction to take against healthcare staff through creating a reference document for employees new and old to train, use and rely on. It is evident that staff experience, training, as well as, workplace stressors all contribute to blood draw errors (Fogolino et al., 2016).

Decreasing errors will further support patient-centered care and improve outcomes (Grundgeiger et al., 2009). Errors within this healthcare setting are very disruptive to the quality and standard of care that is provided to clinical trial patients (Grundgeiger et al., 2009). Clinical trial patients are very complex to manage and treat; therefore, it is crucial to minimize any errors or inconveniences due to any barriers or lack of training. Increasing the quality of care and interactions between patients and staff is proven to show positive disease outcomes and overall quality of life in clinical trial patients (Epstein et al., 2012). As seen throughout both figures 1 and 2, the pre/post-implementation results are quite substantial, with visible

differences between the two time-points. As time goes on, the improvement across all categories decreases in proportion to the number of weeks the program was implemented.

The main research question surrounded whether there would be greater staff engagement, as well as, reduced blood draw errors after this training document has been implemented into staff training. With the development of this reference document to help guide staff through the processes, rate of procurement errors decreased in proportion to the level of training obtained. This will benefit the patient, staff, and study as a whole with strict adherence to study protocol. Both the primary and secondary hypothesis were supported by both the literature as well as the data obtained from the implementation at the institution.

The impact of staff burnout and wellbeing is significantly associated with higher rates of patient safety and quality of care errors (Hall et al., 2016). In order to deliver and sustain a high caliber of care, the organization must provide a work environment that fosters staff wellbeing, provides adequate training, and protects staff against burnout (Hall et al., 2016). Further to maintain this high caliber of care, staff must be adequately trained. Errors and interruptions within a healthcare setting can be highly disruptive in maintaining a high standard of care for clinical trials patients who are a very frail patient population (Grundgeiger et al., 2009). Clinical trials are typically offered and run because none of the standard and approved methods of treatment work, or side effects are not tolerable. Clinical trials provide another option when standard therapy has failed. All clinical trials have guidelines and eligibility criteria that outline who can participate. The criteria are based off of age, sex, type and stage of disease, and previous treatments. Therefore, it is important that not everyone who applies or wants to be on a clinical trial will be accepted (FDA, 2018). Furthermore, because of the complexity of clinical trials patients' care there are many fields dedicated to the extent

of interruptions leading to adverse events within the patient's care (Grundgeiger et al., 2009).

Barriers to patient accrual in cancer clinical trials must be identified and overcome to increase patient participation. Barriers to cancer clinical trial accrual in this particular case are largely due to enrollment blood draws not occurring in window and rendered un-usable; therefore, the patient cannot enroll onto the clinical trial of their choice (Primo et al., 2001). If clinical trials were better executed by thorough staff training and elimination of common barriers, the hypothesis would support the reduction of staff errors. Furthermore, the reduction of fatigue and stress have removed the negative impact on the staff's performance.

Interpretation

The issue of clinical trial enrollment is at the foundation of cancer clinical trial endeavors. Less than 5% of all adult cancer patients participate in clinical trials, in contrast to 70% of pediatric cancer patients. This low enrollment has significant consequences to the study as a whole, causing delays in new therapy's, premature closure of study, as well as increased costs to conduct the study (Basnet et al., 2017). Cancer clinical trials are crucial for improving patient outcomes; however, with such low patient enrollment to begin with, it is important to address any potential barriers (Primo et al., 2001). With only 3% of new patients diagnosed with cancer participating in clinical trials, the room for error on behalf of the health care provider is non-existent (Primo et al., 2001). In comparison to the rhetoric amongst other publications, the findings in this research project are quite promising. There is little to no upfront cost or departmental burden other than allocating time to get organized. The time to train as well as create workshops amongst sections within departments can be paired up with mandatory training sessions and included in the syllabus. A clinical trial system that enrolls patients at a faster rate will get corresponding improvements in cancer population outcomes

(Unger et al., 2016). Some of the common barriers are the lack of knowing about the availability of clinical trials (CT) in the institution, CTs never discussed with their primary care providers, and never receiving brochures about CTs. Furthermore, there is a distrust in research from pharmaceutical companies, as well as family disapproval also being huge barriers to cross (Basnet et al., (2017). The fewer barriers to trial participation would enable the trials to be completed more quickly and is crucial to providing patients the opportunity to receive the newest treatments (Unger et al., 2016).

Limitations

Administrative barriers can be broken up into the following three types: procedural, structural, and infrastructural (Dilts et al, 2006). Procedural barriers are steps necessary to activate or perform a study or trial. Structural barriers are created by the design of the institution- how blood draws are performed and where they are performed (Dilts et al, 2006). The structural barrier is created when different participating groups in the overall process have different steps and rules to follow leading to errors, screen failures, as well as increased patient anxiety (Dilts et al, 2006). Lastly, an infrastructural barrier is the design of the underlying system and connection between all the aspects within the system. A screen fail in the clinical trial setting is when a patient does not get enrolled onto the study due to declining health or when blood samples needed for trial entry were not done in time or at all (Dilts et al, 2006). Increasing administrative education amongst staff, knowledge of research methods and clinical practice skills will help facilitate easier workflow across patient care (Bostrom et al., 2002). There are some limitations to the vast level of generalizability of this plan- many limitations having to do with how each health care professional utilizes these resources, how they are interpreted between departments, as well as the routine in which the

training is administered and the frequency of application in the workplace. The most important factor in impacting internal validity is that the training actually occurs, and the document is used. Without the reference document being used, it will be difficult to stand by the cause-and-effect relationship between the training and the increase in quality of patient care.

Conclusions

It is evident that the nature of healthcare is becoming more complex within the profession and it is necessary for teams and individuals to ensure effective and efficient operations within the organization. Rhetoric within the field indicate that healthcare team training is robust and inclusive, training strategies, and the characteristics of the work environment- specifically team training programs that involve feedback (Gregory et al., 2016). The goal of this training document that is going to be implemented is to expand the use of team training and point and rectify areas of improvement and optimizing nurse effectiveness within clinical trial healthcare settings. The implications for future healthcare practice are endless. The training document is a living document which can adapt to new SOP's as well as new regulations within the institution. It must be updated upon the receipt of new relevant information in order to remain current and useful. The next steps for this process are to branch out into different departments within the institution, eventually making this type of workflow the benchmark across clinical research. It is evident that there are many shortcomings and pitfalls when dealing with human error, both from the patient and professional perspective. The goal is to create a plan to divert some of the error and increase the triple aim on all fronts whilst being extremely cost efficient, which this training document clearly supports.

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Appendix A

Integration of the Correlative Studies Program (CSP) and its services within Princess Margaret Cancer Centre (PMH)

Introduction

With the many departments and people involved in organizing care for patients involved in clinical trials, it is critical that all of the teams involved understand how to use the Correlative Studies Program.

This resource/guide/cheat sheet will be part of the initial nursing orientation, and will also serve as a quick reference guide or cheat sheet that will help you determine what to do, who to contact, when to do it, and where. Our hope is that it will help save you time, reduce errors or oversights, and improve the patient experience.

1. How often will this resource help your team organize care and meet its

timelines? Never Seldom Sometimes
Often Always

2. How important do you think using CSP effectively plays in the success of conducting the clinical trial?

Never Seldom Sometimes Often Always

3. When troubleshooting a sample collection issue that has arisen during the study, how often do you know who to contact (i.e. archival tissue, blood samples, requisitions, queries, biopsies)?

Never Seldom Sometimes Often Always

What would you like to see included in this cheat sheet? For example, are there any small things that may be important to your group that are often overlooked?

Figure 1: Question 1 results

How often will this resource help your team organize care and meet its timelines?

Answered: 75 Skipped: 0

Figure 2: Question 2 results

How important do you think using CSP effectively plays in the success of conducting the clinical trial?

Answered: 75 Skipped: 0

Figure 3: Question 3 results

When troubleshooting a sample collection issue that has arisen during the study, how often do you know who to contact (i.e. archival tissue, blood samples, requisitions, queries, biopsies)?

Answered: 75 Skipped: 0

Figure 4: Question 4 results

What would you like to see included in this cheat sheet? For example, are there any small things that may be important to your group that are often overlooked?

Answered: 23 Skipped: 52

Running Head: INTEGRATING CLINICAL RESEARCH

APPENDIX B

A3 No. and Name A3 Correlative Studies Program (CSP)	Team members (name & role) 1. Vanessa Speers (Manager) 2. Larysa Wolanyk (Supervisor) 3. Dave Zwik (Nurse Educator) 4. Nicholas Pasquale (DBH Student)	Stakeholders (name & role) 1. Vanessa Speers (Manager) 2. Larysa Wolanyk (Supervisor) 3. Dave Zwik (Nurse Educator) 4. Nicholas Pasquale (DBH Student)	Department Correlative Studies Program	Organisation objective Reduce Blood Draw Errors Start date & planned duration Summer 2019 (2-4 Months)				
1. PROBLEM STATEMENT (DEFINE)								
<p>Is: Reducing Errors in Blood Draw Process for Clinical Trials Patients</p> <p>Is not: Departmental issues, systemic institutional or political issues</p> <p>Problem statement: The aim of this quality improvement (QI) project is to reduce errors in blood draws, retrain staff and re-measure rates of error in clinical trial related blood draws with the new training. Errors and interruptions within a healthcare setting can be highly disruptive in maintaining a high standard of care for such a trial patient population</p>								
2. CURRENT STATE (DEFINE/MEASURE)								
<div style="display: flex;"> <div style="flex: 1;"> </div> <div style="flex: 1;"> </div> </div>								
3. DESIRED OUTCOMES								
<table border="1"> <tr> <td>1</td> <td>Reduce blood draw errors from 20% to <5%</td> </tr> <tr> <td>2</td> <td>Integrate staff training for new and old staff members, including refresher training</td> </tr> </table>					1	Reduce blood draw errors from 20% to <5%	2	Integrate staff training for new and old staff members, including refresher training
1	Reduce blood draw errors from 20% to <5%							
2	Integrate staff training for new and old staff members, including refresher training							
7. VERIFY RESULTS (IMPROVE)								
<div style="display: flex;"> <div style="flex: 1;"> </div> <div style="flex: 1;"> </div> </div>								
8. FOLLOW-UP (CONTROL)								
<ol style="list-style-type: none"> Decreased blood draw error rate average <5% Adopted by departments across institution, will be incorporated into new employee training, as well as an online module and an in-class training session As seen in control chart above (step 7), Week 8 & 9 there were 0 errors. In comparison in the pre-intervention with almost a 25% error rate this is a vast improvement <div style="display: flex;"> <div style="flex: 1;"> </div> <div style="flex: 1;"> <p>$Y = -0.65799x + 9.5429$ $R^2 = 0.39355$</p> </div> </div>								