Developing a Preclinical Nurse-Nurse Communication Framework for Clinical Trial Patient-Related Safety Information

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Abstract

Clinical trial trials have become increasingly complex in their design and implementation. Investigational safety profiles are not easily accessed by clinical nurses and providers when trial participants present for clinical care, such as in emergency or urgent care. Wearable devices are now commonly used as bridging technologies to obtain participant data and house investigational product safety information. Clinical nurse identification and communication of safety information is critical to dissuade adverse events, patient injury, and trial withdrawal which may occur when clinical care is misaligned to a research protocol. Based on a feasibility study and follow-up wearable device prototype study, this pre-clinical nurse-nurse communication framework guides clinical nurse verbal and non-verbal communication of safety-related trial information to direct patient care activities in the clinical setting. Communication and information theories are incorporated with Carrington's Nurse-to-Nurse Communication Framework to encompass key components of a clinical nurse's management of a trial participant safety event when a clinical trial wearable device is encountered during initial assessment. Use of the pre-clinical nurse-nurse communication framework may support clinical nurse awareness of trial-related wearable devices. The framework may further emphasize the importance of engaging with research nurses, patients, and caregivers to acquire trial safety details impacting clinical care decision-making.

Introduction and Purpose

Clinical trials are conducted with the intention of discovering new treatments and therapies that enhance and prolong quality of life for people with a disease or condition[1]. Inherently complex in their design and operations, ineffective communication

of trial-related information between Sponsor, participants, and research sites has been a widespread challenge across the industry[2]. Of paramount importance is the communication of safety-related information, such as contraindicated medications and side effects of investigative products. Yet, media used to communicate these details (such as wallet cards and Dear Provider letters) are fallible[3]. The novel use of wearable devices is now heralded as the next level of effective communication efforts related to disseminating safety information to healthcare providers outside the research team[4,5]. However, there is a gap in modeling the communication pathway of this safety-related information from the wearable device and the incorporation of the role of the nurse in supporting effective communication.

Wearable technologies to communicate clinical trial-related information are not considered part of a traditional nursing assessment. However, these technologies are becoming more commonplace. Identification is important for care delivery given the safety information housed on the device and depends on nurse situation awareness at time of initial patient encounter. A framework incorporating wearable devices as a means of conveying clinical trial information melds together the relationship between two unfamiliar nursing concepts (wearable technologies and clinical trials) within more familiar means of relaying a message: verbal and non-verbal communication channels. The purpose of this paper is to introduce the pre-clinical communication framework to guide the clinical nurse's interviewing and actions related to care of the clinical trial participant when a wearable device is used to convey safety information. The pre-clinical designation of this communication framework is to connotate the significance of the clinical nurse's acknowledgement and utilization of critical safety information prior to

the cascade of a clinical care pathway for the patient's disease or indication. As part of the pre-clinical designation, the framework accounts for nurse-receiver and nurse-responder characteristics that may influence the effectiveness of communication when presented a wearable device to inform clinical care. Non-verbal and verbal modalities of message communication among channels (media such as the Electronic Health Record or phone call) is also integrated given the melding of digital and face-to-face mechanisms used by clinical and research teams to discuss patient-participant care.

` Background

As of 10 February 2022, there are 26,860 recruiting clinical trials active in the United States[6]. Trial participation exceeds tens of thousands of individuals each year, with 8% of all adult patients with cancer enrolling in a clinical trial[7]. For many individuals, especially children, clinical trials are the gateway to access novel therapeutics otherwise not provided as standard care. For complex diseases like cancer, clinical trials offer targeted investigational treatment for otherwise unique groups with specific genetic mutations[8].

When seeking trial participation or in screening for a trial, health care providers are cited as the most trusted and first source of information[9]. In a survey of 3,689 adults who completed the Health Information National Trends Survey, 66% noted they would enroll in a clinical trial "*get better*" in their disease state[9, p. 4]. With diseases such as cancer, *getting better* may mean a two-pronged approach of an investigative trial product as well as supportive clinical treatment to mitigate symptoms associated with disease progression which hamper quality of life or side effects of the investigative therapy. For example, this approach may include the principal investigator at a research

facility and a medical oncologist within the participant's community. However, effective communication has yet to be sufficiently established between research and clinical providers. In a study of 44 principal investigators, almost 2 out of 3 noted a lack of resources to facilitate engagement with medical oncologists caring for participants who resided in their communities[10]. Persons living in rural environments are 77% less likely to be invited to participate in a clinical trial, in part due to the lack of engagement and means to establish connection between research facilities and community providers[9].

The connection between the research facility and the clinical provider is critical for those rural individuals who do participate, particularly with safety-related information that would dictate course of clinical care. Approximately 1 in 3 rural residents live more than 60 miles from a National Cancer Institute parent or satellite cancer center[11]. When there is an urgent or emergent care need, these participants will remain within their communities for initial care management. In many rural and community settings, regional hospitals and critical access hospitals are the only options when the research facility is distant. For example, in the state of Montana where there are over 180 active clinical trials, 59 out of 65 of its hospitals are located in rural or frontier counties[12]. Clinical trial participants rely on clinical providers to incorporate their unique care needs, especially in the management of safety events.

Safety events, known as adverse events, are untoward medical experiences with the use of a drug or device in humans[13]. Safety events vary in their frequency and severity, dependent upon the phase of therapeutic testing, mechanism of action, and the degree of clinical management at early onset. For example, cytokine release syndrome (CRS) is an inflammatory state known to occur with immune checkpoint

inhibitors and T-cell therapies used in the treatment of leukemias[14]. CRS is challenging to initially pinpoint as a diagnosis as it can mimic other syndromes and sepsis, but failure to identify CRS can lead to multiple organ failure and death[14]. CRS is component of safety profiles for many investigative therapies as a known adverse event but may elude clinical providers if they are unaware of the possibility of CRS if a participant presents for clinical care. The risks associated with a clinical trial then translate to risks of mismatched clinical care due to the investigative nature of trial therapies. For instance, an estimated 1 in 50 children enrolled in a Phase I (early development) cancer clinical trial will die from a drug-related adverse event, with 81% of North American reporting institutions noting a hazard ratio of 1.32[15]. This high likelihood of experiencing an adverse event on early development pediatric cancer clinical trials enrolling in North America demonstrates the elevated likelihood that clinical management of these participants is inevitable during the course of the trial.

Conceptual Approach

The objective of this paper is to propose an adapted framework which focuses on the pre-clinical identification of a wearable device embedded with safety information for clinical trial participant clinical care.

Framework Development

The conceptual framework is crafted as a means of “bringing together interrelated concepts” from multiple sources to explore their relationships[16, p. 189]. Conceptual frameworks permit an inductive approach to research questions[16]. Conceptual frameworks are contextually driven, supporting examination of a specific

research question within a phenomenon[16]. The synthesis of the concepts within the framework allows the continuous integration of new insights and literature to further clarify relationships and offer new avenues of research.

The pre-clinical nurse-nurse communication framework was developed as an adaptation to Carrington's Nurse-to-Nurse Communication Framework[17]. While Carrington's framework is centered on a clinical event, this framework centers on the initial actions surrounding the pre-clinical phase, where the patient has initially presented for care and the clinical nurse is initiating first contact with the patient and patient assessment. A feasibility study was conducted in which a wearable USB wristband was worn and feedback collected from nursing informatics professionals and clinicians on the usability and applicability of wearing such a device to share safety data for clinical trial participants[18]. The feedback included emphasis on the verbal and non-verbal communication channels affected by the integration of the wearable device[18]. Characteristics of both responding and receiving nurses was also highlighted in feasibility feedback, such as nurse bias, perceptions, and pre-existing schemas surrounding technology and clinical trials[18].

With feasibility study feedback and guidance from the Carrington clinical framework, the pre-clinical framework includes eight concepts, noted in Figure 1.0, that influence the communication of participant safety information.

Figure 1.0. Communication Framework Concepts and Their Definitions

Proposed Framework

The safety event is the event that triggers communication to initially occur. An instance of a safety event may include a participant, febrile from neutropenia, presenting at the emergency room. The concept of a wearable device is a communication channel worn by this participant which houses key safety information, such as research-related contract information and contraindicated medications, for a clinical team to use to inform care decisions. The wearable, continuing with the participant example, may be a worn on the wrist and include wording and bright colors to attract the attention of a healthcare provider.

The nurse conducting the initial assessment of the febrile patient in the emergency room examines the wearable device and realizes she may access information on the device. The information, or message, consists of contact information for a research nurse on a clinical trial and a list of medications the clinical nurse cannot give as they would interact with the investigational drug the participant is taking. The nurse begins interviewing the patient about the details collected from the device, employing a verbal channel of communication. Correspondingly, the nurse then contacts the research nurse listed in the device to gain further guidance on how to support the febrile neutropenia experienced by the patient. The nurse then transfers the clinical trial information pertinent to the clinical care the patient into the EHR, where the emergency department physician then views and interprets next best steps in care delivery.

As shown in Figure 2.0, the pre-clinical communication framework is contextualized and influenced by the characteristics, or behaviors, of the receiver and responder. The responder using this framework and example includes the research

nurse, who will guide the clinical nurse through an optimal course of care. The responder may also be the patient or a dyad of participant-caregiver. Characteristics of a responder that can positively influence effective communication of clinical trial safety information includes specificity in detail, accurate messaging, and selecting the appropriate channel to relay the message[19]. Because research nurses are trained to look for the most subtle of cues with possible interventional drug reactions, research nurses are prime responders who can lend their heightened vigilance and in-depth knowledge of the trial protocol to support the clinical team[20].

Figure 2.0. Pre-Clinical Nurse-Nurse Communication Framework

To continue using the example, the receiver is the clinical nurse managing acute care in the emergency department for the trial participant experiencing febrile neutropenia secondary to cancer. Characteristics of a receiver that support effective communication include engagement in the interaction with the participant wearing the device, motivation to explore the device, and predisposition to understanding the significance of a clinical trial[19]. Clinical nurses have voiced feeling ‘under-informed’ and uncertain as to the impact of clinical trial safety information on clinical care[21, p. 6]. The wearable device along with verbal lines of communication with the research nurse and participant-caregiver dyad can strengthen the confidence of the clinical nurse when they are reviewing the embedded information.

The outcome of the pre-clinical nurse-nurse communication framework is receipt of the message related to safety information to support a trial participant’s clinical management. Here, communication continues as part of clinical event management, as demonstrated within the Carrington Nurse-to-Nurse Communication Framework[17]. The

influence of the wearable device is to optimize the outcome with reduced risk of injury and death attributed to standard of care therapy interactions with the investigational product. To close with the example, the clinical nurse was able to notify the team that the febrile neutropenia the patient was experiencing was a common symptom related to the investigational product attacking the leukemic cells. The research team provided a series of medications and treatments that would mitigate the neutropenia and permit blood count recovery in a way that permitted the participant to remain on the trial. Instead of subsequent injury, communication via the wearable device supported recovery and retention.

Framework Evaluation

A pilot study was completed to evaluate the wearability and concept of a wearable device prototype worn by participants as a means of communicating key trial safety information to clinical providers[18]. The development of the framework was initially based on the results of the pilot study given nurse-participant feedback related to potential channels of verbal and non-verbal communication used for clinical trial information exchange. Nurse-participants described the receiver and responder characteristics that are specific to integrating clinical trial information within clinical care plan development and patient care management[18]. This framework supports expanded testing of additional wearable device prototypes used to initiate this communication. Clinical and research organizations may use this framework to increase awareness of wearable device use by clinical trial participants and the cascade of communication anticipated when one is identified during initial patient encounter.

Underpinning Theories

Fawcett's theory evaluation criteria involve analysis of the significance and testability of a theory, which in this case requires examining the communication of safety related information prior to a clinical event[22]. The theories guiding the development of the pre-clinical communication network originate in the disciplines of communication and information science. Their selection gives nod to the firmament of all human interaction, which is communication and the crafting of information to give to one another in order to propagate further thought or action.

Gerbner's Communication Model

Communication of clinical trial patient safety information begins with a safety event. Per Gerbner's Communication Model[23], this triggering event initiates the cascade of subsequent communication and exchange of information. The transactional exchange of information has an underlying motivation to relay a message[23]. With clinical trial participants, the safety event (triggering event) can urgent or emergent in nature. A participant may present at an urgent care facility for support in symptom management, such as worsening nausea or dizziness. Emergency care facilities may encounter clinical trial participants in states of crisis, such as unrecovered neutropenia or altered mental status.

Gerbner's Communication Model is advantageous in the description of communication during these events as the model highlights the criticality of time-order as it relates to message exchange[23]. Such as, if trial information is not provided at time of triage or initial encounter with an emergency medicine provider, care may be already misaligned to the parameters of the trial protocol and safety profile. Injury and withdrawal from the trial could then ensue, initiating a negative cascade of events

affecting quality of care in the clinical setting. Furthermore, Gerbner provides two domains within the model: perception and control[23]. The perception domain relates to the receiver of communication and their attributed meaning to the information provided in the exchange, while the control domain relates to the sender of information and their responsibility attributed to crafting the message for optimum understanding by the receiver[23]. With clinical trial participant safety information, the responsibility for crafting the message is the research team-Sponsor dyad. The message structure must align with the norms, values, and perceptions of clinical care providers for optimum understanding.

Carrington's Nurse-to-Nurse Communication Framework

Grice and colleagues noted in their pivotal study of communication among healthcare professionals that nurses communicate more effectively with nurses than when communicating with other types of providers (physicians, ancillary care members)[24]. To align with the relationship of effective communication and inter-nurse interaction, Carrington's Nurse-to-Nurse Communication Framework is incorporated as it includes the influence of a nurse's personal characteristics on the effectiveness of communication[17]. Verbal and non-verbal communication, particularly electronic means of non-verbal communication, is also considered as a significant channel for effective communication to take place[17]. The overarching goal of the communication between a receiver and responder-nurse within Carrington's framework is patient safety, which aligns to the outcome of clinical trial participant-related communication in the clinical setting[17].

Shannon's Information Theory

Shannon's mathematically-based information theory supports a practical approach to analyzing the flow of information via a message between verbal and non-verbal channels[25]. In this framework, we define the sender of information as the *responder* to describe the research nurse as well as the participant-caregiver dyad who will guide the clinical nurse through development of appropriate care plan development given the information on the wearable device. The *receiver* is then the clinical nurse who will be managing the participant's care. The wearable device acts as an instigative channel to conduct the message via verbal and non-verbal channels to transmit safety information. To dissuade noise generation when transmitting the message, the wearable device further acts as a moderator of message strength (through the structure of embedded information housed within) and message direction (such as the clinical nurse extracting information and inputting into the EHR)[25].

Symbolic Interactionism as a Philosophical Consideration

To complement Shannon's mathematical approach to message transmittal, Mead and Blumer offer a qualitative perspective of message meaning to the receiver and responder[26,27]. Known as symbolic interactionism, Mead and Blumer acknowledged the influence of society and human cognitive behavior on message structure, transmittal, and channel selection[26,27]. Society shapes how an individual describes and perceives situations. For example, a clinical nurse may be biased about the ethics of clinical trials conducted with children and as such, may exhibit untoward behaviors when identifying a wearable device with clinical trial information enclosed. Motivations, biases, and language tangent to societal norms, values, and traditions that then converge to shape a person's behaviors when confronted with a stimulus (situation).

These influences dictate how a person, such as the clinical nurse, may interpret environmental cues to make sense of a situation to then direct decision-making. If the wearable device is an unfamiliar schema for the clinical nurse, the clinical nurse may scan the room and patient to piece together clues as to the device's significance regarding next steps of care. Wording, color, and placement of the wearable device on the trial participant are all important to align with norms and values of clinical nursing such that the device is deemed significant during initial assessment. These elements of symbolic interactionism also act as a cognitive bridge between the safety event and the wearable device to form a complete schema of how trial participation will impact the clinical nurse's plan of care.

Relevance to Clinical Practice

Nurses are traditionally the first point of contact with patients in the clinical setting. The direction of care and development of a care plan are moderated by the initial nursing interview and assessment of the patient. By creating a pre-clinical nurse-nurse communication framework, these nursing actions are placed at the forefront of care delivery. Patient interview and assessment are both actions that the nurse uses to amass key information, such as clinical trial participation and the use of a wearable device for participant safety management by a clinical trial.

The personalization of clinical trials means that safety profiles of investigational products are becoming more individualized and not readily generalizable for provider drug databases[28]. Commonly used for high-risk cancers and rare diseases, personalized N-of-1 trials support longer-term participant exposure and involvement on a clinical trial[28]. The extended exposure and participation on a clinical trial coupled with

more precise dosing of an investigational product leaves clinical providers without standardized resources to retrieve information pertaining to patient care guidance. Specialties such as emergency care, where there is a narrow margin for nurse or provider decision-making error, benefit from the pre-clinical communication framework[29]. The framework guides the nurse through communication channels supporting informed decision-making, such as the incorporation of both patient and research nurse interviewing. Use of a wearable device to house and convey clinical trial safety information acts as a bridging technology to inform nurses and providers in settings, such as emergency care, details which may further influence decision-making (contraindicated medications and therapies).

Education regarding the unique care requirements of patients involved in clinical trials is lacking in the majority of nursing higher-education programs. Due to this, management of a clinical trial participant in the clinical setting is not an established workflow for clinical nurses. This includes omission of simple patient interviewing questions such as, “Are you involved in a clinical trial or research study?” Lack of clinical nurse situation awareness of a wearable device used for safety information communication lessens the opportunity to obtain a fully integrated picture of a patient’s medical history and current health status. Nurses must develop skills to identify wearable devices, integrate trial participation in their patient interviewing workflows, and consider their own communication strengths and limitations when discussing unique components to patient care with nurses outside their specialty. The framework will support nursing process by providing the anticipated concepts and considerations for

how to structure optimal communication prior to the clinical event when clinical trial participant safety information is provided via wearable device.

Development of this pre-clinical nurse-nurse communication framework encourages further generation of technology-based nursing theories. Technology, particularly wearable devices, is now enmeshed in every facet of patient care delivery. Nurses now must not only communicate with one another, but also relationally communicate with machines in order to provide person-centered care. While many nursing theories describe caring as a foundational component of nursing theory, the insertion of technology must also be considered as part of caring[30]. This framework is part of the growing conversation in nursing theory development, describing how nurse-nurse communication may be moderated by a technology.

The framework also can be applied in nursing research. Nurse situation awareness, which is the interpretation of environmental cues to support future actions, is an expanding area of focus for nurse researchers. Low nurse situation awareness is related to poor patient outcomes[31]. Further research and studies regarding nurse situation awareness to wearable devices is needed. One avenue of future research is the use of eye-tracking methods to determine visual patterns of nurse awareness to elements of clinical surroundings, including wearable devices worn by patients. This framework may be used to guide nurse researchers in considering information, technology, and communication components of situation awareness to better understand barriers and facilitators to nurse identification and incorporation of wearable devices in patient care.

Discussion

The profession of nursing prides itself on being adaptive to the needs of patients in order to facilitate the highest quality of care. Clinical trial participants are a unique subset patient population, and care-related decisions come with a higher degree of risk for error. When information within a wearable device is tailored to the norms, values, and perceptions traditionally held by clinical nurses, nurses are then able to facilitate communication of this information with greater ease to members of the clinical care team. Nurses have indicated their overall positive outlook regarding clinical trials and are motivated to navigate differences in care plan development[21].

As technology becomes more integrated into nursing practice, utilization of a wearable device for safety related information communication proves opportune to garner the attention of nurses during their initial encounter with a trial patient. Nurses have noted feeling a lack of power in decision-making related to clinical trial information given a knowledge deficit surrounding research[21]. The wearable device employs an intuitive workflow with a simple interface, dissolving the knowledge deficit barrier. Nurses can then carry over information from the wearable device to the EHR such that the information is integrated with the clinical patient data and is accessible to other care team members.

This conceptual framework acts as a welded bond between wearable device technologies and trial communication of safety-related information in the clinical milieu. The identified communication chasm between research and clinical health care providers affects the quality of patient care. By considering verbal and non-verbal communication as channels to distribute messages relating to trial safety information, the broader care team will be able to optimize clinical outcomes. Bringing receiver and

responder characteristics to the forefront of the pre-clinical communication framework acknowledges the role norms, values, biases, and perceptions play on crafting messages. As wearable device technology gains traction and popularity with industry trials, this framework promotes nurse awareness of their use and need to incorporate them into their care plan development.

There is an unprecedented push for expanded clinical trial access and participation in the United States. Through federal policy shifts related to research funding and participant trial financial benefits, more Americans than ever before will be able to consider a clinical trial as an option when reviewing their next steps in disease management. The social tone related to clinical trials is also overwhelmingly positive, with approximately half of individuals participating in a trial when presented the opportunity, many with altruistic motives[9]. Diversification in trial participation and equity in trial access are next steps for Sponsors and federal oversight bodies, such as the Food and Drug Administration, for expanding the reach of trial benefits.

This progressive movement of clinical trials being more widely available is dependent upon effective communication between research teams and clinical teams to keep participants safe regardless of care setting. Through the use of wearable technologies, safety information may be mobile and easily retrieved to initiate the conversation. While clinical trials are not of extensive focus in nursing programs, wearable technologies provide a visual awareness cue to give rise to normalization of including trial status in initial patient interviewing. This early integration of trial information during a safety event can spark both verbal and non-verbal communication regarding the impact of an investigative treatment to typical standard of care pathways

associated with a disease. Early awareness may decrease the severity and frequency of adverse events, particularly serious adverse events, while supporting continued retention of the participant on the trial.

Conclusion

This pre-clinical framework is developed to guide nursing communication of clinical trial safety information embedded in a wearable device when a participant seeks care in a clinical setting. Based upon a feasibility study and informed by communication and information theories, the pre-clinical framework offers a mapping of verbal and non-verbal communication channel pathways by which safety-related trial information may be cascaded through the clinical setting to dissuade adverse events, participant injury, and participant withdrawal from the trial. Research nurse-clinical nurse communication is included to acknowledge the information exchange that may occur as part of the patient's care plan development given the research nurse's in-depth understanding of investigational product constraints related to standard of care medications or therapies. Novel components of this framework include the receiver and responder characteristics, such as biases or previous experiences of nurses with clinical trials, as influential to the interpretation and subsequent accuracy in communication of trial safety details.

While communication of safety-related trial information may begin with a safety event, such as a participant presenting to an emergency room or urgent care, the outcome as described by the pre-clinical framework concludes with an informed clinical event. The clinical event (outcome) may be optimized through an established contact with a research team and clarified profile of accepted medications and therapies that will not interfere with the investigational product. Clinical nurses may be empowered via this

framework to incorporate wearable devices into their initial patient assessment schemas as a means of trial participant advocacy for informed care delivery. Through the depiction of trial communication in the pre-clinical framework and potentially enhanced nurse awareness of trial participant care considerations, nursing may afford this unique population continuity of care regardless of setting.

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