Clinical Nurses' Identification of a Wearable Universal Serial Bus Used for Pediatric Oncology Clinical Trial Participant Safety Management

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Introduction

Clinical trials have increasingly permeated the bounds between research and clinical care, with over 500,000 active interventional trials around the world[1]. It is now less uncommon that patients are offered clinical trials as an alternative means to explore novel treatments or therapies otherwise commercially unavailable[2]. Clinical trial participation in the United States (US) has become more accessible through measures such as lessening financial barriers via the Clinical Treatment Act, which expands clinical trial reimbursements and benefits to those receiving Medicaid and Medicare support. As such, expanded access to trials has translated to the US enrolling the most clinical trial participants globally (one-third of all participants) and involved in the highest percentage of registered clinical trials[3].

Clinical trial delivery models, which include decentralized and adaptive designs, permit the enrollment of individuals otherwise unable to participate in clinical trials due to travel burdens or inaccessibility due to geographic (rural or frontier) community settings[4]. Use of remote, virtual, and home health-based clinical trial services equate to a permeation of experimental drugs and devices into healthcare organizations and systems which may be unaware of a clinical trial's presence within a community. Since clinical trials investigate the safety and efficacy of novel drugs and devices, there are potential implications for clinical care delivery should the investigational products require unique considerations for quality clinical care. These considerations may range from notifying the research team of clinical decisions to the clinical management of a trial participant during an emergent or urgent safety events within the community care setting.

Particularly with pediatric oncology clinical trials, there are devastating implications if investigational treatments are not considered should a child present for emergent or urgent clinical care within a healthcare system that does not have the research-related safety information available. As high as 50% of all children aged 15 years or less diagnosed with cancer receive first-line treatment via a

clinical trial, with evidence of a possible trend in improved disease outcomes in comparison to children who do not receive initial treatment through clinical trials[5]. Children in the United States with cancer have one of the highest rates for emergency care department utilization for symptoms that are due to their immunocompromised status, such as febrile neutropenia[6]. Adverse events, untoward medical occurrences with or without attribution to the investigational drug or device, such as febrile neutropenia or dehydration spark a higher likelihood of hospital [7,8]. These events leave participants and their caregivers shouldering the burden of describing to external providers (such as emergency care or urgent care) the parameters of clinical trial investigative agents, concomitant medications, contraindicated treatments, and research team contact information. There is an expansive population of children with cancer that may experience adverse events in settings outside the research center and require particular care[9]. Moreover, for those children with cancer residing in rural areas, local health-based centers (such as critical access hospitals, standalone emergency rooms, or urgent care facilities) may be unfamiliar with care management and treatment approaches given the infrequent presentation of children with similar sequelae and thus approaches to care may be varied and incongruent with protocol restrictions[10]. In order to provide comprehensive care to these children and their families that does not exacerbate or increase risk of subsequent adverse events, safety communication modalities (current and explorative) must be reviewed.

The Concerns with Ineffective Communication of Clinical Trial Safety Information

The modified trial design and lessened financial burden of trial participation has further equated to an increased incidence of trial participation from persons in geographical locations outside urban centers. If trial access is limited within a community's healthcare system and travel is required, there is a higher likelihood that community-based providers lack awareness of these trial opportunities and consequently, do not refer their patients to them. In the advent of pragmatic (real world settings) clinical trials, there is heightened need for strong communication between research and clinical teams

to support a clinical trial participant's care[11]. Particularly with investigative, explorative trials where a product's safety profile is not fully understood, a clinical team's appraisal of key information regarding a product (mechanism of action, contraindicated medications) is crucial to patient safety.

Community oncology practices retain more children (especially adolescents and young adults) than any other age group, which is a factor when considering communication pathways once a child enrolls on a clinical trial that is external to the community practice[12]. A survey of 87% of community medical oncologists that feel clinical trials provide high-quality care and the 83% that felt trials benefit enrolled participants[13]. Community practices, inclusive of other outside specialties, then become the critical receiver of clinical trial communication given their roles in participant retention. Retention is necessary to the trial's ability to generalize findings and ultimately seek approval for life-saving treatments.

Clinical trials may involve investigative products or investigative doses of approved products which may interact or interfere with standard of care treatments or therapies. A challenge for clinical trials is ensuring trial participant safety related to their treatment with an investigational product when seeking clinical care, such as in the emergency department or urgent care. Communication of unique needs of a trial participant, such as contraindicated medications or alternative therapies to standard of care, can be critical, particularly if the emergency department or urgent care center is unaffiliated with the research site such as in a community setting. Current research communication mediums, such as the Electronic Health Record (EHR) or paper wallet cards, are inefficient and ineffective for current, mobile access to research-related information that is pertinent to clinical care[14]. The EHR, for example, lacks interoperability between research and clinical patient activities or is too complex to efficiently navigate for pertinent information[15].

Emergency nurses and physicians have cited a lack of information and communication flaws as risks for patient safety, particularly with medication errors[15]. Clinical trials utilize investigative products which are not available for clinical teams to review in commercialized drug databases. As such, this lack of information begets additional safety risk to participants where the investigational product interacts or otherwise conflicts with standard of care treatments utilized by emergency teams. Injury and withdrawal from a trial occurs in part due to lack of communication regarding safety information for trial participants outside the research site. In emergency and urgent care settings, clinical situation-related pressures and time constraints also call for a communication medium with no training requirement, is easily identifiable, and structured to include actionable information[16,17]. Clinical nurses recognize clinical trials and research-related activities as a component of quality patient care but require a means of seamless integration of trial-related communication within busy workflows and high-pressure clinical situations[17].

Rationale for Focus on Use of Wearable Devices in Clinical Research

With the known failures with paper-based mediums (such as wallet cards), lack of interoperability within EHRs, and participant recall knowledge burden pertaining to clinical trial information, the attention then shifts to technology-based mediums that are mobile and transportable with the participant. As encouraged by the Office of the National Coordinator for Health Information Technology, wearable devices and sensors have become popular innovations to promote mobile access to data[18]. Clinical trial participants may wear a device or sensor per a trial protocol for continuous data collection, such as biofeedback measures or activities of daily living[19]. Wearable devices lend the flexibility to be updated as needed by the research team, are malleable to the amount and structure of contained information and permit expeditious exchange of data when passive data is remotely collected[20].

While participants are in favor of devices as part of trial procedures, maintenance (such as charging devices or pairing devices with smartphones) are seen as challenges to daily wear[21]. To address this concern, use of common technology, such as a wearable universal serial bus (USB) is proposed as a medium to communicate key trial-related information (such as research personnel contract information and contraindicated treatments). Researchers recently employed the use of a wearable necklace USB to communicate medical information between providers and organizations[22]. In a separate feasibility study, adult respondents noted positive perceptions of daily wear with the USB device, provided that the wristband was adjustable, the color was discrete for social interactions, and access to enclosed data was secure[21]. Trial participants expect research protocols to include comprehensive plans for safety management while on the study, which this study sought to address through the engagement of frontline healthcare settings (emergency and urgent care) and their identification of the wearable USB device during initial patient assessment.

Use of Wearable Devices in Pediatric Research

The use of wearable devices in the pediatric population, particularly children with cancer, presents challenges particularly with validation of data capture method and results as well as patient-caregiver acceptance of the technology integration as part of clinical or research-based care delivery. Wearable devices may require active data capture, prompting and dependent upon engagement from the child and caregiver to achieve the monitoring or quality threshold necessary for provider or investigator decision-making. Process-related tasks may also require consideration when using wearable devices with children, such as necessary charging, calibration, and internet connectivity to ensure continuous, quality data capture [35,36]. Caregivers and pediatric participants undergo additional education related to the use of the wearable device and its functionality, which necessitates evaluation of technology literacy and addressing barriers to utilization [37].

Where the device is placed on the child's body as well as comfort of the device material are significant factors for compliance as well as accuracy of the generated readings[34]. For example, remote vital sign monitoring via wearable device requires adjustable fit, light weight, moisture resistance, and sleek edges of the machine encasement to prevent injury or discomfort[35]. While wearable devices are commonly placed on the wrist, locations of wearable devices for pediatric populations migrate to other areas which are less restrictive such as the ankle or upper thigh[35,37]. Together, creative placement and attention to human factors within wearable device design have lessened concern of patient distraction by the device or associating it as a toy or toylike machine. When used consistently and appropriately, wearable devices designed with pediatric patients in mind have the capability of providing clinical and research teams with remotely acquired data to complement in-office readings [36,37]. The remote data may then be utilized to detect early indicators of decline in health status and identification of adverse events[37].

Purpose and Design

The purpose of this study is to explore emergency and urgent care nurses' identification of the wearable USB device worn by a clinical trial participant to facilitate care management when outside the research setting. The emergency and urgent care settings were of focus given the variability in patient population and clinical presentations, methods of communication when obtaining the health history, and critical considerations for safe care. This study employed a qualitative descriptive study design to explore these research questions and gained insight into the critical factors of a clinical nurse's perception of a wearable USB device when a trial participant presents in the emergency department or urgent care setting. Qualitative description was selected as it allowed a factual, straightforward description of the phenomenon of wearable technology for trial safety management from the perspective of the clinical nurse[22].

Methods

Selection of Wearable USB Device Characteristics

In the flurry of activity of a clinical situation in the emergency department or urgent care setting, a nurse's situational awareness to wearable devices and sensors is paramount for participant safety. Emergency and urgent care nurses are often the first healthcare providers to encounter participants who seek care for side effects or other untoward symptoms outside of the research facility. Given the time pressures of emergent or urgent care, information related to key safety considerations must be easily identified and accessed with no required training to use the device. In this study, the proposed wearable device that a nurse would identify upon initial encounter with a clinical trial participant is a USB device enveloped within a silicone band placed around the wrist (Figure 1). The USB wristbands utilized in this study were derived from a commercialized, customizable design via 24HourWristbands.com, which was selected as a vendor for this study given customization ability of the technology color and labeling.

FIGURE 1 HERE

Wording and Symbol Selection

The wording on the device in capitalized letters, 'CLINICAL ALERT,' was informed by feasibility study findings, as participants noted a higher likelihood of nurses perceiving the device as significant if the wording utilized was common vernacular and like other common wearables such as medical alert bracelets[21]. To maintain separation between clinical research and clinical management, the word 'medical' was not applied to distance nursing misperception that the content of the device contained medical records rather than research-related information. The word 'alert' and capitalization were incorporated to denote urgency and to garner attention towards the device.

Placement of wording and sign were informed by Gestalt psychology principles of user co-experience, where the visual structure of technology influences the relationship of the user with the technology[23]. These principles were addressed through use of continuous color and spacing of words with prominence of the universal alert symbol to maintain proximity among characters. Warning or alert symbols, such as the one utilized in Figure 1, have been utilized on a yellow background per the U.S. Department of Transportation as being the most effective, focus-directing format[24]. Utilization of a pictorial symbol also supports the consensus-driven value attributed to 'warning' and supports pictorial communication for those individuals who may not easily interpret the band's selected wording[24].

Color

Visual cues, such as use of color, are rated higher in reaction time over hearing and touch[24]. The yellow overall color of the wristband and red-colored wording are well-known colors that prompt human attentiveness and focus[24]. Further feedback from the feasibility study included respondent requests for more neutral toned color schemes for the wristband rather than the royal blue color utilized in the study[21]. While utilization of neutral tones is unsubstantiated in cognitive psychology and human factors literature, recognition of this feedback and its potential support for daily wear will be implemented in this study with a neutral tone wristband for parallel evaluation with the yellow wristband in Figure 1. A black background is selected as this color is common among commercially available wearable technologies (such as smart watches) while remaining complimentarily neutral to the white text; the alert symbol remains red as a stimulating attractor to the nurse[24].

Location and Sizing

Stemming from feasibility feedback, adaptations have been made with reference to the adjustability of the wristband for pediatric sizing[21]. Feasibility informants noted issues with a non-adjustable wristband, such as the band falling off, moving up and down the arm, and discomfort when

band movement impeded daily living activities[21]. Hand breadth at the metacarpal, used here as an approximation for wrist diameter, varies at the 50th percentile among ages 2 to 17 years of age from 1.8 inches to 2.9 inches (females) and 1.9 inches to 3.5 inches (males), which supports adjustability factored into design[24]. The selected wristband was 9.75 inches in length, which then accommodates wrist diameters up to three inches. The pediatric patient-actor for this study had a wrist diameter of two inches at five years of age (male).

Additional Wearable USB Device Design Considerations

The design used for this study was a 'slap band' wristband that automatically conforms to the user's wrist diameter with minor, directed force. The 'slap band' styling permits easy removal of the device in the event of cleaning or medical professional access but may remain affixed due to the band's silicone blend. The wristband prototype weighs approximately three ounces, which is beneficial to the use of this device in pediatric populations as initial testing showed a desensitization of the pediatric patient-actor to the wearing of the device during common daily activities of living. Given the initial adult feedback in the feasibility study, the wearable USB device used in this study was designed as a continuous band and durable material to prevent damage and potential signs of wear or breakage during periods of high activity common with children.

Sample and Recruitment

Emergency and urgent care nurses were eligible to participate in this study provided they held an active Registered Nurse license in good standing with their state's respective Board of Nursing, practiced nursing in the US, had one year of current experience in a direct care capacity, and were proficient in written and verbal English. Nurses were excluded from participation if they held a non-active or retired Registered Nurse license, possessed challenges with vision not corrected by glasses or contacts, or held a current practicing role in a non-direct care capacity (such as administration).

Guided by the concept of information power, a smaller sample size was appropriate given strong informant dialogue potential and focused research questions[25]. Purposive and convenience sampling were employed, which further permitted the specific, targeted enrollment of emergency and urgent care nurses from across the US whose roles are directly impacted by clinical trial industry implementation of wearable device technologies that could possibly affect clinical care. Recruitment was pursued via the social media platforms Twitter, LinkedIn, and Reddit using Institutional Review Board (IRB) approved advertisement language and graphics with the survey link and associated QR code.

Procedure

Once a nurse was deemed eligible, the digital informed consent form was reviewed, which included a checkbox to acknowledge their participation and use of responses for research-related purposes pertaining to the study. Upon consent, basic demographic information was collected on the survey page prior to the photo assessment, which included age, identified gender, race or ethnicity, years of nursing experience, and current nursing role. Participants were then directed to the photo assessment section, which depicted a pediatric patient-actor (five years of age, male) sitting on a patient examination table. The patient-actor displayed either the black or yellow USB band (Figure 1) on the right wrist, and each photo with the different wristband was identical in patient-actor positioning. The determination of participant assignment to either the black or yellow USB band photo was randomized 1:1 (alternating assignment) per Qualtrics survey platform logic built into the image section (Figure 2).

FIGURE 2 HERE

The photo, regardless of wristband, included the same situational awareness questions: *What are elements in the shown photo that you feel are important to note for patient care? What questions do you have for the patient-caregiver based on this photo?* These questions were selected to query if the nurse noted anything of interest in the environment, questions for the patient, and future actions. This

format was in alignment with the SAGAT, which queries the end-user at random time points during a frozen simulation, positing customized questions based on perception, comprehension, and projection in a given situation[26,27]. Considered timeless in the human factors and ergonomics community, the SAGAT format was selected given the digital interfacing with the participant and researcher given the organizational restrictions related to the conduct of in-person research during the COVID-19 pandemic. The SAGAT questions were displayed immediately after review of the randomized photo to lessen the potential effect of working memory and attention bias while still being strongly predictive of projected actions[26,28].

Data Analysis

StataIC V.15 statistical software was used for descriptive statistical analysis of the survey data. SAGAT-format question responses were explored through in-vivo coding and qualitative content analysis These coding strategies allowed for in-depth extraction of action-based responses, comparative responses (consideration of a component of care versus another component of care), and respondents' own words to explain the experience of evaluating the patient photo. Data were then organized by relationship (themes, categories, and subcategories) and agreement was sought among one member of the research team with qualitative expertise. After two iterative rounds of content analysis, full agreement was achieved. The agreement process included review of codes, consensus with category and sub-category definitions, as well as review of justification for categories and subcategories with corresponding evidence through participant exemplars.

Results

A total of 55 nurses participated in the study, with 53 nurses (96.4%) practicing in the emergency room setting and 2 nurses (3.6%) practicing in the urgent care setting. Relating to gender, 40 respondents (72.7%) identified as 'Woman,' 14 respondents (25.5%) identified as 'Man,' and one

respondent (1.8%) identified as non-binary. The majority of respondents (87.3%) identified as 'White' pertaining to their race/ethnicity (N=48), 5.5% identified as 'Asian' (N=3), 3.6% identified as 'Hispanic or Latino,' and one respondent for each category of 'Black or African-American' and 'Multi-Racial/Multi-Ethnic.' Of the 52 respondents who provided an answer for their age in years, the average respondent age was 34.4 years, with a range of 24 years to 54 years. The average number of years of nursing experience was 8.57 years, with a range of one year of experience to 25 years. Almost half the sample had five years or less of nursing experience (N = 26, 47.28%). Additionally, 35 respondents noted they have been in their current role (emergency or urgent care) for five years or less (63.64%), with a range of one year to 22 years.

USB Wristband Identification

The color of the wristband, either black or yellow, was randomized in a 1:1 fashion via Qualtrics-generated logic within the online survey. Of the 44 respondents who progressed to the patient photo portion of the survey, 21 were randomized to see the black band photo and 23 were randomized to see the yellow band photo (Figure 2). Three respondents identified the wristband as part of the SAGAT-format question pertaining to observations deemed important to note for patient care. One wristband was yellow in color while the other two identified wristbands were black in color. Two respondents described the wristband as '*arm band*' and another respondent posited, "*is that a medic alert bracelet?*"

All three respondents who identified the wristband self-reported as working in the emergency care setting. All three respondents self-identified as 'Woman,' and two of the respondents identified as 'White' and one respondent identified as 'Asian.' The average age of the respondent was 35.67 years (range 34-38), the average years of overall nursing experience was 9.67 (range 1-14), and average years of nursing experience in the current role was 6.33 (range 1-13). Since such a small subset of the sample identified the wristband, a correlation coefficient matrix and comparative t-test was not statistically

feasible. The device color nor the role (emergency room or urgent care) were significant predictors of the identification of the device.

SAGAT Question Responses

Four themes emerged from participants' responses to the two SAGAT-format questions (two themes per SAGAT question), which resulted in 13 categories and 20 subcategories. Of these, the category *Patient Appearance* was the strongest with 22 thematic units. The category with the least amount of participant emphasis was *Assessment of Safety*, which had three thematic units. These themes, categories, and subcategories are organized by specific SAGAT-format survey questions: Question one, *Elements of Survey Photo Important for Patient Care* (see Table 1) and SAGAT question two, *Questions for Patient-Caregiver Based on Photo* (see Table 2).

Survey Question One: Elements of Survey Photo Important for Patient Care

Two themes emerged from the respondent observations from the survey photo pertaining to survey question one. The first theme, *Patient Presentation*, is defined as those clues a nurse draws from the photo pertaining to the overall status of the patient as they present to the emergency or urgent care setting. This theme is comprised of the following categories: *Patient Appearance*, *Wristband Identification*, *Patient Identification and General State*, and *Acuity Determination.* The second theme, *Patient Wellbeing*, is defined as nurse-derived observations that pertain to searching the photo for whom is with the patient, location of the patient, and patient emotional status as identified through facial expression. This theme is comprised of the following categories: *Caregiver Support*, *Patient Positioning*, and *Facial Cues and Emotion.* Table 1 outlines the definitions of the categories and subcategories with corresponding verbatim exemplars from participant survey responses.

TABLE 1 HERE

Survey Question: Questions for Patient-Caregiver Based on Photo

After the respondent completed the survey question pertaining to photo-related observations important for patient care, respondents then were prompted to convey what questions they may have for the patient-caregiver based on the photo provided in the survey. The questions provided by respondents were then grouped into two themes: *General Inquiry* and *Patient-Specific Inquiry*. The theme *General Inquiry* includes the categories *Reason for Patient Presentation at ER/Urgent Care*, *Medications and Pain*, and *Medical History and Allergies.* The theme *Patient-Specific Inquiry* includes the categories *Scenario-Specific Questioning*, *Assessment of Patient Safety*, and *Caregiver-Patient Involvement.* Table 2 outlines the definitions of the categories and subcategories with corresponding verbatim exemplars from participant survey responses.

TABLE 2 HERE

Discussion

The infrequency of clinical nurse identification of the wearable band aligns with previous research that found low situational awareness and identification of medical alert bands among nurses and other healthcare providers at time of initial patient interaction. While providers, particularly those in emergency medicine, agree as a majority in the importance of wearable device technology (such as medical identification bands) and a provider's need to incorporate a visual scan for a device during initial assessment, only 71% of queried emergency medicine providers and 3% of Emergency Medical Service (EMS) personnel ever looked for one during a case study simulation[29,30]. This case study simulation demonstrated that while providers are cognizant of the integration of technology and patient care, providers have not made the transition to a hybrid perspective where wearable technologies are quickly becoming the norm as communication channels for critical information safeguarding patients with vulnerabilities otherwise potentially unseen on assessment.

Examining the quality and effectiveness of communication is critical to patient safety. Medical alerts are melding into the wearable device category given the nature in which information is communicated or stored. Wearable devices should be seen as an extension of the patient's history and a contextual cue regarding the direction of care. Wearable devices are worn by patients to highlight disease status, allergies, clinical trial participation, or communication needs (such as deafness). In emergent situations, triage personnel begin the process of inputting foundational patient information within the EHR or another platform, beginning with a patient interview. However, the resulting information from these interviews has been found to be too succinct and missing key details[31]. Approximately 30% of triage notes in the EHR included past medical history in a study of triage documentation at an academic hospital in Southern Arizona[31]. As one nurse noted in a study of Norwegian triage nurses' role in patient interviewing and management, 'It's quick decisions with significant consequences for the outcome[32, p.901].'

If not integrated within the process flow for emergent, urgent, and acute care delivery, care should be taken by practitioners to inquire if the patient uses a wearable device or is wearing an alert. Targeted history can then be pursued if the answer is in the affirmative, with subsequent documentation. Further training for practitioners to scan the patient environment during initial assessment will support visual identification of possible wearable devices or alert bands. While the wearable device was infrequently identified by the nurses who completed the online survey, the use of the SAGAT format questions proved to support collection of detailed responses which will propel the authors' future work in situational awareness testing and identification of patient devices. Nurses were keenly aware as to the facial expressions of the patient-actor, absence of caregiver in the photo, and background setting. Nurses were descriptive in their assessment of the patient-actor, providing insight as to the culture and norms surrounding emergency room and urgent care nurse patient assessment practices.

The nurse-participant responses to the SAGAT format questions reflected their sensitivity to the peculiar dimensions of the patient-actor in relation to the background, as well as the background being an examination room environment rather than traditional emergency room bay settings. Nurses also noted the absence of resuscitative equipment in their responses, among other photo-related effects such as shadow on the patient-actor. Differences in light prompted some nurses to identify contusions, possible hematologic disorders, and evidence of domestic abuse. As the patient-actor was a child, nurses also were searching the environment of the photo for evidence of caregiver presence, noting it was typical to have a parent/guardian present for emergent or urgent care situations. The photo also made it challenging for the nurse-participant to view the wording on the band, which said 'CLINICAL ALERT' and included an alert symbol (Figure 2).

Adjacent wearable technologies, such as wearable medical alert bracelets, remain largely unstandardized in their visual appearance, location on the patient, and effectiveness of communicating critical safety information[33]. This prototype version of the wearable USB device is being evaluated, based on the results of this study, for opportunities to enhance ease of visual identification for clinical nurse awareness and determination of significance for clinical care decision-making to support standardized approach in effective communication of safety information related to clinical trials. Through inclusion of end-users (clinical nurses) in the development of the wearable technology, latent errors may be avoided and accelerated, more widespread adoption of uniform approaches to participant safety may be achieved. Future research includes pediatric oncology clinical trial participant and caregiver feedback related to color, positioning of the device on the body, and ease-of-use when alerting care providers to the wearable and information housed within. As the clinical nurse respondents included the caregiver in their line of questioning and observations during this study, inclusion of the caregiver will be integral for enhanced usability and integration within the child's care. Structure of clinical trial information housed within the wearable USB device, in the form of a software, will include considerations related to the

themes identified in this study (such as chief complaint, changes to outward patient presentation, and implications for signs and symptoms associated with clinical pathways for the cancer type).

Limitations

This study was initiated in March of 2021, where institutional restrictions regarding in-person human subject research were in place due to the COVID-19 pandemic. The study, originally anticipated to be an in-person mock patient assessment, transitioned to an online survey and use of a patient-actor photo. Restrictions regarding use of clinical spaces for taking the background photo were also in effect. To adapt to these restrictions, researchers employed the use of a digitally modified background of an examination office, which was available to photograph and tailor to the patient-actor. The participant sample was largely homogeneous related to role (emergency nurses) and race/ethnicity (non-Hispanic White). The sample of respondents included a majority of emergency care nurses (n=53) with few urgent care nurses (n=2). Additional research is necessary to gain a deeper insight as to the perceptions and experiences of urgent care nurses and prevalence of clinical trial participants seeking care at urgent care facilities.

Conclusion

The increase in patient utilization of wearable devices requires elevated provider situational awareness to locate devices which may influence care. Wearable devices may vary in color, placement, size and utilization and may not be readily apparent. Use of SAGAT in this study was an effective means of assessing nurse situational awareness related to scanning the environment for devices. Clinical nurses are at times the first healthcare providers to engage with patients after triage or patient check-in. Their ability and motivation to identify significant environmental and physical cues, such as wearable devices, is significant for effective communication of patient-related safety information.

Nurses are important stakeholders in the participatory design process to support device fit, form, and function for application in clinical settings as they are triaging patients, particularly vulnerable populations such as pediatric clinical trial participants. Moreover, nurses can consider incorporating wearable device utilization in their initial patient interview and assessment workflow. For example, asking a patient and caregiver to detail if a wearable device is part of the management of health-related conditions or an aspect of clinical research. The engagement of nurses in participatory research, such as this study, only further strengthens nursing's ability to deliver safe, quality care to patients who contribute to science as a trial participant.

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