

# STRENGTHENING THE ROLE OF NURSES IN MEDICAL DEVICE DEVELOPMENT



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Medical devices and innovative technology promise to revolutionize health care. Despite the importance of involving nurses in the collaborative medical device development processes, there are few learning opportunities in nursing programs. The purpose of this article is to provide a conceptual guide for nurse educators and researchers to engage nursing expertise in medical device development processes. A review of the literature guided the creation of the “Strengthening the Role of Nurses in Medical Device Development Roadmap” model. The model was used to describe how nurses can be engaged in multidisciplinary design of medical devices. An academic transdisciplinary team piloted the application of the model. The model includes the stages of needs assessment, planned brainstorm, feasibility determination, concept design, and prototype building. A transdisciplinary team case study of improving an asthma home-monitoring devices illustrates effective application of the model. Nurse leaders in the academic setting can effectively use the “Strengthening the Role of Nurses in Medical Device Development Roadmap” to inform their engagement of nurses in early medical device development and innovation processes. (Index words: Equipment design; Interprofessional relations; Nursing theory; Technology; Asthma) *J Prof Nurs 32:300–305, 2016. © 2016 Elsevier Inc. All rights reserved.*

**N**URSES HAVE BEEN identified as key leaders in the improvement and redesign of future health care systems because of the profession's numbers, close proximity to the patient experience, and scientific understanding of health care processes (Committee on the Robert Wood Johnson Foundation Initiative on the Future of Nursing at the Institute of Medicine, 2011). As technological innovations redefine health care, it is essential that nurses are involved in novel sensor and device development to inform the process and to provide insight from a patient-centered viewpoint of the human–

technology interface. In the academic setting, new interdisciplinary educational and research programs benefit from an underlying model to guide specific strategies and tactics (Posavac, 2011).

There are several reports of research on the outcomes of nurses engaged in technology and device development. Examples include assistive devices for those with limited mobility (McClelland & Kleinke, 2013), smart home sensors for aging in place (Rantz et al., 2013), wound care products, and curtain and intravenous line clips (Bridgelal, Grocott, & Weir, 2008; Weir, Grocott, & Ram, 2006). Exemplars also include nurses' leading usability testing of existing devices and products (Shea, 2015). While the literature outlines technology outcomes and what was accomplished, there is little guidance on how to engage nurses in the early steps of the technology development collaboration. The purpose of this article, therefore, is to present the creation and use of a model for engaging nursing expertise in the early stages of medical device development. To develop our Strengthening the Role of Nurses in Medical Device Development Roadmap for use in academic nursing research and education programs (Posavac, 2011), we modified and utilized the Model of User Engagement in Medical Device Development (Grocott, Weir, & Ram, 2007) and applied the process to our transdisciplinary Center for Excellence in Home Health and Well-Being through Adaptive Smart Environments (Home-BASE)

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Center's Asthma Team (Castner, Klingman, Sullivan, Xu, & Titus, 2015).

## Method

To develop our model process for engaging nurses in multidisciplinary medical device design in the academic setting, we conducted a literature review, revised an existing model, and piloted the process in a case study relayed in this article. The developing model for Strengthening the Role of Nurses in Medical Device Development Roadmap was derived and refined from several existing theories and concepts in the medical device development literature (Bridgelal et al., 2008; De Vito Dabbs et al., 2009; Pietzsch, Shluzas, Paté-Cornell, Yock, & Linehan, 2009; Shah, Robinson, & AlShawi, 2009; Weir et al., 2006). We followed a five-step method of nursing theory derivation (Walker & Avant, 2011) to develop our model.

We piloted our revised model, presented in this article as a case study, through the University at Buffalo's Center for Excellence in Home-BASE (<http://ubhomebase.org/>) (Castner et al., 2015). The center includes faculty, students, and staff from engineering, architecture, computer science, nursing, business, public health and health professions, and medicine. One of the center's focal areas is to design sensors for smart-home environments that promote health and well-being throughout the lifespan. Our case study focuses on improving asthma monitoring and care in the home environment (Natarajan, Castner, & Titus, 2014). While several concepts and prototypes have been produced by the center's asthma-focused team efforts, our first device is a smartphone-compatible, 3-D printed, low-cost peak-flow meter with the target end users of adults with asthma that may worsen in the occupational setting. It is this peak flow meter that is used in this work as the case study for the nurse involvement in medical device development.

There are several underlying assumptions to engaging nurses in the device development process: (a) the nurse will provide leadership on the team to focus the process on person-focused applications, (b) the nurse will contribute expertise on self-care, and (c) the nurse is operating in a multidisciplinary environment. In addition, nurses may represent the professional user and/or end user of the new technology, and we assume that nurses who practice in the community setting are integral to the academic setting as consultants, learners, educators, advisors, and active participants. Definitions of the key terms *person focus*, *end user*, *end recipient*, and *professional user* as utilized by our Strengthening the Role of Nurses in Medical Device Development Roadmap are shown in Table 1. Nurses in the academic setting are in ideal positions to lead such community-engaged efforts, with more flexible and autonomous workload structure compared with those inherent in direct care job roles and responsibilities (Hostgaard, Bertelsen, & Nohr, 2011).

## Results

The process of our Strengthening the Role of Nurses in Medical Device Development Roadmap comprises a cycle of five stages as described below and illustrated in Figure 1.

Our model allows a nexus of multidisciplinary, student, and community collaboration ideas to be inserted as innovation within the process. The cycle can begin at any stage, so long as there is room for authentic multidisciplinary influence in ongoing decision-making and research design improvements. For example, an engineering student may present with a prototype developed from a previous class, a public health student may present with epidemiologically defined need, a nursing student may present a need from a clinical experience, or a planned brainstorming session may produce novel ideas. The relationships among different concepts and phases are all intertwined, allowing for creativity and the revisiting of any previous stage interdependently.

### Needs Assessment Stage

We define the needs assessment for nurses in technology development as the systematic, data-driven, approach to determining the project-specific difference in the actual and envisioned target state of health for the end recipient of technology. Need is the difference between an actual state and one of the following envisioned target states: a minimum, a norm, and a desired or ideal state (Posavac, 2011). Selecting the envisioned target state is project specific. For example, some projects may seek to reduce health disparities (norm target state), whereas others may seek to promote health for all (ideal target state). In addition, assessment, a fundamental skill for nurses, is the systematic and comprehensive collection of relevant subjective and objective data about current health status (American Nurses Association, 2015a). The needs assessment may be summarized with epidemiologic data, evidence from formal research, patient population nursing diagnoses, or systematic collection and interpretation of end-user perceptions and engagement.

In our Home-BASE project on asthma, nursing research activities included a query and analysis (descriptive correlational study) of an available health care claims database to determine asthma health care utilization, a systematic literature review on asthma self-care, maintaining routine dialog about the project with key informants (professionals who work with asthmatics and lay community members with asthma), and a focus group with parents of children with asthma who recently used the emergency department for care. Registered nurses, currently practicing and/or enrolled in a doctoral of nursing practice program, participated by evaluating existing mobile self-care applications, conducting task analysis of the self-care process, synthesizing relevant clinical assessment and patient experiences and maintaining routine dialog about the project with key informants (professionals who work with asthmatics and lay community members with asthma). Through this needs-assessment process, we identified a research and clinical practice gap in the identification and management of work-exacerbated asthma in adults (Henneberer et al., 2011; Tarlo & Lemiere, 2014; Toren & Blanc, 2009). We identified the need for an improved device for the purpose of serial peak flow measures. Current

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