The Healthcare and Technology Synergy (HATS) Framework for Comparative Effectiveness Research as Part of Evidence-Based Practice in Vascular Access

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Abstract

The development of frameworks for nursing research, practice, and education is in its infancy. The focus in clinical research has commonly been on the variables patient and practice, not on the significant variable, technology products. However, in interventional and medical cardiology and orthopedic surgery, for example, products used are significant variables that affect clinical outcomes and subsequent recalls. The purpose of this article is to introduce the Healthcare and Technology Synergy (HATS) framework and discuss its use in comparative effectiveness research on health care-associated infections as well as its usefulness in nursing practice, education, and policy. Research in nursing that focuses on product as a variable has examined intravenous connectors and their association with catheter-related bloodstream infections, but more research specific to technology products is needed. The significance of products in nursing has been underappreciated, and the variable has been underutilized in research. This is a study limitation that can significantly affect research outcomes. Use of the HATS framework in nursing research can facilitate the development of clinically relevant nursing curricula, practice interventions, and policy based on research results. Appropriate development and evaluation of research that uses the HATS framework also has implications for cost-benefit analyses, product evaluation, and implementation of evidence-based practices.

Keywords: *catheter-related bloodstream infections, comparative effectiveness research, evidence-based practice, health care-associated infections, health care and technology synergy, vascular access*

Introduction

The use of frameworks in nursing is not new, but it is difficult to find one that is applicable to comparative effectiveness research (CER) on health care-associated infections (HAIs).[1] The Congressional Budget Office defines an analysis of comparative effectiveness as "… a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients."[2(p3)] This may include comparing competing drugs or technologies as well as health care costs and benefits. Methods used include pragmatic trials, randomized clinical trials, cost-effectiveness analyses, and observational studies. CER is needed to ensure that population health is enhanced. CER also has great potential for identifying preferred therapies such as implantable cardiac defibrillators in patients with nonsustained ventricular tachycardia and use of inexpensive diuretic medications as being more effective than higher cost

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http://dx.doi.org/10.1016/j.java.2013.05.001

medications in preventing heart attacks.[3,4] CER has been a long-term priority in cardiovascular patient care with extensive funding from the Heart, Lung, and Blood Institute of the National Institutes of Health.[5]

CER on HAIs requires special consideration regarding the increasing use of technology in clinical settings. However, one major limitation of HAI research is that technology often is not considered as a variable. Hence, technology is not statistically adjusted as a confounder and is not noted as a limitation in publications. The result is erroneous conclusions that can negatively affect patient outcomes as recently seen in cardiology[3] and orthopedics studies.[6] The purpose of this article is to introduce the Healthcare and Technology Synergy (HATS) framework and discuss its use in CER on HAIs as well as its usefulness in nursing practice, education, and policy.

Literature Review

One HAI research area is the prevention of catheter-related bloodstream infections (CRBSIs). A CRBSI is a clinical occurrence that involves the intravenous (IV) catheter and associated connector technologies as 2 potential sources of laboratory determined infectious agents.[7] CRBSI "is a clinical definition, used when diagnosing and treating patients, that requires specific laboratory testing that more thoroughly identifies the catheter as the source of the BSI."[8(p21)] The Centers for Disease Control and Prevention has determined that, despite implementation of numerous prevention strategies, CRBSIs have decreased by only 33%, and recent research reveals that patients with HAIs have an increased risk of hospital readmission.[9] In the United States, 80,000 cases of CRBSIs occur annually in intensive care units, and 250,000 cases in hospitals; financial costs are estimated at $2.3 billion annually, and poor patient outcomes include 30,000 deaths annually in intensive care units.[8,10-13] CRBSIs are important indicators of quality care. Twenty-two states have legislation that requires the reporting of CRBSIs, and hospitals in 44 states participate in the National Comprehensive Unit-Based Safety Program to prevent CRBSIs.[14,15]

Like studies in the United States,[16] international studies do not include technology as a factor in CRBSI research, and this can affect outcomes.[17-22] For example, the conclusions drawn by Lissauer et al[20] on differences in CRBSIs were associated with nursing care, but connector product type was not addressed. The outcome could have been related to the product as opposed to practice, but this cannot be determined because the framework used did not include a product variable. Consequences of not considering product variables in research involve possible inappropriate interventions and increased health care costs. If the result is product-related, then re-education of nurses with respect to their practice is not needed and is not cost-effective. There is recent news of an improved method for diagnosing CRBSIs.[23] Early diagnosis is critical to rule out infection or initiate needed treatment as early as possible. However, prevention should continue to be the primary focus for CRBSIs and other HAIs.[24]

There are numerous vascular access products that need to be studied with respect to their influence on HAIs. One example is catheter site dressings as a type of product.[25] For example, CER can be used to compare the infection rates among gauze dressings, chlorhexidine patch dressings, and clear occlusive dressings. Other products for comparisons include catheter stabilization devices, hub connectors, and alcohol caps.[7,22,26] CER is needed to study combinations of products as well, such as knowing which connectors require the use of alcohol caps to reduce infections, because it is known that connectors have many differences in features of septum surface, septum seal, fluid pathway, dead space, internal mechanisms, clamping sequence, visibility, and reflux.[27] CER is needed to determine which central-line site dressing is best to reduce infection and how often dressings should be changed based on patient diagnosis. CER on the use of catheter stabilization devices compared with no stabilization device also is needed, although it is known that use of the stabilization device StatLock (Bard Access Systems, Salt Lake City, UT) in nursing practice bundles of vascular access care might aid in obtaining zero rates of CRBSIs.[28] There are in-vitro and clinical studies on differences in bacterial growth specific to some connector products, but more research is needed, particularly with the Food and Drug Administration having recently issued a warning on the use of all positive connectors.[29] Furthermore, there is no CER on which connectors require alcohol cap use to decrease CRBSIs. An additional product such as alcohol caps do not need to be used on connectors that have design features to negate their use, such as the zero connector InVision-Plus (RyMed Technologies Inc, Franklin, TN).[7,30,31] Also, requiring nurses to use an additional product that is not needed increases the possibility of negative outcomes. When designing new products, manufacturers should take into consideration the product's ease of use in patient care.

Evaluations of poor patient outcomes in HAI research have often evolved around patient and practice variables, with little or no thought of products.[32,33] If product is not a significant variable, why are there product evaluations for computers, toasters, lamps, and cars, and journals specific to the consumer product concept? Certainly the product must matter in health care, which relies on the use of numerous manufactured products.[3,6,34] For example, there is valuable research on products in cardiovascular imaging, cardiac defibrillators, and metal arthroplasties.[3,6,34]

Practitioners have a sense of angst over the fact they are doing what they were taught to do in practice, yet positive outcomes are not being seen. The missing variable is the health care product. Although health care delivery is complex, prevention of a majority of CRBSIs is attainable. To achieve this goal, there is a need for "… prospective assessment of hazards associated with new technology"[35] such as IV connectors.

HATS Framework

The HATS framework (see the Figure) formalizes nurses' observations regarding the importance of taking into account the product as well as the patient and practice components of

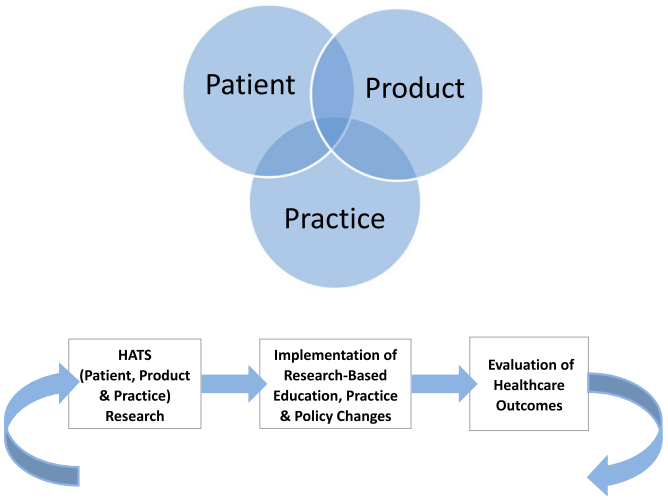

Figure. **Healthcare and Technology Synergy (HATS) framework.**

health care. The framework represents a synergy among these patient, product, and practice components, with each one affecting and being affected by the other. It is the combined effect or interaction of patient, product, and practice working together that affect health care outcomes. The best outcomes can be achieved when there is synergy among all 3 of these health care components (as represented by the overlap of all 3 circles in the Figure).

There are a multitude of patient, product, and practice variables that may need to be considered when using the HATS framework with research on HAIs. Patient variables to consider include, but are not limited to, demographics, comorbidities, therapeutic regimens, mental health status, finances, disease type and stage, and living setting or environment. Examples of practice variables include the number of seconds you scrub the hub of an IV connector; how often a vascular access dressing is changed; how often a specific technology, such as a peripheral IV site, IV connector, IV tubing or alcohol cap, is changed; the education and skill levels of nurses specific to vascular access technologies; nurse—patient staffing ratios; the existence and availability of specialized vascular access teams as they relate to time to implement excellent vascular access care; and supply availability. Product variables may include IV connectors categorized on the basis of reflux so that the categories include a connector as being either positive (reflux with connection), negative (reflux with disconnection), or neutral/zero (no reflux with connection or disconnection); peripherally inserted central catheters categorized by material, number of lumens, and power versus nonpower use; automatic blood pressure cuffs categorized on machine accuracy of pulse pressure and accuracy over time; antibiotic impregnated compared with nonimpregnated urinary catheters; burn dressings impregnated with zinc versus silver ion technology; and stabilization devices. Research studies with some of these product variables have already been implemented, presented, and published.[30,31,36-42]

These patient, product, and practice variables need to be studied with respect to their influence on multiple health care outcomes. There are many issues to consider when selecting outcomes to include in CER.[43] Outcomes of importance in research on HAIs may include morbidity, mortality, infection rates, quality of life, patient satisfaction, length of hospitalization, health care costs, and product bleeding and dislocation rates.

An evaluation of research findings using the HATS framework can lead to implementation of education, practice, and policy changes, such as more or different education for health care providers, revised policies and practice guidelines, and/or use of different products. After changes have been made, it is important to continue evaluating health care outcomes. Depending on the outcomes being implemented, the institution's quality management, human resources, finance, and/or other departments may be involved with monitoring and evaluating the outcomes. This becomes an iterative process in that the outcome evaluation may lead to further research, which in turn may point to the need for additional education, practice, and/or policy changes. The goal is to maximize the patient, product, and practice synergies that can lead to the best possible health care outcomes.

One example of using the HATS framework is in the study of central line-associated bloodstream infections. In this example, patient variables that may need to be considered include the patient's condition, such as immunosuppression and current infection status. Practice variables to be considered may include the actual policies and procedures implemented for both extraluminal (insertion checklist, insertion site, and dressing management) and intraluminal (swabbing or flushing) care. Product variables may include the IV connector type (positive, negative, or neutral/zero), type of disinfectant (chlorhexidine gluconate or alcohol), amount of time the connector hub is disinfected, use or lack of use of a catheter stabilizing device, type of dressing (transparent or chlorhexidine gluconate-impregnated gauze), catheter material (impregnated or coated), number of peripheral and central vascular access devices (as well as therapeutic related accesses), and/or associated length of dwell. Possible outcomes to be studied may include mortality rates, infection rates, health care costs, and/or quality of life. Interpretation of the research findings may lead, for example, to changes in health care practices and/or changes in the product. Research-based health care changes need to be monitored and subjected to an evaluation of health care outcomes iteratively as new patient, product, and/or practice changes are made.

Application of the HATS Framework

HATS has been used as a framework for comparing IV connectors and associated infections.[40,42] Academics and clinicians need to use the HATS framework in research, education, and practice so that it can be validated and further developed. This is important in that the HATS framework can facilitate the design, implementation, and evaluation of CER that includes technology. It also can be useful in CER and interprofessional evidence-based research. Other research areas that can benefit

from use of the HATS framework include patient and family centered care, human simulation and safety, quality assurance, and cost−benefit research.

The HATS framework may add a more holistic and comprehensive approach to evidence-based practice and quality assurance, especially when translating research findings to bedside care. Patient conditions (eg, diabetes, hypertension, and cardiac disease) and health care practices (eg, hand washing, swabbing, flushing, and dressing changes) are often considered common variables in research and prediction of patient outcomes. Product rarely has been thought of or included as a variable, yet it may be a significant variable as well as a limitation of a research study if it is not addressed. In June 2009, the Federal Coordinating Council for Comparative Effectiveness Research noted a heightened need to consider the influence of technology on clinical events, mortality, and quality of life.[44]

The HATS framework can be used for research regarding the best possible treatments and care for patients in the real world leading to best health care outcomes. For example, in studying IV connector types (positive, negative, or zero), the outcome may be the incidence of CRBSIs. If outcomes do not meet the best standards as they are defined, further research needs to be conducted, and evaluation of the implementation of research outcomes needs to continue. Outcomes should be evaluated at specific intervals and whenever a change to 1 or more of the 3 variables of patient, product, and/or practice occurs.

There are multiple issues to consider when planning the study design and statistical analysis for CER on HAIs using the HATS framework. Managing confounding variables is one issue of concern. Traditional analysis techniques, such as linear and logistic multivariable regression models, as well as newer methodologies, can be used to adjust for confounding variables during data analysis.[45]

Discussion

The relationship between technology, humane care, and nursing practice needs to be enhanced.[46] Technology cannot care for the whole being in the current health care crisis.[47] Devices are needed that operate to enhance, rather than hinder, health care workers' jobs, whether it is disinfecting or flushing the device.[27] Correctly designed technical devices as well as a set of simple preventative measures may be useful for preventing major CRBSIs.[48] A call for the manufacturers of vascular access devices to include fail-safe engineering advances into their products is needed to further mitigate the risk of infection in the complex hospital environment.[49] Technology, being a product, makes a significant difference and has an affect on outcomes in many areas of nursing care such as trauma, oncology, cardiology, outpatient centers, community health, and neonatal care.

The importance of the HATS framework will increase in the future as more technology continues to be infused into the healthcare environment. The HATS framework can be used in CER, evidence-based practice, and quality assurance with a goal of efficiently and effectively shortening the pipeline from research discovery to practice implementation. The use of CER, particularly in vascular access, can lead to the development of research priorities and practice guidelines for widespread implementation in the real-world setting, thereby helping to decrease the number of infections.

Conclusions

The HATS framework is useful for observation as well as intervention studies that include technology in multiple settings, especially in CER that examines efficacy, efficiency, and cost as part of best health care outcomes. The HATS framework focuses on the interplay of 3 critical variables that affect health care outcomes: patient, product, and practice. The relationships among these 3 variables are an essential component of nursing care.[50] If any of these 3 variables are not included in outcomes research that includes technology, this may need to be addressed as a study limitation. The implementation of CER outcomes using the HATS framework can lead to clinically relevant nursing curricula, practice guidelines, and policies. This helps provide meaning, understanding, and description for critical issues in nursing education and practice to meet the learning needs of nurses as well as students.[51]

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