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Evaluation of Conceptual Frameworks Applicable to the Study of Isolation Precautions Effectiveness

Catherine Crawford, COHEN, RN, BSN [PhD Candidate] and
Columbia University School of Nursing, Center for Health Policy

Jingjing Shang, PhD, RN [Assistant Professor]
Columbia University School of Nursing

Abstract

Aims—A discussion of conceptual frameworks applicable to the study of isolation precautions effectiveness according to Fawcett and DeSanto-Madeya's (2013) evaluation technique and their relative merits and drawbacks for this purpose

Background—Isolation precautions are recommended to control infectious diseases with high morbidity and mortality, but effectiveness is not established due to numerous methodological challenges. These challenges, such as identifying empirical indicators and refining operational definitions, could be alleviated through use of an appropriate conceptual framework.

Design—Discussion paper

Data Sources—In mid-April 2014, the primary author searched five electronic, scientific literature databases for conceptual frameworks applicable to study isolation precautions, without limiting searches by publication date.

Implications for Nursing—By reviewing promising conceptual frameworks to support isolation precautions effectiveness research, this paper exemplifies the process to choose an appropriate conceptual framework for empirical research. Hence, researchers may build on these analyses to improve study design of empirical research in multiple disciplines, which may lead to improved research and practice.

Conclusion—Three frameworks were reviewed: the epidemiologic triad of disease, Donabedian's healthcare quality framework and the Quality Health Outcomes model. Each has been used in nursing research to evaluate health outcomes and contains concepts relevant to nursing domains. Which framework can be most useful likely depends on whether the study question necessitates testing multiple interventions, concerns pathogen-specific characteristics and yields cross-sectional or longitudinal data. The Quality Health Outcomes model may be slightly

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preferred as it assumes reciprocal relationships, multi-level analysis and is sensitive to cultural inputs.

Keywords

Theoretical models; conceptual analysis; nursing; patient isolation; cross-contamination; healthcare-associated infection; barrier precautions; contact precautions; infection prevention; infection control

INTRODUCTION

Isolating those with communicable pathogen(s) has been a key means to control disease since the black plague in the 14th century (Landelle *et al.* 2013). Today, isolation precautions are still a preferred method in many healthcare systems to control infectious diseases with high morbidity and mortality, such as Methicillin-resistant *Staphylococcus aureus* (Smith *et al.* 2008, Siegel *et al.* 2007). However, high resource requirements (Kirkland 2009), associated adverse events (Morgan *et al.* 2009) and evidence-based medicine prioritization (Swanson *et al.* 2010) have sparked debate as to whether existing data regarding isolation precautions are adequate to guide effective practice (Gasink & Brennan 2009). This debate intensified following transmission of Ebola virus to healthcare workers in the U.S. despite use of isolation precautions (Santora 2014). It is important to generate new, consistent data regarding optimal infection control techniques to improve clinical practice (Centers for Disease Control and Prevention 2013).

However, it remains challenging to demonstrate isolation precautions are effective. Recent studies of isolation precautions effectiveness took place in many different countries including France (Gbaguidi-Haore *et al.* 2008), Great Britain (Cepeda *et al.* 2005), Hong Kong (Cheng *et al.* 2010), Israel (Cohen *et al.* 2011), Taiwan (Lin *et al.* 2011) and the United States (Bearman *et al.* 2010, Bearman *et al.* 2007). Similar studies were rarely repeated in the same country. As wide variation exists in clinical practice guidelines regarding isolation precautions, even among those from English-speaking countries (Aboelela *et al.* 2006), variation in the healthcare systems and isolation precautions processes threatens external validity of study results (Zastrow 2011). Therefore, it is difficult to combine and draw conclusions from this international body of literature.

Although substantial methodological barriers exist in this area, improvement is possible. Challenges that are difficult or impossible to address include establishing temporality between exposure and infection given new resistance and asymptomatic colonization periods (Gasink & Brennan 2009) and blinding intervention and outcomes (Aboelela *et al.* 2006). As isolation precautions are not recommended in all countries, randomized controlled trials of isolation precautions are uncommon. Because the most relevant study designs (quasi-experimental and observational studies) limit the researcher's ability to control for confounders (Siegel *et al.* 2007), addressing confounders and accounting for bias is critical. Future studies may also improve on existing literature assessing compliance with all aspects of the intervention (Landelle *et al.* 2013) as well as fully describing the environment and outcome assessment methods. Careful study design to evaluate isolation precautions is essential, not only to produce rigorous results, but also to fully consider all the risks and

benefits to patients, providers, facilities, allowing interpretation of findings by an international audience.

Background

Using a conceptual framework can be an effective tool to guide research of complex problems by helping to define concepts relevant to the phenomenon of interest and outline the relationships between these concepts (Fawcett & Desanto-Madeya 2013). Conceptual frameworks also can help to refine operational definitions and identify empirical indicators for these concepts. They aid derivation of theories, research questions and corresponding logical hypotheses to be tested in empirical research (Fawcett & Desanto-Madeya 2013). Given the difficulties of studying isolation precautions, appropriate conceptual frameworks may advance theory generation and improve evaluation through empirical research.

When designing a study, it is essential to ensure that the chosen conceptual framework and theory under investigation are logically aligned (Fawcett & Desanto-Madeya 2013). While infection control and prevention is inherently a multidisciplinary effort, nurses are a critical component given their frequent, direct patient contact, education and research roles. Therefore, effectiveness research should consider nursing roles, perspectives and theory to maximize applicability of research findings. Models from other disciplines which appear potentially applicable to nursing issues 'should be critically analyzed and evaluated before it is introduced into nursing curricula, empirically tested or applied in nursing practice' (Sullivan 1989).

The objective of this paper is to support study design by identifying, analyzing and evaluating conceptual frameworks to study the effectiveness of isolation precautions. This paper discusses the relative merits and drawbacks of each to frame empirical research on this topic and compares which conceptual frameworks are best-suited for various study designs used to evaluate isolation precautions effectiveness. Further, it outlines a critical thinking process regarding how to choose a conceptual framework, which may be useful beyond infection control research.

Data Sources

In mid-April 2014, C.C.C. performed a systematic search of electronic, scientific literature databases for peer-reviewed publications using or describing a conceptual framework applicable to examine the effectiveness of isolation precautions. Databases included PubMed, Ovid Medline, EBSCO Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Clinical Trials and Cochrane Database of Systematic Reviews. Keyword searches were supplemented by Medical Subject Headings (MeSH) terms in the search criteria, where applicable and related to the following concepts: Patient isolation (i.e., 'barrier precautions', 'contact isolation', 'contact precautions', 'isolation precautions', 'quarantine') and conceptual frameworks (i.e., 'theoretical model', 'conceptual model', 'organizing framework', 'theoretical framework'), in singular and plural forms. Search parameters included publication in English. Searches were not limited by publication date.

C.C.C. examined titles and abstracts of papers returned through database searches for potentially applicable conceptual frameworks. Additional publications were sourced through reference lists of papers returned in the database search. Conceptual frameworks previously known to the authors were also considered. C.C.C. then identified original literature that proposed these frameworks of interest as well as publications by the original author(s) that further elaborate on these frameworks.

Frameworks selected for analysis were included based on 1) applicability to the study of isolation precautions effectiveness and 2) the number of times the publications that originally proposed this conceptual framework has been cited on PubMed. Applicability and usefulness of the identified conceptual frameworks were evaluated following the analysis technique outlined by Fawcett and DeSanto-Madeya (Figure 1) (Fawcett & Desanto-Madeya 2013).

DISCUSSION

Searches of electronic databases yielded 128 publications, 25 of which were duplicates. Six conceptual frameworks were identified relevant to the study of isolation precautions (Table 1). Among the six frameworks, the epidemiologic triad of disease (though not always titled as such, as discussed below) was most frequently cited by other publications in PubMed (247 times), followed by Donabedian's healthcare quality framework (67 times) and Quality Health Outcomes framework (21 times). The other two frameworks were each cited less than four times. We described the three more frequently cited frameworks and evaluated their usefulness to study isolation precautions effectiveness (Table 2).

Epidemiologic Triad of Disease

Description—The epidemiologic triad of disease is also referred to in the literature as the 'epidemiologic triad of agent/host/environment' (Bernardo *et al.* 2002), 'host-agent-environment complex' (Smith 1986), 'agent-host-environment model' (Zastrow 2011), 'epidemiologic triangle' (Huerta & Leventhal 2002) and the 'traditional public health triangle' (Wilde 1997). As detailed in a textbook focused on 'health promotion and disease prevention' in medicine and dentistry (Leavell & Clark 1958), the motivation for development of this model was to frame infection prevention strategies (Clark 1954) and assemble facts in a body of knowledge regarding the natural history of disease (Leavell & Clark 1958). Although originally developed to describe infectious disease, the framework was also used in studies related to non-infectious disease, such as lead poisoning (Clark 1954) or nutrient deficiency (Leavell & Clark 1958).

The epidemiologic triad of disease identifies three components necessary to initiate and propagate illness (Leavell & Clark 1958), including a host (i.e., susceptible individual), an agent (i.e., a pathogen) and environment compatible with transmission of a disease-causing entity (Figure 2). As such, the environment, described as 'all things except man himself' (Leavell & Clark 1958), also includes biologic and socioeconomic factors in addition to the physical environment that 'may be preparing the way long before pathogenesis is initiated' (Clark 1954). In the original framework, Clark (1954) targeted interventions to intercept the causes contributing to disease process and proposed five 'levels of application of preventive

measures' (Clark 1954). Variations of this model including a central 'vector' concept linking the other three (Huerta & Leventhal 2002) and presenting the framework as a tripod (or triangle) of the three concepts (Scholthof 2007) rather than a balance between agent and host with environment as the fulcrum (Leavell & Clark 1958).

Analysis—Because this framework is originally from the medical discipline, it purports no philosophical beliefs, values, goals or descriptions with regard to nursing practice. The authors' views regarding the general purpose of nursing interventions are not stated in descriptions of the framework, neither are relationships to the domains of nursing. The general method of knowledge development using this framework is deductive as Leavell and Clark (1958) believe that knowledge of the natural history of disease can 'fill in the gaps' regarding what is known of the agent, host and environment in a particular situation (Leavell & Clark 1958), that is, using theory to deduce what empirical observations may occur (Reed 2012).

Regarding nursing metaparadigm domains of nursing, environment, health and person(s)/client/human beings (Peterson & Bredow 2013), the model could be interpreted as addressing client and the environment. Human beings are described as both a reservoir of disease and also a compilation of 'habits and customs' and that influence the interaction between agents of disease and the individual (Clark 1954). As mentioned above, environment is described as multi-factorial influences on the 'life and development of an organism', including biologic and socioeconomic as well as physical entities (Clark 1954). Because the authors wanted to outline a health promotion philosophy when developing this framework, health is implied in this model through the host's level of susceptibility. Nursing is not included, which might be interpreted as a significant weakness of this model for framing interventional research.

Evaluation—The origins of the model in medical epidemiology are not an inherent weakness for nursing or multidisciplinary studies as many conceptual frameworks of non-nursing origin have been successful to generate and test nursing theory (Fawcett & Desanto-Madeya 2013). This framework has been used in nursing research (Bernhardt & Langley 1999, Bernardo *et al.* 2002), including for infection control (Massanari 1989, Wilde 1997). In applications to the study of isolation precautions, this framework emphasizes a means to change the environmental component, breaking the links to both presence of an agent and contact with a susceptible host. The model was also specifically identified as a useful tool to study contact precautions (Zastrow 2011). Indeed, simplicity of the framework and breadth of concepts are strengths that enhance the model's applicability to diverse disciplines and topics.

However, the model is limited in comprehensiveness of content regarding nursing inputs and perspectives. The lack of a nursing or intervention-specific concept in the framework may not be a concern for describing the natural history of disease or even testing a single intervention's effects. However, to compare multiple interventions, the framework may require adaptation to capture effects of the interventions, especially if they affect the same concept (e.g., host) in different ways (e.g., education regarding isolation precautions procedures versus vaccination). Despite these weaknesses, researchers have used this

framework from nursing perspectives. For example, in the study of occupational nursing, Smith (1986) used the framework from a different worldview by assuming mutable agent, host and environment as well as dynamic relationships between these concepts (Smith 1986). Similarly, Reifsnider (1995) adapted the framework to show multiple inputs to each concept as well as reciprocal relationships between environment and host (Reifsnider 1995). Given that nurse scientists saw fit to adapt the model for use, the original framework may fail to capture the complexities of nursing interventions required to study isolation precautions.

Donabedian's Healthcare Quality Framework

Description—In 1966, Avedis Donabedian proposed that the quality of medical care can be evaluated through consideration of structure, process and outcomes of that care (Figure 3) (Donabedian 1966). Structure, the setting where medical care takes place and 'instrumentalities' that produce care processes, includes the 'adequacy of facilities and equipment' needed to provide care, provider qualifications, 'fiscal organization' as well as 'administrative and related processes that support and direct the provision of care' (Donabedian 1966). Process, 'medical care' (Donabedian 1966), includes not only technical skills, but also whether medical evidence has been applied in decision-making, the 'appropriateness, completeness and redundancy' of information obtained regarding the client and whether the client values the care provided (Donabedian 1966). Outcomes of medical care, the 'recovery, restoration of function and of survival' of a client (Donabedian 1966), is described by Donabedian as product of structures and processes.

This framework applies to the study of isolation precautions as isolation precautions are represented in structure and process concepts. For example, structure encompasses the availability of a private room and processes include the use of gowns and gloves for contact with the patient and the patient's environment. Outcomes related to isolation may be infection or colonization with a specific pathogen, among others.

Analysis—With its medical field origin, Donabedian specifically focused on quality evaluation of physician-patient interaction, as this was 'familiar territory of care' (Donabedian 1966). Similarly to the epidemiologic disease triad, Donabedian's model is not built on any philosophical beliefs and values specific to nursing nor does it inherently include any strategies for nursing knowledge development. It therefore does not have a unique focus in nursing. Donabedian's method of knowledge development using this model appears to be abductive system of reasoning, as it represents 'a conceptual leap from experience, beliefs and a pre-knowledge of patterns to arrive at an educated guess or theory about a phenomenon' (Reed 2012).

When Donabedian described this framework, he did not address domains of the nursing metaparadigm; however, when applying this framework to evaluate nursing or interdisciplinary care, the framework could incorporate all domains. *Human beings* are included both in structures (e.g., health care provider staffing) and in the influence of client characteristics on processes. Structure also describes the *environment* where healthcare is delivered. *Health* is measured by outcomes. Donabedian's model previously received

criticism that structure and process concepts are ill-defined for *nursing* which may, at times, fit into both (Closs & Tierney 1993). However, for the sake of evaluating isolation precautions, both structure and process factors would certainly need to be considered in a well-designed study. Therefore nursing activities and attributes need not fit into a single concept in this model.

Evaluation—The Donabedian model is so well established in healthcare quality research that, despite its origins in medicine, one could argue that it is very well aligned and logically congruent with most nursing theory and knowledge developed in its wake. In nursing, it has been used to evaluate quality of hospice care (Richie 1987), elderly discharge planning (Closs & Tierney 1993), nurse practitioner services (Gardner *et al.* 2014) and obstetrical/ labor and delivery patient perceptions (Hosek *et al.* 2014), among others. Research studies that use this framework demonstrate its social congruence in multiple geographic location and cultures (Chen *et al.* 2007, Closs & Tierney 1993), indicating the international relevance of its content. Considering that this framework has successfully guided nursing theory development and testing in this way, its empirically adequate use is a distinct strength (Fawcett & Desanto-Madeya 2013).

While the content of the framework is purposefully broad to be widely applicable, it may not be ideal to study isolation precautions as it lacks a clear component or role regarding the characteristics of pathogens (e.g., the ‘agent’ concept in the epidemiologic triad of disease). This reflects that the unique focus of the model is not infection control. To use Donabedian’s model in infection control studies, the structure component may best incorporate the concept of a dangerous agent present in the environment and perhaps the pathogen’s virulence and pathogenicity.

Another limitation of this model is that ‘the relation between structure and process is poorly understood’ (Donabedian 1978). This lack of clear relational propositions between concepts may be a significant drawback for guiding studies on this topic. As such, nursing researchers have defined the relational propositions interactions more explicitly (Richie 1987) and also proposed new, adapted models (Chen *et al.* 2007, Shield *et al.* 2014, Mitchell *et al.* 1998).

Furthermore, the relationship between outcomes and other concepts in the Donabedian model also may not be ideal to study isolation precautions. For example, during a suspected influenza outbreak, confirmation of each additional case in a facility (outcomes) may change the process for isolation precautions for the next individual with a suspected case of influenza. The propensity to isolate and hence structures and processes of practice, will have changed as a result of what the Donabedian model identifies as outcomes. It is not clear how this reciprocal influence might be reflected in the Donabedian model.

Quality Health Outcomes Model

Description—Building on Donabedian’s linear framework of healthcare quality improvement, the Quality Health Outcomes Model (Mitchell *et al.* 1998) includes four components: system, client, interventions and outcomes (Figure 4). System characteristics incorporate structure and process elements of the Donabedian model. Similar to processes in the Donabedian model, the interventions component represents clinical processes and related

activities by which they are performed. Unlike Donabedian, Mitchell and colleagues specify client characteristics, which are indicators of health status, demographics and disease risk factors of individual patients, families and communities. Outcomes are health indicators such as morbidity, mortality and other variables dependent on the previously listed components (Mitchell *et al.* 1998). Relational propositions between concepts in the Quality Health Outcomes framework are dynamic and the relationship between interventions and outcomes is indirect and mediated by system and client components (Mitchell *et al.* 1998).

This framework applies to the study of isolation precautions effectiveness as it was developed to facilitate testing complex relationships between concepts with attention to nursing contributions (Mitchell *et al.* 1998). Interventions represent the processes of isolation precautions, while the system characteristics (e.g., nursing staffing ratios) and client characteristics (e.g., isolation adherence related to mental status) mediate the intervention's effects on the outcome (e.g., facility infection rate). The decision to isolate includes client and system characteristics, balancing the negative consequences of isolation on the individual with the benefits of reduced infection risk to a larger group of individuals. In this way, the content of this nursing conceptual model is appropriate to study isolation precautions.

Analysis—The origin of this model was the Outcomes Measures and Care Delivery Systems Invitational Conference (Mitchell & Lang 2004), which targeted defining categories of outcome indicators that can affect health policy. As such, the unique focus of this model is outcomes, especially nursing outcome research and management. The authors believe that a model with multiple feedback loops between the components and outcomes would be more sensitive to nursing inputs than the Donabedian model (Mitchell *et al.* 1998). The authors also incorporated multi-level analysis, as proposed by Holzemer and Reilly (1995) and clinical and functional outcomes introduced by Wilson and Clearly (1995). Their motivation was to establish a model broad enough to guide database development, suggest key clinical intervention variables, provide a framework for research and influence health policy (Mitchell *et al.* 1998).

The authors appear to have used abductive reasoning (Reed 2012, Sullivan 1989) to develop this conceptual guide as it was derived from 'expert panel members' ongoing research, expert opinion and literatures of nursing and health services' (Mitchell & Lang 2004). However, the authors specifically support use of this model for inductive knowledge development ('the process of subjecting the theoretical ideas to empirical test' (Reed 2012)). Influences of specific philosophies are not stated. However, the authors' description of the model notes that the impacts of nursing inputs are mediated by individual client characteristics and contextual factors of the system where care is provided. This appears to take a postmodern approach (i.e., outcomes are dependent on context) (Reed 2012). Hence, both outcomes and mediators require sensitive measures to capture nursing value.

Mitchell and colleagues specifically incorporated all four nursing metaparadigm domains in this model (Mitchell & Lang 2004). The desire to incorporate broader outcomes than negative events (i.e., the 5-Ds: death, disease, disability, discomfort, dissatisfaction) (Mitchell & Lang 2004) reflects the domain of *health*. It may also be argued that

environment is present in the system characteristics concept, intervention contains *nursing* and both client characteristics and outcomes can differentiate between illness and non-illness states. The *person(s)* domain might be interpreted as aspects of healthcare workers in system characteristics as well as influencing client characteristics.

Evaluation—Regarding the study of isolation precautions, the Quality Health Outcomes model is similar to Donabedian's framework in that it lacks an 'agent' concept as described by Leavell and Clark (1958). In this model, the system characteristics concept best incorporates presence of a disease agent. Another potential flaw in this model is that direct relationships between intervention and outcomes are not possible. As stated above, this framework purports that the relationship between intervention and outcomes is always mediated by system and client characteristics. Therefore, in a hypothetical study population that is homogenous with regard to system and client characteristics, the authors question whether relational propositions described by the model are meaningful. However, though individual studies regarding isolation precautions are often performed in a single unit or facility, it is unlikely that system and client characteristics can be sufficiently homogenized based on existing studies. In this way, the model appears to be appropriate for empirical research regarding isolation precautions with these mediators influencing the intervention-outcome relationship.

The strengths of this model are its intentionally broad concepts and numerous published examples of use in nursing research. This model has influenced theory relating health outcomes to nurse staffing (Shang *et al.* 2014), patient experience (Lundgren & Wahlberg 1999), system characterization (Dubois *et al.* 2012) and recognition of nursing excellence (Lake *et al.* 2012), among others. Contributions to the nursing discipline also include guiding several nursing report card initiatives (Mitchell & Lang 2004). The studies using this model indicate that the model has international relevance as they take place in multiple countries and represent different cultures (Brooks-Carthon *et al.* 2011, Shang *et al.* 2014). In summary, this model has been sufficiently validated through contributions to the nursing discipline.

Other key strengths of the Quality Health Outcomes model are the incorporation of system and client characteristics concepts and the assumption of multi-level analysis. First, the mediating concepts of system and client and indirect relationship between interventions and outcomes compels researchers to account for differences between populations and settings where studies of isolation precautions effectiveness are performed, for example, different resources available in another healthcare system and cultural influences of that country on psychological adverse events associated with isolation precautions. This is particularly important for repeating studies in diverse settings, interpreting findings from studies performed in other countries and synthesizing data collected in diverse geographic regions, which is particularly relevant to the highly international body of literature regarding isolation precautions effectiveness. Second, incorporation of Holzemmer's multi-level analysis (Mitchell & Lang 2004) allows the model to address risk and benefits at both the individual and group levels. Including variables at multiple levels is integral to the study of isolation precautions as the isolation precaution benefits (e.g. reduced infection risk) are realized by a group of patients at the facility or unit level and the harms (e.g., depression)

are specific to the individual in isolation. Therefore, the Quality Health Outcomes framework allows detailed reflection in study design of isolation precautions and considerations for cross-cultural sensitivities.

Implications for Nursing

Our review of scientific literature revealed that comparative evaluations of conceptual frameworks for their applicability to a given topic are rarely published, although researchers often evaluate and compare conceptual frameworks when designing research studies. This paper outlines thought processes to compare usefulness of conceptual frameworks. Therefore, this paper may be of use to researchers designing new studies and administrators and clinicians evaluating results of these studies in multiple fields beyond infection control practices.

Analysis and comparison of frameworks, as described in this paper, may be helpful to assist multidisciplinary projects and/or international collaborations in infection control as well as other fields. Multidisciplinary research necessitates conceptual translation, establishing uniform language and 'common or at least correlated approach to individual questions' (Kessel *et al.* 2008). Collaboration across cultures and healthcare systems also requires mutual conceptual understanding for success. For example, combating the on-going Ebola epidemic requires a coordinated, global effort to maximize effectiveness of isolation precautions and other infection control practices with attention to local health beliefs, resources and disease strains. Evaluating and using a conceptual framework may be ideal to level expectations among stakeholders before beginning a study or intervention.

Regarding isolation precautions, use of a conceptual framework may improve empirical research design, leading to improved clinical practice. In previous studies, it is unclear whether authors did not address confounders or biases because it was impractical or whether these issues were not considered. However, application of one of these conceptual frameworks may have prompted authors to compare 'client characteristics' in the Quality Health Outcomes Framework (or 'host' in the epidemiologic triad) of the pre and post-intervention groups. For example, some previous studies did not report the proportion of the respective sample with immunocompromised status or indwelling devices (Bearman *et al.* 2010, Bearman *et al.* 2007, Cheng *et al.* 2010, Cohen *et al.* 2011), which are known risk factors for infection (Siegel *et al.* 2006). Further, operationalizing the process concept in Donabedian's framework (or 'intervention' in Mitchell's) may have prompted Gbaguidi-Haore *et al.* (2008) to report compliance, Cohen *et al.* (2011) to track compliance consistently across different phases of the study or Cepeda *et al.* (2005) and Cheng *et al.* (2010) to record compliance for all components of the intervention. Detailing structure and processes (or 'environment' or 'system characteristics') would be helpful to understand equipment access, regular provider training and case communication, especially for studies conducted in different healthcare systems. Understanding the representativeness of the sample, level of intervention compliance and system characteristics would help clinicians to determine whether to apply these interventions in clinical practice.

All three conceptual frameworks reviewed in this paper could be used to guide study of isolation precautions, though none are ideal. While the epidemiologic triad of disease does

not contain a clear concept for interventions but is sensitive to pathogenicity and virulence of specific infectious agents, the reverse is true of Donabedian's framework and the Quality Health Outcomes model. As isolation precautions are initiated in response to infection, lack of a pathway by which outcomes influence structure and process may be problematic. In this way, the Donabedian model would not help to address temporality between exposure and outcome, which is a significant challenge in infection control intervention studies (Gasink & Brennan 2009). In contrast, Mitchell et al.'s (1998) recognition of need for multi-level analyses may help researchers to distinguish between individual-level outcomes that trigger isolation precautions and facility-level variables that follow isolation precautions use. Furthermore, The Quality Health Outcomes model also has a strength that differentiates it from Donabedian's framework and the epidemiologic triad of disease: incorporation of system and client characteristics concepts. Hence, the Quality Health Outcomes model may be slightly preferred for nursing studies regarding isolation precautions, depending on outcome(s) of interest and study design.

The strengths and weakness of the three conceptual frameworks indicate they may be better-suited to specific study designs used to evaluate isolation precautions. The epidemiologic triad of disease may be most useful for observational studies, especially cohort studies (i.e., exposure has already occurred (LoBiondo-Wood & Haber 2006)) where there is no need to observe the effects of an intervention, but perhaps a need to capture biological characteristics of the agent (e.g., presence of specific strains or pathogenicity). An example of such a study is Tschudin-Sutter et al., (2010) which assessed risk of developing extended-spectrum Beta-Lactamase-Producing Enterobacteriaceae among roommates of infected individuals (i.e., exposure prior to being moved into isolation precautions) (Tschudin-Sutter *et al.* 2012). Donabedian and Mitchell et al.'s frameworks are more efficient for interventional studies. The dynamic nature of the Quality Health Outcome framework would be well-suited to both mathematical model-based studies where all factors related to isolation precautions are simultaneously influencing others (e.g., cross-sectional analysis) (Chow *et al.* 2011), as well as capturing dynamic responses over time. While neither the Donabedian or Mitchell model has a direct path between outcomes and structure/process or intervention, respectively, Mitchell's framework contains an indirect pathway by which outcomes can influence interventions. Therefore, longitudinal studies may not benefit as much from the Donabedian model as from Mitchell's framework. However, pretest-posttest studies, as are often used to study isolation precautions (Aboelela *et al.* 2006), would not be affected by this drawback.

Limitations—Selecting seminal frameworks by the number of papers citing the original publication underestimated the importance of the oldest and newest frameworks. Publications influenced by a framework point to its associated theory generation, legitimacy and contributions to nursing knowledge (Fawcett & Desanto-Madeya 2013). However, the most used framework is not necessarily the most useful. Further, studies using a framework may not always cite or indicate it in the corresponding publication. This is especially true of the epidemiologic triad of disease, which is not always named as such, despite description of 'host', 'agent' and 'environment' concepts in relation to disease control in many papers

(Stirling 2004). As such, it is impossible to know all the ways these frameworks have been used in research and practice to date.

CONCLUSIONS

Going forward, the authors recommend that researchers carefully consider study design elements needed to determine the effectiveness of isolation precautions using one of the three conceptual frameworks discussed above. Future systematic reviews and meta-analyses should frame data abstraction and quality analysis through the Quality Health Outcomes framework as it incorporates elements that can be sensitive to cultural differences. Cross-cultural sensitivities will be important to interpret outcomes of studies conducted in many different countries, especially outcomes such as psychological adverse events of isolation precautions. Administrators, clinicians and researchers may draw from the critical thinking process outlined here when deciding between conceptual frameworks for study design, policymaking or intervention implementation. Hence, this paper has the potential to facilitate future research, international collaboration and multidisciplinary interaction in infection control and other fields.

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SUMMARY STATEMENT

Why is this research or review needed?

- Evidence regarding the effectiveness of isolation precautions remains weak due to numerous methodological challenges.
- Although infection control is inherently multidisciplinary, nursing practice is an important component; hence, effectiveness research in this field should incorporate nursing perspectives.
- Study design and therefore strength of research findings may be improved through use of a conceptual framework congruent with nursing theory.

What are the key findings?

- Three conceptual frameworks were identified that may be most applicable to guide study design for isolation precautions effectiveness research.
- Which framework can be most useful likely depends on whether the study question necessitates testing multiple interventions, concerns pathogen-specific characteristics and yields cross-sectional or longitudinal data.
- The Quality Health Outcomes framework has the advantages of assuming reciprocal relationships and multi-level analysis and incorporating sensitivity to cultural differences.

How should the findings be used to influence policy/practice/research/education?

- Future research regarding isolation precautions effectiveness should use a conceptual framework such as one of the three identified in this paper.
- This paper outlines a critical thinking process to decide between conceptual frameworks for study design, policymaking or intervention implementation.
- Those reviewing and synthesizing evidence regarding isolation precautions should consider the Quality Health Outcomes model to encourage culturally sensitive data abstraction and quality assessment.

QUESTIONS FOR ANALYSIS**Step 1. Origins of the Nursing Model**

- What is the historical evolution of the nursing model?
- What motivated development of the nursing model?
- On what philosophical beliefs and values about nursing is the nursing model based?
- What strategies for knowledge development were used to formulate the nursing model?
- What scholars influence the model author's thinking?
- What world view is reflected in the nursing model?

Step 2. Unique Focus of the Nursing Model

- What is the unique focus of the nursing model?

Step 3. Content of Nursing Model

- How are human beings defined and described?
- How is the environment defined and described?
- How is health defined? How are wellness and illness differentiated?
- How is nursing defined?
- What is the goal of nursing?
- How is nursing practice described?
- What statements are made about the relations among the four metaparadigm concepts?

QUESTIONS FOR EVALUATION**Step 1. Explication of Origins**

- Are the philosophical claims on which the nursing model is based explicit?
- Are the scholars who influenced the thinking of the model author acknowledged, and are bibliographical citations given?

Step 2. Comprehensiveness of Contents

- Does the nursing model provide adequate descriptions of all four concepts of the meta-paradigm?
- Do the relational propositions of the nursing model completely link for meta-paradigm concepts?
- Is the practitioner given sufficient direction to be able to make pertinent observations, decide that an actual or potential need for nursing exists, and prescribe and execute a course of action that achieves the goal specified in a variety of practice situations?
- Is the researcher given sufficient direction about what questions to ask and what methodology to use?
- Does the educator have sufficient guidelines to construct a curriculum?
- Does the administrator have sufficient guidelines to organize and deliver nursing services?

Step 3. Logical Congruence

- Does the model reflect more than one world view?
- Does the model reflect characteristics of more than one category of nursing knowledge?
- Do the components of the model consistently reflect a logical translation or reformulation of diverse perspectives? Is the model logically congruent?

Step 4. Generation of Theory

- What theories have been generated from the nursing model?

Step 5. Legitimacy of the Nursing Model

- Is the nursing model a useful guide for nursing activities?
- Does evaluation of the use of the nursing model reveal that the content of the nursing model is sound and believable?
- Are education and special skill training required before applying to nursing model in nursing practice?
- Is it feasible to implement practice protocols derived from the nursing model and related theories?
- To what extent is the nurse model actually used guide nurse practice, research, education and administration?
- Does the nursing model lead to nurse activities that meet the expectations of the public and health-care professionals of various cultures and in diverse geographic regions?
- Does application of the nursing model, when linked with relevant theories and appropriate empirical indicators, make important differences in the health conditions of the public?

Step 6. Contributions to Nursing Knowledge and the Discipline of Nursing

- What is the overall contribution of the nursing model to advancement of nursing knowledge the discipline of nursing?

Figure 1.

Framework for Analysis and Evaluation of Nursing Models (Adapted from Fawcett and Desanto-Madeya, 2013).

Figure 2.
The Epidemiologic Triad of Disease (Clark 1954)

Figure 3.
Donabedian's Quality Health Outcomes Framework, Note that the following is sometimes depicted with a separate 'client characteristics' concept leading to/influencing 'processes' (Donabedian 1966)

Figure 4.
The Quality Health Outcomes Framework (Mitchell *et al.* 1998)

Table 1

Identified conceptual frameworks applicable to the study of isolation precautions, presented in chronological order of publication

Framework Name	Source	Description	Constructs Included	PubMed Citations
Epidemiologic triad of disease	Clark 1954	Describes the three categories of factors and their interrelationships that influence epidemics	<ul style="list-style-type: none"> • Agent • Host • Environment * 	247 **
Donabedian's healthcare quality framework	Donabedian 1966	Identifies three factors by which to assess the quality of health care delivery and the linear flow of influence between them	<ul style="list-style-type: none"> • Structure * • Process * • Outcome 	67
Conceptual model of an infection surveillance and control program (ISCP)	Haley et al. 1981	Relates nosocomial infection (a patient characteristic) to all activities performed by an ISCP for the purpose of evaluating those activities' impact on the patient characteristics	<ul style="list-style-type: none"> • Approval by hospital authorities • Sources of program direction • Overall structure and function • Direct action * • Training • Influence of ISCP staff • Potential obstacles • Patient care staff's characteristics * • Patient characteristics * 	1
Quality health outcomes framework	Mitchell et al. 1998	Building on Donabedian, introduces dynamic interrelationships between concepts and an indirect path between intervention and outcomes influenced by the system and client(s)	<ul style="list-style-type: none"> • System • Client • Intervention * • Outcome 	21 ***
Predisposing, reinforcing and enabling factors in education and health diagnosis and evaluation model (PRECEDE)	Mody et al. 2011	Describes the process to implement interventions in high risk groups by health care workers, model proposed specifically in relation to prevention of HAI	<ul style="list-style-type: none"> • Predisposing aspects • Enabling factors • Reinforcing factors • Evaluate outcomes 	3
HAI prevention system framework	Kahn et al. 2014	Specifies system-based components for HAI prevention and mitigation	<ul style="list-style-type: none"> • Infrastructure development * • HAI data and monitoring • Knowledge development * • Adoption of HAI prevention practices * 	0

* Represents concept(s) in which isolation precautions are incorporated

** Includes papers containing Agent-Host-Environment as in Clark (1954), though not cited and/or titled differently

*** Incorporates Mitchell and Lang (2004) and cited articles

HAI = Healthcare associated infections; ISCP = Infection surveillance and control program.

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Table 2
Evaluation of three most-cited frameworks applicable to the study of isolation precaution effectiveness

Evaluation Criteria	Clark (1954)	Donabedian (1966)	Mitchell (1998)
Explication of Origins	Yes. Desire for increased health promotion and disease prevention to meet patient demands in medicine and dentistry stated. Works of numerous named and 'unnamed' authors credited for 'epidemiologic viewpoint' as a lens for framework development (Leavell & Clark 1958)	Yes. Personal experience with individual level physician-client relationship implicated as well as publications for framework development and explication, such as Sheps (1955), among others	Yes. Influences of the goals of Outcomes Measures and Care Delivery Systems invitational conference and work of Donabedian (1966), Holzemer & Reilly (1995), Wilson and Cleary (1995) acknowledged
Comprehensiveness of Content	Incomplete. Nursing inputs/interventions not included in model	Complete. All nursing domains and relational propositions addressed, though not identified as such	Complete. All nursing domains and relational propositions addressed
Logical Congruence	Yes. Consistent with Reaction World View, person-environment and intervention categories of knowledge	Yes. Consistent with Reaction World View, outcomes and interventions category of knowledge	Yes. Consistent with Reciprocal World View, outcomes category of knowledge
Generation of Theory	Yes. Few examples in the literature that use the model to generate nursing theory	Yes. Numerous nursing publications use this framework to generate testable hypotheses	Yes. Multiple nursing publications use this framework to generate testable hypotheses
Legitimacy	Mixed. Few examples found of successful hypothesis testing in nursing, inspired creation of adapted nursing model (Reifsnider 1995)	Mixed. Model has been used to guide nursing research and practice successfully, but has also inspired creation of adapted nursing models (Mitchell <i>et al.</i> 1998, Shield <i>et al.</i> 2014)	Yes. Successful hypothesis testing published without limitations due to the model
<i>Social Utility</i>	Moderate. No education or skills required. Ability to implement protocols derived from model based on expert opinion (Zastrow 2011, Massanari 1989)	High. No education or skills required. Ability to implement protocols	High. No education or skills required. Ability to implement protocols
<i>Social Congruence</i>	Unknown. Usefulness across cultures and geographies not published in nursing	High. Cross-cultural/diverse geographic application published in nursing research (Chen <i>et al.</i> 2007, Closs & Tierney 1993)	High. Applied to nursing care among facilities in diverse geographic locations and with diverse patient demographics (Brooks-Carthon <i>et al.</i> 2011, Shang <i>et al.</i> 2014)
<i>Social Significance</i>	High. Versatility of model yields high applicability in diverse subjects and fields	High. Model is well-integrated into nursing research with high impact on practice	High. Model directed at nursing outcomes with significant influence
Contributions to Nursing Knowledge and nursing Discipline	High. Effective organizing framework though few papers identified using this model to generate theory	High. Breadth of model concepts yield broad applicability in nursing	High. Model has effectively guided nursing activities such as several report card initiatives