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Health Care Interventions and Harm: An Introduction

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In This Chapter

Nurses frequently have to choose among alternative interventions for patients. For example, should we advise new mothers to swab their infants' umbilical cords with water or with alcohol? Should we introduce telephone-based peer support to help primiparous mothers breast-feed longer or should we continue with usual care? If we teach relaxation techniques to patients with chronic pain, will they experience more pain relief than if they use conventional pain medications alone? Will exercise or dietary change reduce the risk of developing diabetes? What are the benefits of screening patients for pressure ulcer development or prostate cancer or of instituting a smoking cessation program? What benefit may people with asthma or diabetes anticipate from learning self-management techniques? Equally important, what short-term or long-term adverse effects could they expect as a result of these interventions?

These questions address two related issues. First, when we implement an intervention, does it result in the intended outcome? For example, do primiparous mothers breast-feed longer when they receive telephone-based peer support? This is an issue of *treatment*. Throughout this book we will use the terms *treatment, therapy, nursing intervention,* and *health care intervention* interchangeably to mean those maneuvers that we, as nurses, engage in (usually in collaboration with others), with the aim of benefiting patients and their families, populations, or communities. Second, what adverse consequences do individuals experience either as unintended deleterious effects of treatment (e.g., increased risk of breast cancer with hormone replacement therapy) or as a result of exposure to a harmful agent (e.g., smoking)? This is an issue of *harm*.

When we address questions of either harm or treatment, we are confronting issues of causation. For example, in healthy men or women, is there a causal relationship between an exposure (e.g., long flight on an airplane) and a particular anticipated outcome (e.g., deep vein thrombosis) or between an intervention (e.g., compression stockings) and an unanticipated outcome (e.g., toe ischemia resulting from an ill-fitting compression stocking in a person with undiagnosed peripheral vascular disease)?

These questions have underlying true answers. If our inferences about the underlying truth are wrong, the consequences may be disastrous. Consider how many lives must have been lost over the course of several hundred years when physicians were convinced that bloodletting was an effective treatment for a wide variety of illnesses. Consider how many postoperative infections occurred when nurses were convinced that preoperative shaving was preventing those very infections.

Why has the health care community made such disastrous blunders, and what can we do to prevent them in the future? The answer lies in health care professionals, including nurses, learning rules of evidence that allow them to differentiate misleading research reports from valid ones. This book provides a practical approach to determining when you can believe study results and when you cannot.

THREE STEPS IN USING AN ARTICLE FROM THE HEALTH CARE LITERATURE

When using the health care literature to answer a clinical question, approach the study using three discrete steps.

1. In the first step, ask "**Are the results of the study valid?**" This question has to do with the believability or credibility of the results. Whether the study provides valid

results depends on whether it was designed and conducted well enough that the study findings accurately represent the direction and magnitude of the underlying true effect. Another way to state this question is: "Are the study methods sufficiently rigorous to ensure that the study results represent an unbiased estimate of the true effect, or are the study methods sufficiently biased to lead to a false conclusion?" If the study methods are rigorous, then the results are worth examining further.

2. In the second step, ask "**What are the results?**" This question considers the size and precision of the estimate of effect. The best estimate of that effect will be the study findings themselves; the precision of the estimate may be superior in larger studies.
3. Once you understand the results, ask yourself the third question: "**How can I apply these results to patient care?**" This question has two parts. First, can you apply the results to patients in your clinical setting? For instance, you should hesitate to provide an intervention if the patient in your setting is too dissimilar from those who participated in the trial. Second, if the results are generalizable to patients in your setting, what is the net impact of the intervention? Have the investigators measured all outcomes of importance to patients? The impact depends on both benefits and risks (adverse effects) of the intervention and the consequences of withholding it. Thus, even an effective intervention may be withheld if a patient's prognosis is already good without it, especially if the intervention is accompanied by important adverse effects.

HEALTH CARE INTERVENTIONS AND HARM: STUDY DESIGNS

Randomized Controlled Trials to Evaluate Nursing Interventions

Researchers have much more control when investigating whether an intervention is effective than when exploring whether an agent causes harm. For instance, they can determine who receives the experimental intervention and who receives the alternative (e.g., no intervention or an inert substance called a placebo). Ideally, they will allocate patients to groups according to a process analogous to a coin flip, called *randomization*, and they will conduct a randomized controlled trial. Through the process of randomization, the investigators aim to create groups that are similar in all respects except exposure to the intervention. In this way, at the end of the study, any differences between the groups can be attributed to the intervention.

Observational Studies to Assess Harm

By contrast, researchers looking at issues of harm generally do not have this sort of control. They cannot randomly allocate people to smoke or not smoke or to live in high- or low-pollution environments or in spacious or overcrowded settings. As a result, investigators use observational study designs. In one type of observational study design called a *cohort study*, the investigators follow groups of study participants who, as a result of preference or circumstances, either have or have not been exposed to a harmful stimulus. Investigators follow the study participants forward in time to determine how many in each group experience the outcome of interest or target outcome (e.g., follow up a group of laborers who work near coke ovens and a group of laborers who

do not for 20 years to compare the occurrence of genitourinary cancer). Alternatively, researchers may conduct a *case-control study,* in which they select persons who have already suffered the target outcome and persons who have not suffered the target outcome and compare the extent to which the two groups were exposed to the agent suspected of causing harm (e.g., select two groups of men, one with genitourinary cancer and one without, and compare their past exposure to coke ovens) (see Chapter 5, Harm).

APPLYING APPROPRIATE CRITERIA

The conclusions or inferences we can draw from studies investigating harm are generally much weaker than those drawn from studies of health care interventions. As a user of the nursing and health care literature, you must apply different criteria to studies evaluating nursing interventions from those investigating potentially harmful exposures. We therefore provide separate chapters on the issues of treatment (Chapter 4, Health Care Interventions) and harm (Chapter 5, Harm).

There are exceptions to this general rule. Sometimes the harmful exposure may be a health care intervention, such as a piece of equipment (e.g., a pressure-relieving bed) or a drug, and researchers will perceive the suspected harmful effect as occurring quickly and frequently. Under these circumstances, investigators may be able to use the study design usually associated with treatment (i.e., randomized controlled trial) to determine whether a causal relation exists between an intervention and an adverse effect. This was the case in the recent randomized controlled trial that was stopped early because combined hormone replacement therapy was found to increase the risk of breast cancer.[1] Similarly, there may be no randomized trials available—or even feasible—that evaluate a particular health care intervention. Investigations of rare conditions, community interventions, care delivered in different hospitals (see Chapter 17, Health Services Interventions), or the quality of care within a hospital (see Chapter 10, Moving From Evidence to Action Using Clinical Practice Guidelines) do not easily lend themselves to randomized trials. For example, randomizing health care systems to rely more on nurse practitioners or clinical nurse specialists seems improbable, at least for the foreseeable future.

In situations when nurses find that randomized trials of certain nursing interventions are unavailable, they need to rely on cohort and case-control studies—the strongest evidence available. In doing so, nurses must apply the appropriate criteria for the evaluation of these studies, criteria that ordinarily would be associated with investigations of potentially harmful exposures. When relying on cohort or case-control studies to address issues of therapeutic benefit, however, nurses must bear in mind that the strength of any inferences about the causal relation between an intervention and an outcome is much weaker than when evidence comes from a randomized trial.

Reference

1. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA*. 2002;288:321-333.