
Knowledge Translation Consensus Conference: Research Methods

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Abstract

The authors facilitated a workshop session during the 2007 *Academic Emergency Medicine* Consensus Conference to address the specific research methodologies most suitable for studies investigating the effectiveness of knowledge translation interventions. Breakout session discussions, recommendations, and examples in emergency medicine findings are presented.

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The transfer or translation of knowledge derived from well-designed, quality studies has long been a challenge. Understanding how and why knowledge is transferred is vital to getting high-level evidence to the patients in the emergency department. However, the specific study of interventions designed to facilitate knowledge translation (KT) has not been a main focal point of emergency medicine (EM) researchers

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in the past. Designing a study of knowledge transfer is not within the experience and training of most EM investigators and deserves special consideration.

A variety of study designs can be used to evaluate KT interventions, such as guideline implementation strategies. For this reason, the Society for Academic Emergency Medicine's peer-reviewed journal, *Academic Emergency Medicine*, sponsored a consensus conference to address KT in EM, specifically establishing a research agenda and guide map for evidence uptake. This occurred on May 15, 2007, in Chicago, IL. This workshop session focused on the evaluation of methodologies in KT research and, in particular, which methodologies should be used to identify the most effective strategies for bridging the research-to-practice gap in EM. Before the consensus conference, an Internet-based communication tool (Google Group) was used to discuss potential content and set the agenda for this breakout session. The authors then facilitated a workshop session during this conference to address the scientific methods available to investigate KT. Breakout session discussions, recommendations, and examples in EM findings are discussed in the following sections.

OBSERVATIONAL (DESCRIPTIVE) STUDIES

The major study designs used in observational studies are case-control, cross-sectional, and cohort.¹ Observational studies have a variety of strengths. They are typically less costly than experimental study designs, can generate hypotheses for further testing, and provide insight into the feasibility and design of randomized controlled trials (RCTs).² Observational studies are useful when logistical and ethical constraints make conducting more rigorous investigations difficult or infeasible. They

are especially useful when RCTs are not available and oftentimes can help to demonstrate the “real world” effectiveness of therapies outside the highly controlled setting of an RCT.³ In the context of KT, observational studies may be useful in providing additional insight into the process of behavioral change.² Moreover, observational data are often needed to establish baseline rates of adherence to evidence-based practices and the need for KT to narrow the research-to-practice gap.

Although associations measured in observational studies may reflect causal relationships, their magnitude and direction may be influenced by bias, confounding, and chance.¹ Selection bias is one of the most important limitations. When patients and providers self-select treatments, the treatment and control groups may differ in ways other than the interventions being compared, leading to biased estimates of treatment effects.² Statistical techniques such as analysis of covariance and propensity score methods are often necessary to create an analysis that resembles that which would have occurred had the patients been randomized.^{3,4} Despite these methods, residual confounding of the treatment effect often remains.⁵

Recommendation

Observational research is foundational to establishing the research-to-practice gap and the need for KT. It is useful for hypothesis generation and establishing the need for more rigorous evaluations. Selection bias and confounding associated with observational study designs are substantial methodological limitations. Investigators conducting observational research for KT should be cautious when conducting statistical analyses and ensure that data on the most important patient characteristics are collected. When feasible, more rigorous study designs should be used.

QUASI-EXPERIMENTAL STUDY DESIGNS

Opportunities often arise within individual organizations to evaluate interventions of evidence-based improvement strategies before and following implementation. The evaluation of these strategies is tempting for at least two reasons: 1) to assess whether the strategy is having the intended effect locally and 2) to assess factors that are associated with the intended effect that may generalize externally to a broad variety of locations and environments. The development of a methodological approach, therefore, should serve both purposes equally well. Unfortunately, though, this pretest/posttest intervention style does not necessarily include random selection or assignment of participants and has, therefore, historically been referred to as “quasi-experimental.”⁶ Although there are several logistical features that make this design attractive, there are significant limitations to consider when interpreting results of this methodology.

This study design does not control important factors unrelated to the intervention itself, such as events that take place simultaneously with the intervention or at least between premeasure and postmeasure, or for the growth (maturity) of the members between measures. In addition, this design is particularly susceptible to the Hawthorne effect, which increases the apparent effect of an intervention due to individuals who change their behav-

ior because they know they are being observed. For example, efforts to improve care of a given disease entity, through a specific intervention, are often presented in a pre/post format. However, most of the programs are designed to implement guidelines that are being promulgated by a variety of sources. The results of these studies are inherently difficult to interpret, which calls into question the generalizability to other settings.⁷

There are several approaches possible to improve upon the single-group pretest/posttest study design. First, when it is impossible to randomize an intervention or to identify an appropriate comparison group, a method to improve the interpretability of the effect of the intervention is to obtain several preintervention measurements and an equivalent number of postintervention measurements. This study design is referred to as an interrupted time series design. Essentially, the value added by these additional measurements provides the ability to identify trends in the outcome measure that would go unnoticed in a single pretest/posttest design. For example, there is an apparent increase in the outcome measure from the pre to post measurements (Figure 1); however, unbeknownst to the researcher, the change is merely part of a trend, which is represented by the dotted line. A time series study would allow for detection of this trend.

A second approach to improve the interpretability of the pretest/posttest study design for evidence of KT is to compare the results of a group that received the intervention with those of a group that did not receive the intervention. This design is referred to as a “nonequivalent pre-post design” and can provide important interpretations to the effect of the intervention. However, that is not to say that there are not considerable problems with the design. The ability to obtain an adequate control group similar to the intervention group is often problematic. This dissimilarity between groups is often undetectable, and these differences could potentially impact the effectiveness of the intervention differently. An important component of both time series and untreated control group designs to increase validity is to blind the outcome assessment to the period of study.

Recommendation

Single pretest/posttest study designs have many limitations and should be avoided. To improve the interpretation of results obtained from single-group studies of KT interventions, it is preferable to include several pre and

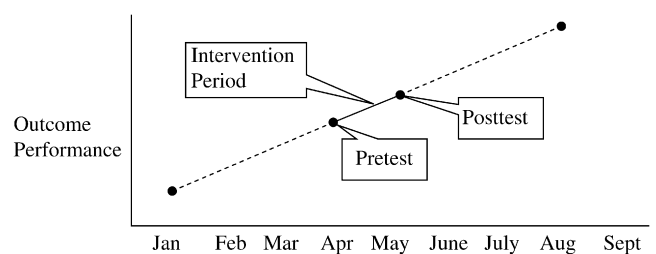


Figure 1. Illustration of interpretation hazards for single pretest/posttest study designs. The dotted line represents an unmeasured secular trend that could be detected in a time series design.

post measures of the outcome in a time series design fashion. Studies of nonrandomized comparison groups are inherently limited due to the lack of confidence that one can place in baseline comparison of groups; however, they are an improvement from single pretest/posttest study designs. Efforts should be made to determine if competing sources of knowledge were similar in all groups.

Examples and Opportunities in EM

Due to the increasing quantity of guideline adherence initiatives and other KT issues, there will undoubtedly be many opportunities for the evaluation of the effectiveness of KT interventions in a pre/post fashion. For example, a pre/post study was conducted at two hospitals to determine whether implementing the Agency for Health Care Policy and Research's unstable angina practice guideline improves emergency physicians' decision-making in patients with symptoms of possible acute coronary syndrome, including those for whom the diagnosis of unstable angina is uncertain.⁸ In this study, the investigators blinded the physician reviewers who assigned the cardiac outcomes and also performed serial measurements for three months before the intervention and six months after the intervention.

RANDOMIZED TRIALS

Patient RCTs are appropriately considered the ideal experimental design for evaluating the effect of medical interventions. They are able to control for both known and unknown bias inherent in nonrandomized studies.⁹ However, patient randomized trials present certain problems when applied to KT research. Providers required by a study protocol to use different resources for patient care based on which group the patient is randomized to are likely to use some or all of the experimental protocol for care of the control group. This bias, called contamination, may minimize the actual effect of the experimental intervention.²

One solution to the problem of contamination is to use a cluster randomized strategy.^{10,11} This approach involves randomizing groups or clusters of providers to differing KT interventions. Randomization of the intervention occurs at the group level, while patients within groups receive the same or similar care. If randomization is performed at the hospital level, the concern for contamination can be minimized. All the patients at a given hospital in a study receive the same KT intervention, minimizing the chance for contamination from providers using the experimental intervention on the control group.

There are several areas of concern with cluster randomized trials. First, there is a significant impact on the statistical power of the study. Depending on the variance among clusters, sample size to detect a significant effect can be more than double that of a patient randomized study.¹² In cluster randomized trials, sample size needs to be corrected for the design effect relating to the number of clusters, the average number of patients per cluster, and the statistical extent of clustering (intracluster correlation). In general, increasing the number of clusters has greater impact on power than increasing the number of patients per cluster.^{13,14} In addition, factorial-designed cluster random-

ized studies allow for assigning different clusters to more than one intervention, so that clusters will receive either no intervention, intervention A, intervention B, or intervention A and B. This allows for comparison of more than one intervention at a time without significantly increasing the sample size.⁹ Analyses of cluster randomized studies also need to account for the fact that patients within clusters can no longer be considered independent of one another, because patient management is similar within clusters and dissimilar from patients in other clusters.^{15,16}

Correcting for the Hawthorne effect (the nonspecific beneficial effect of taking part in research) can be difficult in KT research. The balanced incomplete block design can correct for this phenomenon.⁹ In this design, clusters receive one of two interventions and then act as the control for the other intervention, so that all clusters are taking part in research.¹⁷ However, data analysis for this strategy can become more complicated.

Cluster randomized trials may also, but not necessarily, require a large capital investment and may not be feasible in some settings. Research networks may be one solution to this problem. With networks, institutions can combine resources, use standardized protocols, and share large amounts of data. Reporting of randomized trials has been variable and flawed in the past. Randomization strategies and enrollment criteria are often underreported in the literature. Researchers conducting KT randomized trials should consider using Consolidated Standards of Reporting Trials (CONSORT) guidelines where appropriate to assist in quality reporting of results.¹⁸ Despite their limitations and challenges to completion, the cluster randomized design is generally considered the ideal approach to investigating the effect of a KT intervention.

Recommendation

Randomized trials are a robust study design for KT interventional research, with the ability to determine a causal relationship between a KT intervention and a quality-of-care outcome. Cluster randomized trials, in particular, represent an ideal means to evaluate the effect of KT interventions. Methodological issues of ensuring adequate sample size must be addressed, but there remains no more valid way to evaluate interventions on health care behavior.

Examples and Opportunities in EM

There are numerous areas for potential KT research in EM using cluster randomized trials, particularly in the area of guideline implementation research. Yealy et al.¹⁹ conducted a cluster randomized trial to evaluate three different guideline implementation strategies to improve compliance with community-acquired pneumonia practice guidelines. Their multicenter study was randomized at the hospital level to minimize the risk of contamination from differing guideline implementation strategies. They randomized hospitals to one of three guideline implementation strategies designed to measure the effects of interventions of varying intensity. They were able to demonstrate a significant increase in appropriate outpatient treatment of low-risk patients with community-acquired pneumonia at hospitals randomized to receive a high-intensity guideline implementation intervention versus a low- or moderate-intensity intervention.

QUALITATIVE METHODS

Qualitative research is one of the two major approaches to research methodology in the social sciences. Qualitative research involves collecting, analyzing, and interpreting data by observing what people do and say. This approach to research focuses on the meanings, concepts, definitions, characteristics, metaphors, symbols, and descriptions of things. In general, qualitative research generates rich, detailed descriptions that contribute to an in-depth understanding of the phenomena of interest. While quantitative research techniques are more suited for testing specific hypotheses and defining causal relationships between specific interventions and outcomes, quantitative and qualitative research methods can complement each other because they generate different kinds of knowledge that are useful to clinical practice. Questions that arise when trying to understand why gaps exist between what we know from best research evidence and what we do in clinical practice as well as questions that may be relevant when trying to understand the successes and failures of an evidence implementation strategy may benefit from alternative approaches, such as qualitative methods. A debate of the differences between quantitative and qualitative research methods is beyond the scope of this article; however, the main feature that distinguishes qualitative from quantitative research lies in the nature of the data derived and the analytical process associated with it.

The importance of qualitative research is reflected in the fact that the practice of medicine is far more complex than the purely scientific and mechanistic approaches to pathologic disease states might suggest. Thus, the strength of qualitative data is that it is rich and holistic with strong potential for revealing complexity nested in a real context. There are important questions about the human experience and social interactions that influence much of medical care and that require interpretive or qualitative research techniques to understand well. Qualitative research enables us to make sense of the world around us, to describe and explain the social work, and to develop explanatory models and theories.

Qualitative research can answer the questions of what, why, and how, around poorly understood or complex behaviors in medicine. Qualitative research can lead to the development of theory, whereas quantitative research tests extant theory. As it pertains specifically to KT in EM, qualitative research can advance our understanding of the barriers and facilitators to KT, as well as help to disentangle confounding effects in intervention studies. Furthermore, qualitative research can help us to understand why specific evidence-based KT interventions were not successful. It is just as important to understand why an intervention did not work as it is to understand why an intervention was successful.

An important distinction is worth making between survey-based research and qualitative research. While both can yield information on perceptions about barriers and facilitators to evidence uptake, for instance, the contribution of qualitative research comes in the rich description of these factors. Approaches for the critical appraisal of qualitative research have started to be published in the literature; consequently, compelling debates are emerg-

ing in the literature as to the contribution of qualitative research to systematic reviews, for instance.²⁰

Recommendation

Qualitative research is an important technique that should be used for advancing KT in EM. Participant observation, focus groups, and interview techniques are ideal for data collection, while validated qualitative data analysis methods also need to be utilized. Specifically, qualitative research can enrich our understanding of the KT process and potentially lead to the development of KT interventions for EM contexts.

THEORETICALLY INFORMED KT RESEARCH

High-quality clinical and health services research is frequently informed by and conducted using structural frameworks or theoretical models. A theory is “a coherent and non-contradictory set of statements, concepts or ideas that organizes, predicts and explains phenomena, events, behavior, etc.”²¹ Theoretical models are created and used in exploring and testing hypotheses relating to complex scientific and social problems. KT research can benefit from framing research based on theory derived from a variety of disciplines.²¹

Closely related to KT research are numerous theoretical models developed in an attempt to explain human behavior at the individual level. For example, the theory of planned behavior²² has been used to explain behavioral change, as has Rogers’ diffusion of innovation model^{20,23} to examine the process of dissemination, implementation, and uptake of innovative models of care. A theoretical model may be implicit or explicit; explicit theories were mentioned previously. Implicit theories are personal constructions about particular phenomena, and while they may be valid, they are more difficult to generalize and replicate. Explicit theories have the advantage of transparency, reproducibility, and generalizability.²¹

Knowledge translation research evaluates different levels in the process, such as individual-level behavior (patient and provider behavior) and system-level behavior (community-based and health care systems). It also examines at the micro level (person/family level or provider practice level) and at a macro level (health and social policy).²¹ Because KT research encompasses a broad range of observational studies and interventions across these various levels, theoretical models from various disciplines may be used to frame the research. Thus, theoretical models developed and used in other medical and nonmedical disciplines might be used in KT research depending on the type of study or intervention tested. Use of theoretically informed interventions can allow for a more thorough examination of the multifaceted components of a problem or intervention. When used appropriately, each component of the model can be examined and evaluated and lead to a greater understanding of the individual components of a problem or intervention.

Recommendation

This panel recommends that KT intervention research methods should, when possible, explore, use, or test theory-driven models of behavior and behavioral change to maximize the internal validity of the study and the

reproducibility and generalizability of research findings. We further suggest that KT research include a multidisciplinary approach to explore and test theoretical models from various disciplines to better understand the complex process of KT at various intervention levels and among different target populations.

CONCLUSIONS

This article provides important recommendations to consider when developing studies to evaluate the effect of KT interventions. The careful consideration of these recommendations may help facilitate transcending the research-to-practice gap that currently exists in EM.

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