

JOURNAL SERIES:

Statistics Review Part 9: Research in Policy

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This article discusses the roles of studies in researching health care policy as well as transforming research into meaningful health care changes.

Objectives

1. Discuss the role of randomized controlled trials when researching health care policy
2. Identify seminal studies evaluating health care delivery and financing
3. Describe steps that may be taken to transform research into meaningful health care changes

Research is conducted not only to help determine the most efficacious medicines and treatments, but it is also used to determine the best policies and methods of health care delivery. Health care in the United States is now being impacted by health care reforms such as the Affordable Care Act, which allocated \$10 billion in funding to research the most effective ways to deliver health care.¹ Given the ever-evolving world of health care, it is important to take a step back and look at how evidence is provided to help guide health care policies.

Methods of Health Care Policy Research

Researching policies for health care is challenging. Randomized controlled trials (RCTs) are the gold standard in medical research, due to their rigorous methodology (Table 1.). However, these types of studies are rarely conducted in policy research due to the high cost, level of difficulty to perform, and ethical issues that may be encountered. For example, when evaluating policies related to health insurance coverage, it may not be ethical to randomize patients to having no health care coverage at all. Additionally, individuals who are randomized to control groups (i.e., do not receive coverage) tend to drop out of studies, making it difficult to form reliable conclusions.

Due to limitations with using RCTs,

observational studies are more commonly used in health care policy research. These studies typically compare patient and economic outcomes before and after a policy change is implemented, and do not randomly assign subjects to treatment and control groups. This type of study allows for broader inclusion criteria and provides more real world results applicable to a broader population. These studies are also considerably cheaper to conduct than RCTs, which allows researchers to include more patients and follow them for a longer period of time, especially if a health care study is retrospective.

Studies of Health Care Delivery and Financing

Several important studies have been conducted to help shape how health care delivery and financing may be improved. The RAND Health Insurance Experiment (HIE) was a long-term randomized experimental study of health care costs, utilization, and outcomes, and was conducted between 1971 and 1982.² Participants in the Rand HIE were randomized to one of several different coinsurance amounts for health care services, and the resulting health care utilization and outcomes were compared between the various groups. The study found that higher cost sharing amounts reduced the use of health care services compared to those with little or no cost sharing, marked by decreases in both prescriptions and physician visits. The RAND HIE study has long been considered the seminal study on the impact of cost sharing on health care use.

A more recent study is the Oregon Health Insurance Experiment, which used a randomized experimental design to evaluate the impact of a Medicaid expansion program on the health care costs, utilization, and clinical outcomes of low-income adults.³ Results of this study have

found that Medicaid enrollment resulted in increased emergency department visits, physician visits, and prescriptions, leading to an overall increase in health care costs. However, no short-term improvements were seen in patient health outcomes. The findings from this study have been highly controversial, as they raise questions about the effectiveness of state Medicaid programs.

These randomized controlled trials continue to shape discussions over health care policy and health care reform. However, both of these were large studies which may not be realistic for future research. As a result, many health care policy studies rely on smaller-scale RCTs or on large observational studies looking at new solutions or challenging old ideas. These studies may not individually revolutionize health care, but the accumulation of knowledge from multiple studies can lead to the identification and development of best practices.

In pharmacy, policy research has helped derive new practice models and approaches to managing patients' health care. With a heavy reliance on observational studies or small-scale RCTs, policy research projects test and evaluate new pharmacy practice models, such as Medication Therapy Management. One such example is a study conducted in Iowa which demonstrated improvement in blood pressure control with physician and pharmacist collaboration.⁴ Another example is a study conducted in Wisconsin evaluating a team-based approach to caring for black patients with hypertension that involved pharmacists and technicians resulting in increased adherence to refill medications and better blood pressure control.⁵ These studies of innovative programs provide evidence to policy makers of the pharmacist's value in patient care.

Future Research Opportunities

The Affordable Care Act created the Centers for Medicare & Medicaid Services

TABLE 1. Pros and Cons of Randomized Controlled Trials in Health Care Policy and Delivery Research

<i>Pros</i>	<i>Cons</i>
<ul style="list-style-type: none"> • Eliminates bias • All unknown and known variables evenly distributed between the groups • Results suggest causality • Most reliable type of study 	<ul style="list-style-type: none"> • May not be ethical to randomize patients • Expensive • May not represent the “real world” • Difficult to perform

(CMS) Innovation Center to help explore the most effective models of health care delivery and financing. The stated goals of the Innovation Center are to test new payment and service delivery models, evaluate results, advance best practices, and engage a broad range of stakeholders.¹ However, the Innovation Center has been criticized for relying heavily on demonstration projects (small-scale, non-randomized pilot projects that test new ideas) rather than on RCTs.⁶ Opponents believe the opportunity to improve health care delivery is not being matched with the utilization of gold standard methodology, which would provide the soundest evidence for reorganizing our health care system. In contrast, others argue that demonstration projects provide evidence of policies being implemented in the real world. Though demonstration studies are not as rigorous as RCTs, they allow for the development of hypotheses that may be tested in future studies. One example of a demonstration project funded by CMS is the Wisconsin Pharmacy Quality Collaborative, an initiative of the Pharmacy Society of Wisconsin that aims to connect community pharmacists with patients, physicians, and health plans to improve the quality and reduce the cost of medication use across Wisconsin.⁷

Implementation of Research into Policy

Though a study for delivering health care may have results showing potential progress in health care delivery or cost savings, implementation of these processes

into practice are not always seen. Some studies showing significant cost savings that have been published in leading journals have not been implemented into our health care practices on a larger scale. Translating quality research into impactful changes in health care nationally may prove challenging. One essential component of public health research is understanding and advocacy by decision makers.

Because health care policy change often rests in the hands of policy makers, researchers and clinicians need to better communicate and disseminate impactful changes in order for it to be implemented into health care practices nationwide. AcademyHealth has published step-by-step advice for researchers which pharmacists can adapt on how to navigate dissemination and implementation of published research (Table 2).⁸ These guidelines may also be helpful to pharmacists who want to make patients, legislators, and other stakeholders aware of innovative programs or practice models they are using to improve patient care. The first steps are to define the target audience and have open discussions with policymakers to outline the need for pharmacy services or research and how these needs can best be addressed. This will also help develop relationships with important stakeholders to bridge the gap between research and actual real world changes. Pharmacists and researchers must then frame their findings in a way that is meaningful to the stakeholders. It is also important to keep in mind that policy makers may not be experienced in the health care field, so using simple language to convey results and ideas may allow for

better understanding of how to implement research findings. The final step is to develop a dissemination strategy, such as using not only journals to publish results, but also using social media and news outlets.

Whether research is a randomized controlled trial, or a demonstration project such as the WPQC initiative, it is important that good ideas and results are disseminated to implement meaningful change. The current time of changing health care has given pharmacy a window of opportunity help shape future health care delivery and practice. Pharmacists and pharmacy researchers must take this opportunity and meet it with preparation and continual innovation to enhance health care policy for future generations to come.

Summary

This article reviewed why randomized controlled trials are often difficult to conduct when researching health care policy, as well as past and present studies focusing on the delivery and financing of health care. Other research such as observational studies or demonstration projects may help provide evidence under real world conditions. Once high quality and meaningful research is conducted, it is important to translate this into impactful changes by involving and actively engaging policy makers. ●

Practice Questions

- What is the gold standard research methodology to develop health care policy?
 - Case control study
 - Cohort study
 - Demonstrative study
 - Randomized controlled trial
- The Wisconsin Pharmacy Quality Collaborative is an example of what type of study that helps research health care delivery?
 - Randomized controlled trial
 - Demonstrative study
 - Case control study
 - Cohort study
- Which of the following is important for pharmacists to do when trying to demonstrate the value of pharmacists' patient care services?
 - Develop a dissemination strategy

TABLE 2. Steps to Implement Research into Health care Policy⁸

<ol style="list-style-type: none"> 1. Define the target audience 2. Have open discussions with policymakers 3. Build stakeholder relationships 4. Identify meaningful findings to stakeholders 5. Develop a dissemination strategy (social media, national journals, news outlets)

- b. Reach a target audience
- c. Build relationships with stakeholders
- d. All of the above are important to demonstrate the value of pharmacists

Answers:

1. **d** Randomized controlled trials are the gold standard methodology for health care research.
2. **b** Pharmacy Society of Wisconsin initiated this program which serves as a demonstrative study to improve quality of health care in Wisconsin.
3. **d** All of the above answers are correct, as multiple steps need to be taken to most effectively demonstrate the value of pharmacists.

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