Annals of Global Health
VOL. 82, NO. 6, 2016

ISSN 2214-9996/$36.00
http://dx.doi.org/10.1016/j.aogh.2016.10.013

ORIGINAL RESEARCH

Legal and Regulatory Barriers to Reverse Innovation

Virginia Rowthorn, JD, LLM, Alexander J. Plum, MPH, CHES, John Zervos, JD
Baltimore, MD and Detroit, MI

Abstract

BACKGROUND Reverse innovation, or the importation of new, affordable, and efficacious models to high-income countries from the developing world, has emerged as a way to improve the health care system in the United States. Reverse innovation has been identified as a key emerging trend in global health systems in part because low-resourced settings are particularly good laboratories for low-cost/high-impact innovations that are developed out of necessity. A difficult question receiving scant attention is that of legal and regulatory barriers.

OBJECTIVES The objective of this paper is to understand and elucidate the legal barriers faced by innovators bringing health interventions to the United States.

METHODS Semistructured qualitative interviews were conducted with 9 key informants who have directly participated in the introduction of global health care approaches to the United States health system. A purposive sampling scheme was employed to identify participants. Phone interviews were conducted over one week in July 2016 with each participant and lasted an average of 35 minutes each.

FINDINGS Purely legal barriers included questions surrounding tort liability, standard of care, and concerns around patient-administered self-care. Regulatory burdens included issues of international medical licensure, reimbursement, and task shifting and scope of work challenges among nonprofessionals (e.g. community health workers). Finally, perceived (i.e. not realized or experienced) legal and regulatory barriers to innovative modalities served as disincentives to bringing products or services developed outside of the United States to the United States market.

CONCLUSIONS Conflicting interests within the health care system, safety concerns, and little value placed on low-cost interventions inhibit innovation. Legal and regulatory barriers rank among, and contribute to, an anti-innovation atmosphere in healthcare for domestic and reverse innovators alike. Reverse innovation should be fostered through the thoughtful development of legal and regulatory standards that encourage the introduction and scalable adoption of successful health care innovations developed outside of the US, particularly innovations that support public health goals and do not have the benefit of a large corporate sponsor to facilitate introduction to the market.

KEY WORDS innovation, legal, healthcare, health system, barriers, regulation

Conflict of Interest Statement: The authors have no conflicts of interest to declare. Ethics committee approval was not solicited for this study.

From the Francis King Carey School of Law, University of Maryland, Baltimore, MD (VR, AJP, JZ); Global Health Initiative, Henry Ford Health System, Detroit, MI (VR, AJP, JZ). Address correspondence to V.R. (vrowthorn@law.umaryland.edu).

Annals of Global Health, VOL. 82, NO. 6, 2016
November–December 2016: 991–1000

INTRODUCTION

Although innovation is a hallmark of our species and therefore just as old, the term is a buzzword in most professional fields today and used to denote new ways of thinking that have the potential to improve people's lives and, in some cases, impel important societal change.[1] Over the past 20 years, the global health and development fields have embraced the concept of innovation as both a process and an outcome.

Reverse innovation, or the importation of new, affordable, and efficacious models to high-income countries from the developing world, is an offshoot of the innovation movement and has emerged as a way to improve the health care system in the United States (US). The opportunity for reverse innovation to bring needed solutions to a country struggling with enormous health care costs, inefficiency, and inequity, has led to increased interest in this model.

However, there are multiple barriers to implementing global innovations in the US, including legal and regulatory barriers relating to reimbursement, standard of care, and scope of practice, among other things. Virtually no research has been conducted to identify and study legal and regulatory barriers to reverse innovation in the United States. This paper reports on a survey of key global health informants to identify barriers to reverse innovation and initiate the process of making recommendations to facilitate the global spread of good ideas. Where legal and regulatory requirements threaten to stand in the way of global innovations, recommendations are needed to move forward with advocacy efforts for policy change that acknowledge the critical balance between safety and innovation.

BACKGROUND

In the development field, innovation has been defined by the US Agency for International Development (USAID) as "a new solution with the transformative ability to accelerate impact" that involves "new social and business models or policy, creative financing mechanisms, or path-breaking improvements in delivering essential services and products" to reach "sustained, scalable solutions to the world's complex problems."[2]

Major global health organizations, including the Gates Foundation,[3,4] the Program for Appropriate Technology in Health (PATH),[5] and USAID's Global Development Lab, have embraced innovation since the mid-2000s as a critical interprofessional approach to understanding and reducing health disparities and strengthening health systems in communities across the globe.[6] These and other organizations take multiple approaches to support innovation, including providing financial support to innovations developed in the US, investing funds to identify and catalyze innovation in developing countries, and creating educational pathways to develop the next generation of innovators, and identifying innovations likely to accelerate progress toward the health targets of the Sustainable Development Goals.[7]

In large part, these efforts are focused on the promise of innovation to improve the health of communities in low-resourced countries. However, the innovation movement has dovetailed with the growing awareness that global health interventions should be used to improve health and health care in the US.[8] This is particularly true where domestic health challenges share commonalities with challenges in the developing world. The US has historically not looked outside its borders for health care advances. However, as the world becomes more global and the value of other nations' practices become better known, and perhaps because the Affordable Care Act (ACA) opened widespread dialog regarding problems with the US health care system, there is growing recognition of the need to seek solutions beyond our borders. The concept of adapting global innovations for use in the Global North is often referred to as reverse innovation.

The term "reverse innovation" was first coined by Vijay Govindarajan, former chief innovation consultant for GE, to describe ideas "seen first or used first in the developing world before spreading to the industrialized world."[9] It was in the business setting where the profitability of looking abroad to identify innovative ideas that could be commercialized in domestic markets was first demonstrated. Pointing out how low-resource settings look for "value for many" instead of "value for money," Govindarajan suggested that innovators in these settings must think in radically unconventional ways about how to achieve acceptable quality at a very low cost. In applying the term to the health care sector, DePasse and Lee[10] define reverse innovation practically as "learning from and investing in poorer settings as one way to tackle problems in wealthier settings that require out-of-the-box solutions."

Reverse innovation has been identified as a key emerging trend in global health systems not just because good ideas exist beyond our borders, but because low-resourced settings are particularly good laboratories for low-cost/high-impact