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Journal
Healthcare, 2(3)

ISSN
2213-0764

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Publication Date
2014-09-01

DOI
10.1016/j.hjdsi.2014.05.002

Peer reviewed

Published in final edited form as:
Healthc (Amst). 2014 September 1; 2(3): 170–172. doi:10.1016/j.hjdsi.2014.05.002.

The Peltzman effect and compensatory markers in medicine

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Abstract

Unintended consequences of health care interventions are unavoidable. For example, computerized order entry systems, implemented to reduce prescription errors, catalyze novel errors of their own, with providers unexpectedly relying on these systems to provide default dosing information rather than locating appropriate treatment guidelines. We argue that unintended behavioral responses by patients and physicians to health care interventions may explain why certain health care interventions that seem logical and foolproof fail to demonstrate real-world benefits. We argue that compensatory markers which measure behavioral responses in clinical trials should be implemented to better understand why real-world benefits fail to materialize.

Unintended consequences of systems interventions in health care are unavoidable. For example, computerized order entry systems, implemented to reduce prescription errors, have been shown to catalyze novel errors of their own, in this case, providers unexpectedly relying on these systems to provide default dosing information rather than locating appropriate treatment guidelines.[1] Similarly, increases in quality measurement, public reporting, and pay-for-performance have led to unintended consequences among providers. For example, age-based quality measures for colorectal cancer screening have been associated with dramatic declines in screening of men above the age 75 cutoff, with the unintended consequence that 76-year old men who are in significantly better health than 74-year old men are substantially less likely to receive screening.[2] Public reporting for percutaneous coronary intervention (PCI) outcomes in patients with acute myocardial infarction has led to unintended declines in the propensity of providers to perform PCI on

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Authors contributions: Drs. Prasad and Jena contributed to the design and conduct of the study, data collection and management, analysis interpretation of the data; and preparation, review, or approval of the manuscript.

high-risk patients for whom outcomes would be expected to be worse.[3] Unintended effects such as these reflect a behavioral response by providers to an intervention, which may mitigate the intent of the intervention itself. These unanticipated responses may explain why certain health care interventions that seem logical and foolproof fail to demonstrate benefits in real-world studies.

In 1975, University of Chicago economist Samuel Peltzman first described the phenomenon of compensating behavior – often termed the ‘Peltzman effect’ or in epidemiology, “risk compensation” or “risk homeostasis.” In his classic analysis of automobile safety regulation,[4] Peltzman argued that federally mandated improvements in U.S. automobile safety in the 1960s (e.g., seat belts for all occupants, energy-absorbing steering columns, dual braking systems) failed to reduce highway safety fatalities due to offsetting increases in driver risk taking behavior. Although Peltzman's original analysis was controversial, a number of studies have since confirmed similar findings related to automobile safety. [5,6] For example, a recent analysis of Munich taxi drivers examined taxis with and without anti-lock breaking systems (ABS) and showed that drivers who operated vehicles with ABS created more traffic conflicts, such that ABS cars offered no clear benefit.[5]

The Peltzman effect has also been used to explain the unintended consequences of a number of health care interventions. For example, efforts to curtail smoking by raising state cigarette taxes have been met by smokers increasing use of cigarettes with elevated levels of tar and nicotine.[7] Unintended consequences of policies have not always involved compensating behavior among those directly targeted by those policies either. For instance, mandatory helmet laws have had a mixed impact on cyclist mortality, partly explained by compensating behavior by motorists who pass closer to cyclists when helmets are worn.[8]

An important but unrecognized implication of the Peltzman effect is that may also explain why many clinical trials fail to demonstrate positive effects of interventions, even when the interventions seem foolproof. For example, consider the rapid response team (RRT), which although employed by most hospitals to assist in the early care of acutely ill patients, have not been demonstrated to lower hospital mortality in meta-analyses.[9] One explanation for these findings is biological—RRTs are simply unable to alter the course of illness. But, the other possibility is that the presence of RRTs leads to unintended practice changes among providers. Primary providers who may be best suited to correct their patient's underlying acute issue may take the ‘back seat’ and defer responsibility and management to the RRT. Likewise, busy providers may simply ‘call a rapid response’ and move on to other clinical responsibilities rather than fully attending to the patient in acute medical need.

Another example concerns null findings of nighttime intensivist staffing. Prior observational studies have shown that intensivist presence correlates with improved ICU outcomes, leading some to believe that 24-hour nighttime intensivists c benefit high-risk patients. This rationale has gained so much traction that a third of U.S. academic centers and three-quarters of European hospitals now utilize nighttime intensivists.[10] However, a large RCT comparing in-house nighttime intensivists to intensivists available by telephone found no benefit in length of stay, mortality, readmission or discharge to home.[10] While several reasons could explain the trial's results—including being underpowered, increased handoffs between shifts, and already robust ICU procedures—the Peltzman effect suggests unconsidered possibilities. For instance, morning rounds are widely considered to be a key moment in reconsidering the events surrounding a patient's illness, re-evaluating causes and treatments. However, attending physicians who would normally scrutinize the decision making of junior physicians during morning rounds may be less scrutinizing if they believe adequate clinical supervision was already provided by a more senior overnight intensivist. The compensating behavior in this case would be for attending physicians to devote less attention to a given case if they believe a thorough work-up was already done overnight.

At its core, the Peltzman effect asks us to creatively consider unanticipated ways in which not only health care providers respond to medical interventions, but patients as well. For example, breakthroughs in the treatment of HIV have coincided with increases in the incidence of the disease, leading some to question whether improved HIV treatment outcomes have led to offsetting increases in risky sexual behavior among those infected with HIV.[11,12] An analysis of state Medicaid eligibility rules towards treatment of HIV+ individuals demonstrated that increases in treatment eligibility within states were associated with increased HIV treatment uptake and a near-doubling of sexual partners among those being treated.[11] Similarly, in a survey of high-risk men who have sex with men, nearly 35% of those who reported that they would use pre-exposure prophylaxis to reduce risk of HIV infection also stated that they would likely decrease condom use while on prophylaxis.[10] Despite concerns raised by studies like these, evidence on compensating behavior in HIV has been mixed. For example, a large, secondary analysis of HIV-uninfected partners of heterosexual HIV-serodiscordant couples who were randomized to pre-exposure prophylaxis did not report increases in risk-taking sexual behavior.[13]

Our discussion so far raises the question: how can the Peltzman effect be used to gain better information about why interventions studied in trials fail to demonstrate benefits? To our knowledge, outside of studies on compensatory risky sexual behavior among patients receiving treatment or pre-exposure prophylaxis for HIV, few studies which demonstrate null or negative effects of interventions explicitly look further into whether compensatory responses by patients or providers can explain those findings. We believe that trials should measure compensatory markers to understand why interventions fail, akin to the growing use of biological markers to understand failure in oncology trials. Consider, for instance, emerging evidence that mutations in the RAS oncogene family predict failure of anti–epidermal growth factor receptor antibodies among patients with colorectal cancer.[14] Biomarker information is now increasingly being collected prospectively in RCTs of oncologic therapies in order to retrospectively understand why some patients respond and others do not. In the same way, measurements of human responses to system interventions – i.e., compensatory markers – may be measured in trials of health system interventions. For example, trials of gown-and-glove precautions to reduce rates of nosocomial antimicrobial bacterial resistance – which in a multicenter trial failed to reduce multi-drug resistant infections[15] – may examine rates of hand-washing and physical closeness of provider-patient interaction. A demonstration of lower rates of hand washing or increased physical closeness of patient-provider encounters after a gown-and-glove intervention would suggest that gown-and-glove interventions themselves could be effective, but only if providers are counseled to avoid other compensating behaviors which may counteract the intervention.

Compensatory markers have already made their way into studies of anti-retroviral pre-exposure prophylaxis for HIV. For example, rates of sexual activity among HIV sero-negative individuals have been shown to be unaffected by whether these individuals received pre-exposure prophylaxis.[13] In this case, the compensatory marker of sexual activity served as a secondary endpoint to the primary endpoint of rates of HIV conversion in this patient population.

The Peltzman effect in medicine is not simply an unanticipated effect of an intervention, but a specific compensating compensatory response by patients or providers to a perceived sense of safety, consciously or unconsciously determined. Although the phenomenon has been documented largely outside of the medical arena, we believe it may play an underappreciated role in medicine. In our view, as the costs of debuting, maintaining and evaluating system interventions are formidable, future studies should anticipate behavioral responses of patients and providers and explicitly monitor for these compensatory marker effects. The only way to appreciate the Peltzman effect in medicine is to know to look for it.

Acknowledgments

This study was funded by the Office of the Director, National Institutes of Health (Early Independence Award, 1DP5OD017897-01, Dr. Jena).

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