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Commentary: Impact of Cost on the Safety of Cancer Pharmaceuticals

Karen A Fitzner[1]*, Milda Plioplys[2]

[1]FH Consultants, 554 Hillcrest Dr, Sawyer, MI, USA
[2]Clinical & Human Research Protections, City of Hope, Duarte, CA, USA

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***Correspondence:**
Dr. Karen A Fitzner, Health Economist, FH Consultants, 554 Hillcrest Dr, Sawyer, MI 49125, USA;
E-mail: Fhconsultants.kf@gmail.com.

ABSTRACT

A chapter, Impact of cost on the safety of cancer pharmaceuticals, by Fitzner and Oteng Mensah in a recent book, Cancer Policy: Pharmaceutical Safety[1], aims to inform readers about the economics associated with the interplay between safety, costs of cancer treatment, and outcomes of cancer care. That chapter includes a general discussion of safety-related costs, cancer care expenditures, and processes that aim to ensure drug safety. It also identifies the negative effects of the high cost of care on patients with cancer and their families. The authors' focus on safety and cost of cancer pharmaceuticals, while appropriate for the book in which it appears, is limited. Pharmaceutical costs and their impact are only part of the safety story. A more holistic approach to thinking about patient safety can be constructive.

High quality care results in fewer errors, less harm and possibly lower cost than does low quality care[2]. Today's health care safety policies leverage quality improvement (QI) initiatives, which are guided by Donabedian's quality of care medical framework[3]. Since the 1999 publication of To Err is Human[4], health policy has aimed to improve patient safety by implementing a vast array of reimbursement policies and regulatory requirements, all of which have understandably provided ample opportunity for health systems to engage in provider- and system-level QI efforts. While policy makers may implicitly consider the cost impact of safety-related policy requirements on health care providers and systems, the economic impact is not always possible to discern *a priori*. But it is a critical factor for those aiming to maintain regulatory compliance. This commentary addresses safety-related cost factors in the organization using an economic lens.

The modern patient safety movement borrows from systems and methods used by other non-healthcare related engineering industries in an effort to reduce harm. As an example, the Systems Engineering Initiative for Patient Safety (SEIPS) model of work system and patient safety, stresses the importance of the environment (facility design) and organization and implicitly, its labor skills, in which healthcare is provided[5,6]. Greatly developed from the aviation industry, the use of checklists in the operating room setting has been widely implemented to assist providers with decision support during both complex and routine cases while promoting collaborating and communication in error-prone settings.

Healthcare organizations are barraged with requirements, both soft and hard, to support delivery of high quality care. The Centers for Medicare and Medicaid (CMS), the largest payer for healthcare in the United States, has made accreditation part of their Conditions

of Participation[7]. CMS star ratings, a complex weighting system using measures such as mortality, safety of care, readmission, patient experience and several others, identify for the healthcare consumer how hospitals compare nationally, particularly relevant in highly competitive markets such as New York City and Los Angeles. These measures are also used as part of CMS's Value Based Purchasing program, authorized by the Affordable Care Act to offers incentives for high quality care, and penalties for the alternative[8].

The literature stresses the providers' and healthcare system's role in patient safety and the importance of QI initiatives to support risk management. The latter "comprises the clinical and administrative systems, processes, and reports employed to detect, monitor, assess, mitigate, and prevent risks[9]." A complex community of policy makers, accreditors, consultants, and others now exists to achieve these aims. The majority of standards promulgated by the primary United States accrediting body, The Joint Commission, are related to safety. The Agency for Healthcare Research and Quality (AHRQ) has published annual rates of healthcare-acquired conditions in Medicare patients treated in US hospitals[9] In response, healthcare organizations have established committees to formalize written policies and procedures to promote compliance with regulations, statutes, and accreditation requirements at the local, state and national level[10]. Policy has been impactful, both operationally and practically.

The cost story is not so clear. In 2017 the OECD stated that national efforts to reduce harm and improve safety efforts will deliver considerable savings[11,12]. However, the American Hospital Association (AHA) in 2017 argued that, "documenting conditions of participation adherence and billing/coverage verification processes are the most burdensome[13]." This is attributable to the increased workload for care providers and the need to hire additional staff ranging from housekeeping to IT workers to support the increased administrative demands necessary to maintain regulatory compliance in all aspects of healthcare delivery. The AHA (2017) also reported that "Nationally, health systems, hospitals and PAC providers spend nearly $39 billion on the administrative aspects of regulatory compliance." These costs were due in part to the fact that more than 25 percent of the FTEs dedicated to regulatory compliance were physicians, nurses and allied health staff. Such workers are costly inputs who are redirected away from patient care responsibilities.

In assessing the intended positive impact of accreditation on the quality of care patients receive, researchers found that accreditation is not associated with lower mortality rates and only slightly associated with reduced admission rates for 15 common medical procedures[14]. These measures are factored into an organization's star ratings, and do not seem to support the large labor system and costs associated with maintaining regulatory compliance.

Economic theory identifies labor as essential to production of the desired output – in this case safe, high quality care. Healthcare serves as one of the primary labor markets in the United States, predicted to surpass all other industries by 2026[15]. As the demand for labor increases, the costs of production rise. Economics also predicts that distortions to the marketplace such as regulatory and compliance requirements will impact cost, typically upward.

In summary, provider- and organizational-level regulations and requirements that aim to achieve patient safety are beneficial but add costs and burden to health care systems and providers. An army of risk managers and QI-related staff ensure that the way the cancer care is provided meets compliance requirements that contribute to high levels of safety. Surely additional human labor and risk management is necessary. But, at least some of the expenditure and effort may be attributed to the unintended consequences of policy requirements and requirement-induced inefficiencies.

"The concerns raised in this commentary are very important to the health and well-being of cancer patients, providers and health care systems as a whole," says Dr. Charles Bennett, Josie M. Fletcher Professor / SC Smart State Center in Medication Safety and Efficacy / Clinical Pharmacy, a hematologist and oncologist whose research focuses on preventing adverse drug reactions. "Moreover, in the United States, the cost and safety situation not only applies to cancer but is likely to occur for several other diseases, such as diabetes, heart disease, stroke, and HIV. The generalizability of using economic theory to inform and improve health care is increasingly important-- as evidenced by the large numbers of physicians who enroll in MBA programs or increasingly in executive training programs for physicians."

Although beyond the scope of Fitzner & Oteng Mensah's chapter, staffing to satisfy quality and safety requirements is vitally important to patient care. But it adds cost. Policy makers, accrediting bodies, and the other entities involved in risk management and QI are urged to seek optimal value for every healthcare dollar spent on quality and safety by seeking input from providers and health systems. Mechanisms for adjustment once the effects of implementation are understood are needed. This approach can achieve efficiency, value, and high-quality care that augments patient safety with minimal burden. These steps, coupled with the pre-clinical safety measures taken during drug development discussed in the source chapter, will enable a healthcare delivery system that works effectively within itself to provide high quality at the optimal cost.

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