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Considering a Holistic Approach to Thinking about Patient Safety and Cost

Karen Fitzner[1*] and Elizabeth Heckinger[2]

*[*1]FH Consultants, 554 Hillcrest Dr, Sawyer, USA.*

[2]University of Chicago, IL. Biomedical Informatics, USA.

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ABSTRACT

A question was recently posed, how relevant is a 2019 commentary, Impact of Cost on the Safety of Cancer Pharmaceuticals, to the field of blood diseases and transfusions? This brief review considers that commentary as well as related and recently published materials on the cost and safety of interventions and therapies in the context of blood diseases and transfusion, to address that question. Our assertion is that the commentary is relevant; its call for a holistic approach is even more so because of ongoing concerns about the complexity of achieving safe, high quality care, patients' out-of-pocket (OOP) expenditures for pharmaceuticals and insurance, and evolving quality requirements faced by providers, health systems and suppliers. All of these factors impact patient compliance and outcomes, the ultimate safety issues.

Keywords: Cancer, Review, Safety, Cost

REVIEW

In addition to the commentary [1] and manuscript that it critiques this brief review considers recent oncology-specific publications including "Safety of Cancer Therapies: At What Cost?" [2] and "Impact of Cost on the Safety of Cancer Pharmaceuticals" [3]. Each of those manuscripts uses a health economics lens noting that high cost can be an impediment to safety, and to identify the complexity of the safety story [4]. These papers also suggest the need for a more holistic way of thinking about achieving high quality care that results in fewer errors, less harm and possibly lower cost than does low quality care.

We posit that three main types of safety and drug costs are relevant no matter the diagnosis or procedure type: 1) safety-related costs, 2) treatment and drug cost growth, and 3) out-of-pocket (OOP) spending. We present a real-world example about a multiple myeloma (MM) specialty pharmaceutical product. Studies on transfusions for traumatic brain injury (TBI) and sickle cell anemia provide relevant cost and safety examples.

Safety-related costs

The focus on safety increased since 1999 when To Err is Human [5] was released. Overall, healthcare literature since then has stressed the importance of multiple stakeholders -- providers', clinics hospitals, suppliers, patients, policy makers and healthcare systems' -- in achieving patient safety. Quality improvement (QI) initiatives also gained importance as a means of supporting risk management.

Costs and benefits associated with safe care delivery are notable, as demonstrated by pharmaceutical development. But aside from drug development, these have proven difficult to define, quantify and control. The Organization for Economic Cooperation and Development (OECD) has stated that national efforts to reduce harm and improve safety efforts will deliver considerable savings [6]. Conversely, the American Hospital Association (2017) is more skeptical, reporting that "Nationally, health systems, hospitals and PAC providers spend nearly $39 billion on the administrative aspects of regulatory compliance" [7].

Safety-related cost increases may be attributed to factors beyond those directly associated with treatment, including patient safety legislation, the advent of quality improvement departments, and accreditation requirements [8]. Healthcare organizations continue to be barraged with requirements, both soft and hard, to support delivery of high-quality care.

Corresponding author: Karen Fitzner, Health Economist, FH Consultants, 554 Hillcrest Dr, Sawyer, MI 49125, Tel: 13127716362, E-mail: fhconsultants.kf@gmail.com

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One example is STARS evaluation that assesses and penalizes, or rewards pharmacy providers based on number of members staying healthy, success in managing chronic conditions, drug safety and accuracy of pricing [9]. Entire industries - accreditation and consulting, for example – have matured to guide and ensure safety and compliance. In addition, payer strategies (i.e., value-based purchasing) and policy initiatives can be impactful, both operationally and practically.

Treatment and drug cost growth

Costs of treatment and therapies are driven by a multiplicity of interrelated and complex factors - arising from things as varied as provider payment to health system design and patient satisfaction. One of the most notable factors is annual drug price growth, which has been as much as 21% in recent years. The cost of developing new drugs of which a significant portion is safety driven, continues to be a significant cost driver. According to research released in March 2020, the estimated cost to bring a new pharmaceutical to market was $985 million from 2009-2018, largely attributable to research and development [10].

Advances in patient care also influence safety and cost. New thinking in blood transfusion protocols for traumatic brain injury (TBI) patients is contributing to both hospital safety and cost-efficiency [11]. Research on blood loss and moderate anemia, compared a restrictive (target hemoglobin level >7 g/dl) versus a liberal (target hemoglobin level >10 g/dl) transfusion protocol for TBI patients. The study found that hospital direct and indirect costs savings of approximately $115,000/yr occurred with a restrictive transfusion protocol that was deemed to be safe and cost-effective in patients with TBI [12]. This is finding could prove to be a benefit for all.

Out-of-pocket costs

OOP costs matter for blood diseases because the interplay between patient safety and drug costs affect clinical outcomes. Insured patients receiving chemotherapy reportedly pay an average of $10,000/month on OOP expenses [3]. As an example, the direct medical OOP cost borne by an MM patient taking Reviimid can be more than $2,600 for a one-month dose (21 pills). In addition to that amount, Medicare and the patient's supplemental insurance cover more than $19,000 [13]. While this drug is powerful and useful as a maintenance therapy for MM, the cost imposes considerable strain on most any budget. Patients facing such high OOP costs are highly susceptible to treatment non-compliance, a safety issue, and possibly bankruptcy. Such patients may also face rising insurance premiums, adding to their OOP expenditures.

Pharmaceutical and treatment costs are only part of the safety story. While it is clear that patients benefit considerably from high quality safe care, nearly all players in the healthcare arena share the burden of safety-related costs. It remains unclear how the cost and benefit impact should be shared across patients and other stakeholders.

In developed countries, proven safety and desired clinical outcomes have driven a shift to outpatient care, reducing treatment costs, altering healthcare facility income, and lowering costs of hospital- acquired nosocomial infections [14]. However, few options are available in poor countries where cost is an extremely serious impediment to access and safety. For example, sickle cell patients in the Democratic Republic of the Congo receiving regular treatment, face yearly OOP cost for partial exchange transfusions of US $ 3,345 without iron chelation ($ 5,000 or more with chelation). Even though such transfusions are safe, effective and tolerated, their cost makes them available only to a minority of sickle cell patients in that country [15]. This is a serious safety concern.

Safety-oriented incentives: Payer-led strategies for reimbursement and quality incentives (i.e., pay for performance) have and continue to foster safety improvements, but there are trade-offs [16]. Payer, provider- and organizational-level incentives and requirements that aim to achieve patient safety are beneficial but add costs and burden. Reimbursement mechanisms that encourage safety (e.g., value-based purchasing, and pay for performance) can be very complex. Patient enthusiasm for vexing cost containment approaches wans as insurance premiums and OOP payments continue to rise, although at a slowing rate. The healthcare industry continues to support safety initiatives even as it grapples with costs and adapts to an uncertain and evolving policy and legislative environment.

Recent advances in safety-based pricing methodology are testing modeling for predictive contracting and pricing. Such modeling integrates factors to adjust for the probability of adverse events occurring, and the probabilities then inform price calculations. If successful, it is likely that future, economic and actuarial modeling will prospectively incorporate adjustments for safety in payment calculations. Safety-based pricing approaches could serve as levers to boost overall patient safety and quality no matter the diagnosis or practice area.

To summarize, currently, inefficiencies and discontinuities exist. a more holistic approach to thinking about patient safety, could transcend specialties and be built on a culture involving health care providers, professionals from other fields, healthcare systems and organizations, payers, suppliers and patients. Whether oncology or blood diseases and transfusions, an integrated health economic approach can help achieve efficiency, value, and high-quality care that augments patient safety with minimal burden. Steps need to be taken that will enable the healthcare environment to work effectively within itself to provide high quality, safe care at the optimal cost.

CONCLUSION

This brief review examines a prior commentary and related writings on patient safety, pharmaceutical cost and cancer in the context of blood diseases and transfusions. Our assertion is that the commentary is quite relevant in this context. Emerging therapies and technologies continue to be associated with the complexity of achieving safe, high quality care. Issues are safety-related costs (evolving quality and safety requirements faced by providers, health systems and suppliers), treatment and drug costs (with a rising cost trend); and patients' OOP expenditures for therapies, treatment and insurance. Each of these factors impact patient compliance and outcomes, the ultimate safety issues.

Advances in pharmaceutical technology, research, clinical practice, and infrastructure can yield effective and safe therapies that reduce physical or treatment-related toxicity. To achieve this vison, a holistic approach with coordinated actions is needed to achieve financial, therapeutic and clinical safety for all players in the health care arena.

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