US health reform and value: hit or miss?

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"…the blueprint for US health reform is centered around improving value in healthcare, where value reflects incremental benefits in the context of incremental costs."

The USA is about to undertake a major transformation of how it delivers healthcare, and *The Patient Protection and Affordable Care Act* is the blueprint for reform [1]. This legislation employs the idea of 'value' as a unifying principle, and as a descriptor for various new incentives that it will apply to healthplans and practitioners. While the Act does not define value explicitly, it repeatedly juxtaposes this word with statements about the importance of improving quality and/or lowering cost. Therefore, it appears reasonable to conclude that the blueprint for US health reform conceptualizes value as improving quality from healthcare while steadying or decreasing costs. Furthermore, because this legislation states that the first priority of 'quality' measures is to assess 'health outcomes and functional status of patients,' quality is viewed as a proxy for benefit [1]. Putting these observations together, the blueprint for US health reform is centered around improving value in healthcare, where value reflects incremental benefits in the context of incremental costs.

Since the US health reform law creates numerous incentives to improve value, it would be logical to assume that these incentives are linked as directly as possible to a metric that reflects value, such as incremental cost–effectiveness ratios (ICERs). However, the Act appears to explicitly forbid creating incentives based on ICERs under certain circumstances, stating that authorities "shall not develop or employ a dollars-per-quality-adjusted life year as a threshold to establish what type of healthcare is cost effective or recommended" and "shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs" [1].

"Americans dislike making explicit tradeoffs between healthcare costs and benefits…"

Why then would a blueprint for health reform embrace the overall objective of increasing value while eschewing the most direct means for obtaining it? While there are many plausible reasons, two appear to be dominant: first, Americans dislike making explicit tradeoffs between costs and benefits in the sphere of healthcare [2]. Second, there has been successful opposition by the drug and device industries that shelters them disproportionately from even implicit tradeoffs between cost and benefit. Indeed, the complexities of the law can be viewed as an attempt to maximize healthcare value subject to these two very formidable constraints.

Constraints imposed by USA culture & political environment

Preferring implicit rather than explicit tradeoffs

Americans have a persistent and pervasive aversion to explicit tradeoffs between healthcare costs and benefits. Peter Neumann suggests "at some level, people do not believe that resources are limited, or they recoil from the explicit nature of cost–effectiveness exercise itself – that it

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forces them to think consciously about stark tradeoffs between money and health that they would rather leave at a subconscious private level" [2]. For this reason, health reform law has disaggregated incentives for value, which would involve explicit tradeoffs, into incentives for the components of value, benefits and cost, so that these tradeoffs can remain implicit. For example, the Act creates incentives for 'value-based purchasing' for hospitals and other institutions and 'value-based payment modifiers' for physician fees, but these incentives are pegged not to a measure of value, but rather to a separate construct ('performance') that is then defined in terms of quality, cost, and other components [1].

> "Although industry opposition is strong to explicit tradeoffs between costs and benefits, this opposition is likely to be misplaced and may even be harmful in the long-term."

Even though disaggregating value into its components and incentivizing them separately is a less efficient means of promoting value than incentivizing value directly, it is arguably the closest approach that keeps the tradeoff between cost and benefit implicit rather than explicit. Indeed, one may observe that these individual incentives may imply a shadow willingness to pay for benefits. For example, if an incentive program would pay an additional US$1000 for a quality initiative that adds 0.01 quality-adjusted life-years (QALY), it would imply a willingness to pay for health benefits of at least US$100,000 per QALY.

Industry opposition to any consideration of cost/benefit tradeoffs

The drug and device industries have great influence over the legislative process in the USA, and this is the most likely reason why *The Patient Protection and Affordable Care Act* features an abundance of language describing how new incentives promoting value will be applied to healthplans and practitioners, and a paucity of language describing how these new incentives would be applied to drugs and devices. Although industry opposition is strong to explicit tradeoffs between costs and benefits, this opposition is likely to be misplaced and may even be harmful in the long-term. The same incentives that may lower prices for innovations with minimal incremental benefit over existing alternatives, may increase prices for new innovations with substantial incremental benefit over existing alternatives. For example, if society is willing to pay US$100,000 for an additional QALY of benefit, a drug that has a negligible incremental benefit (e.g., 95% probability less than 0.001 additional QALY compared with next best alternative, for 1 year of the drug) may have its annual price capped at within US$100 of that alternative. However, a drug that has a substantial incremental benefit (on average, 0.1 QALY compared with next best alternative) may be able to justify a US$10,000 annual premium compared with that alternative. Indeed, value-based incentives could shift the development pipeline by discouraging development and marketing of 'me too' drugs while increasing the reward for developing of higher-risk 'game changers.'

Have constraints misdirected efforts towards quantity-reduction rather than value-enhancement?

Numerous studies have documented variations in volume of healthcare services in different areas in the USA, without corresponding variations in outcomes or benefits [3]. Therefore, an enticing target of cost control is to diminish the volume of health services, particularly in high-use regions. This has motivated the health reform blueprint to endorse payment methods that move away from rewarding volume (e.g., fee for service) towards alternative modes that are not volume-sensitive (e.g., 'bundling', 'medical homes' and other frameworks that are conceptually akin to capitation)[1]. But these observations are based on studies that have little ability to distinguish which of the higher volume services are high value and which are low value. Indeed, removing volume-based incentives for services that are high value might reduce healthcare benefit because then high-value services may not be delivered as often. Furthermore, if a service is high value, not only would society want to avoid attenuating volume-based incentives, but might well consider augmenting them by increasing the fees for those services.

> "If there is a more efficient alignment of incentives with value, including demand- as well as supply-based measures, the USA may be able to extract a magnitude of healthcare benefit that is more commensurate with its expenditures."

Fortunately, there is one initiative in the law motivated by volume-minimization that will likely have the collateral effect of increasing value. Health reform law provides for additional funding of 'comparative effectiveness research,' defined as research to compare the outcomes of alternative strategies used to prevent, treat and manage health conditions for different populations [4]. In addition to potentially decreasing volume (by identifying services that have no incremental benefit), comparative effectiveness research will determine the incremental benefits and costs of new and existing technology, and therefore will permit estimation of its value. Indeed, the main usefulness of comparative effectiveness research will likely involve value estimation rather than volume minimization, because for every technology that is demonstrated to have a lesser than anticipated incremental benefit in a particular clinical setting or patient subgroup, there may be a larger than anticipated incremental benefit in a different clinical setting or patient subgroup.

Value-based insurance design & the current blueprint for US health reform

Value-based insurance design (VBID) is a framework for varying cost-sharing systematically with value, so that greater value interventions incur less cost-sharing, and lesser value interventions incur more cost-sharing [5,6]. For the purposes of VBID, 'cost-sharing' may be viewed broadly, encompassing all demand-based incentives that apply to patients (e.g., copayments, deductibles and the patient's share of insurance premiums). While some have posited that VBID is particularly well

suited to the cultural and political environment in the USA because it eschews nonprice-based rationing and centralized controls [6], VBID does not figure prominently in the current reform law. Indeed, the only provision in the current law that remotely resembles VBID is a mandate for cost-sharing to be waived for selected preventive care services, which is a poor and limited proxy for VBID because it only incentivizes in one particular direction (towards more volume rather than less volume) and because many preventive services are not high-value.

Two of the most important reasons why enthusiasm for VBID is soft in the current reform blueprint are likely to depend on the constraints outlined previously. In order to keep tradeoffs of cost versus benefit implicit rather than explicit, value-based incentives would need to be disaggregated into distinct incremental quality- and incremental cost-based incentives. This disaggregation would require a distinct evolution in current conceptions and implementations of VBID. In addition, since quality measures are currently inefficient proxies for magnitude of benefit, quality measures would need to evolve to reflect their likely impact on benefit (e.g., weighted so that a measure conferring a smaller improvement in benefit does not count as much as a measure conferring a larger improvement in benefit).

Opposition of drug and device industry to even implicit cost/benefit tradeoffs, is also likely to be a critical factor limiting the role of VBID in the current health reform blueprint. VBID is typically applied at the individual health service level, and services often involve drugs or devices. If the incentives of VBID were applied solely on a more aggregated, healthplan level (e.g., decrease the patient share of insurance premiums for higher quality healthplans and/or for lower cost healthplans), it is unclear whether its impact would be altered.

Prospects for value-based insurance design in future health reforms

It appears likely that the current blueprint for health reform will necessitate subsequent reforms because it does not contain a large-scale systematic initiative that is likely to control healthcare costs (Table 1). Therefore, healthcare expenditures may continue to rise, and the blueprint for healthcare reform is likely to evolve in a way that emphasizes more effective cost–control measures. Some possible responses include:

- The magnitude and scope of cost–control incentives already in the bill may be increased, as they are currently small (typically 1–3% of baseline payment amounts);
- Cost- and quality-based incentives may be applied more broadly to demand-based decisions (e.g., the portion of insurance that patients pay), while still protecting drug and device makers from the application of these incentives to individual health services;
- Some breaks in industry resistance may eventually occur, and cost- and quality-based incentives may be applied to individual health services;
- There may be increased emphasis on discriminating among more important versus less important quality measures, with more weight and incentive given to those measures that are better proxies for magnitude of benefit. For example, a quality measuring conferring a benefit of 0.25 QALY may warrant a large incentive (e.g., up to US$25,000, at a willingness to pay of US$100,000 per QALY), whereas a quality measure conferring a benefit of 0.001 QALY may merit a small incentive (e.g., up to US$100, at the same willingness to pay of US$100,000 per QALY). In either case, incentives may be withheld if evidence supporting a quality measure is insufficiently robust.

Table 1. Selected initiatives in the current blueprint for USA health reform and their likely impact on health expenditures.

Initiative	Affects supply or demand?	Affects healthplans/ clinicians or services?	Provides incentives to lower volume and/or prices?	Provides incentive to increase quality and/or benefit?	Likely to lower health expenditures?
Accountable care organizations	Supply	Healthplans/clinicians	Yes	Yes/no	Yes
Medical homes	Supply	Healthplans/clinicians	Yes/no	Yes	Yes/no
Bundling	Supply	Healthplans/clinicians	Yes	Yes/no	Yes
Chronic disease management	Supply	Healthplans/clinicians	Yes/no	Yes	Yes/no
More informed consumer decisions	Demand	Healthplans/clinicians and service	Yes/no	Yes	Yes/no
Value-based purchasing	Supply	Healthplans/clinicians	Yes	Yes	Yes/no
Value-based modifier to physician fees	Supply	Healthplans/clinicians	Yes	Yes	Yes/no
Eliminating copays on prevention	Demand	Service	No	Yes	No

Since health reform will initially include VBID only in an extremely limited and inefficient form, VBID may have some small impact, but one much less than has been mathematically modeled [7]. However, this modeling work may become more relevant to US health reform as cost–control approaches evolve, and application of VBID principles becomes more direct and more efficient.

Conclusion

The US healthcare system is on the verge of major changes. The direction of these changes is influenced by multiple constraints, especially the preference for implicit rather than explicit cost–benefit tradeoffs, and the strong opposition of the drug and device industries to cost–benefit tradeoffs in any form. Because the current blueprint for reform is likely to increase costs rather than to reduce them, the subsequent evolution of health reform is likely to include measures that erode but do not demolish these constraints. If there is a more efficient alignment of incentives with value, including demand- (e.g., VBID) as well as supply-based measures, the USA may be able to extract a magnitude of healthcare benefit that is more commensurate with its expenditures.

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