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Stanford's Biodesign Innovation program: Teaching opportunities for value-driven innovation in surgery

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Abstract

The Stanford Biodesign Innovation process, which identifies meaningful clinical needs, develops solutions to meet those needs, and plans for subsequent implementation in clinical practice, is an effective training approach for new generations of healthcare innovators. Continued success of this process hinges on its evolution in response to changes in healthcare delivery and an ever-increasing demand for economically viable solutions. In this article, we provide perspective on opportunities for value-driven innovation in surgery and relate these to value-related teaching elements currently integrated in the Stanford Biodesign process.

Rising healthcare costs—A call for action

Growth in US annual healthcare spending outpaces general inflation. Spending growth in excess of inflation is a point of concern and scrutiny, especially when healthcare increases are greater than those in production sectors of the economy and healthcare is increasing in its share of gross domestic product (GDP). Healthcare spending made up nearly 18% of the US GDP in 2017 with an annual growth rate of 3.9%.^{1,2} Surgical services are an important component of overall spending: nearly one third of healthcare spending is secondary to surgical expenditures.³ Healthcare spending is projected to continue to increase in all developed countries over the next several decades.⁴ The average growth in US, yearly, per-capita spending on healthcare is 4.9%.⁵

The reasons for rising healthcare costs are the topic of constant debate.^{6,7} Commonly cited drivers are the increasing prevalence of specific diseases, such as cancer, heart failure, or diabetes mellitus,^{8,9} and the increasing eligibility for costly treatments, such as the genomic tests that the Centers for Medicare and Medicaid Services first began covering in 2018 (other private payors have not followed).¹⁰ The Congressional Budget Office looked at several spending-increase factors including aging of the population, changes in third party payment, personal income growth, healthcare costs, administrative costs, defensive medicine and supplier-induced demand, and technology-related changes in medical practice. They

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concluded that over half of all growth in healthcare spending is due to changes in medical care made possible by advances in technology,⁵ with advances in surgical technology as 1 component. In the United States, the cost of services¹¹ and the potential exploitation of payments for medical services¹² drives a greater percentage of a limited GDP toward healthcare and away from other public sector goods such as education, environmental protection, and public health.

Outcome examples are clinical endpoints, quality or safety factors, patient satisfaction, or provider efficiency. In a time of rising healthcare costs, it remains uncertain whether adoption of new medical innovations increases healthcare spending overall once improved outcomes are factored in. Consequently, the value, in terms of outcomes and costs related to any innovation, should be objectively assessed; a cost effectiveness analysis can be used as a tool for this assessment.¹³ Although new technologies may not always lead to increased costs, it is important to determine whether the new technology generates a health outcome that justifies the cost.¹⁴ Consequently, these considerations should be embedded early in the development process of new surgical technologies.

Examples of value assessment and value contribution in health innovations

Cost effectiveness is a useful tool for exploring the question of how medical devices affect healthcare costs. The inputs for cost-effectiveness studies include cost together with quality of life and outcomes metrics and frequently require the projection of long-term outcomes affected by the primary intervention. In the following paragraphs, we present a few real-world examples to exemplify the process of cost-effectiveness analysis and how the value of new technologies and clinical approaches—or lack thereof—can be systematically assessed and quantified. This general understanding about measurement of incremental costs and outcomes of new approaches is central to our value teaching, as will be discussed in later sections of this paper.

Example 1: Meniscus repair

Meniscal tears are a common precipitating event for knee surgery. Surgical treatment modalities include meniscal repair or meniscectomy. Although the success rates of each surgery have been reviewed, there is limited information on long-term costs and effects. In a model-based projection, Feeley et al found that meniscal repair was associated with greater cost savings and improved long-term outcomes.¹⁵ This proved true despite the increased failure rate of meniscal repair when compared with meniscectomy. When assessing the overall cost to payers, \$43 million could be saved annually if just 10% of meniscectomies were converted to meniscal repair procedures. When specifically assessing the patient's health outcome, the authors reviewed the surgical failure rate, rate of osteoarthritis development, need for total knee replacement, mortality, and quality of life. Furthermore, the study helped identify the specific patient population subsets for which these findings held true. The overall, long-term investment reduction, a major element contributing to the value assessment, adds value for patients, payors, and large healthcare systems because it identifies clear upfront costs that are offset over the natural disease progression for a patient with knee osteoarthritis.

Example 2: Deep brain stimulation for Parkinson's disease

Another analysis from the US healthcare system perspective performed an assessment of the cost effectiveness of a deep brain stimulation (DBS) device compared with best medical therapy for Parkinson's disease.¹⁶ Findings indicated treatment with DBS—over a 10-year period—improved patient quality of life, but also added cost, driven by the device, its implantation, and necessary reinterventions to replace the nonrechargeable generator. Despite the cost increases, DBS was found to be cost-effective based on the incremental improvement in patient outcome. Several insights could be derived from the study about opportunities to further improve the cost-effectiveness through technology innovation. Paramount among them is the development of technologies that would have an expanded lifetime and not require reoperation. This could save substantial costs to the healthcare system and avoid complications associated with any replacement surgery. Similarly, in an analysis based on systematic review of clinical studies, the added cost of providing drug eluting endovascular treatment over the existing standard of care was justified by the improved clinical outcomes achieved¹⁷ and concurrent need to re-intervene less frequently.

Example 3: Weight loss surgery

As another example, a cost-effectiveness model of type 2 diabetes compared weight loss surgery with conventional diabetes management¹⁸; outcomes measured included complete remission of type 2 diabetes, active type 2 diabetes, or death. This model predicted cost savings and health improvement for the patients who underwent surgical weight loss therapy. Weight loss surgery health benefits included, at a cost, remission of newly diagnosed type 2 diabetes that would otherwise ensure long-term costs of diabetes management. This study highlights a therapy associating both patient-centric health improvement and cost savings to the healthcare system: a mean healthcare saving of 2,400 Australian dollars and 1.2 additional quality adjusted life years per patient.

These 3 examples—like other examples—suggest that some surgery and device innovations, while adding initial cost, achieve worthwhile cost savings over the time course of the disease or achieve outcome improvement that justifies increased cost. Alternatively, some health technologies are less valuable to patients and provide marginal improvement in health outcomes; such technologies might lack the justification for an increased cost. These potential value implications need to be appreciated early on by innovators. As we teach our fellows, this process is arguably more challenging when no or only limited evidence exists about the underlying clinical condition or the existing standard of care. In this case, there is more uncertainty regarding assumptions and outcomes needed to develop an initial cost-effectiveness assessment, and hence higher uncertainty about the expected value contribution of a new product. We teach methods, such as Markov modeling, that allow exploration of the range value consequences of technology adoption when outcomes are uncertain.

Lessons learned—Defining value

A range of definitions of healthcare value exist in published literature and some include cost-analysis assessments. Commonly, value definitions first include a description of the patient effect, measured by morbidity, mortality, or quality of life, as compared with a

baseline state or alternate care option. Second, value definitions include an understanding of the stakeholders, how each one may be affected by the therapy, and whether they are decision makers or influencers. Third, the link between cost and time is important in order to predict both upfront and long-term costs; cost effectiveness assessments compare new technologies to existing solutions.

Further, value can be defined more broadly to also include a commercial value consideration. For example, as described in the Biodesign textbook, health-economic value is an expression of the health improvement(s) a new technology offers relative to its incremental cost.¹⁹ Health economic value is usually an interplay between clinical outcomes on one hand and costs on the other. Commercial value employs those observations to assess the point when a given stakeholder, including investors, would actively pursue bringing an innovation to market. An understanding of how a new technology can become a viable business often dictates whether it ever obtains enough startup funding to be implemented into patient care and become revenue generating. Watkins explained that commercial value links the customer and entrepreneur²⁰ because the entrepreneur decides if there is an opportunity to build what the customer defines as valuable. Assessment of commercial value focuses on potential revenue and includes stakeholders who might benefit from the profits. Both variations in value assessment are important at various stages of innovation, and different stakeholders are logically more concerned about one over the other.

In our teaching, both aspects need to be determined. Indeed, without commercial value, a novel technology will never be able to reach patients, and a novel technology ideally should contribute health-economic value in order to be part of a long-lasting viable healthcare system. The importance that Stanford Biodesign has placed on value is even evident in its mission statement. The mission, “Educating and empowering health technology innovators, and leading the transition to a value-driven innovation ecosystem” was revised in 2017. Value assessment now underpins every step of the innovation fellowship training.

Summarizing the Stanford Biodesign Innovation process and finding value opportunities

The Biodesign Innovation process is a constantly evolving innovation teaching methodology first introduced in 2000 at Stanford University.¹⁹ The process, one that stresses detailing the clinical unmet need before any solution is considered, has evolved just as the medical device sector and healthcare economy has, but remains true to its original core principles. The Stanford Biodesign Innovation fellowship is a 10-month, fulltime, innovation teaching program (Figure 1).²¹ Each year, 12 fellows with diverse backgrounds join the program. Typically, the cohort includes 4 to 6 physicians in training or post residency fellowship training, 4 to 6 engineers or scientists with master’s or doctoral degrees, and 1 to 2 fellows with a business background; some fellows have a mix of these backgrounds. The fellows are assembled in teams of 4 and are paid a stipend during their fellowship. The teaching process is mainly experiential and combines a small number of theoretical lectures with intensely mentored, project-based teaching. We further describe the makeup of the Biodesign Innovation fellowship program within a recent book chapter.²² The impact of the training

program on alumni has been studied and suggests positive results in the areas of productivity, leadership, and career focus when compared with publicly available data of finalists who applied to the program.²³

Value is taught in a systematic fashion throughout the Biodesign process in the form of lectures and workshops in addition to structured deliverables, as described in subsequent sections. Value is integrated into the core Biodesign process, which has three phases: identify, invent, and implement. The Biodesign process is described in detail in the Biodesign textbook.¹⁹ To summarize this complex process, we will briefly describe the high-level components of the Biodesign Innovation process. During the identify phase, unmet clinical needs are observed and explored in the clinical setting, and needs statements are developed to communicate those clinically unmet problems in a given population for which a specific outcome is desired. Each need statement includes a problem, population, and outcome for which a solution will later be explored. The healthcare impact of each need is screened and compared in detail against the other needs; the parameters include an understanding of disease state, the competitive landscape, stakeholder impact, and actual market. The invent phase begins the process of concept ideation, screening, and validation. Concept generation, via brainstorming, is an iterative process of developing new solutions that potentially solve the given unmet need. The emerging concepts then enter a screening process. This part of the process evaluates concepts based on several factors including intellectual property, regulatory pathway, reimbursement, business model, and technical (often engineering) feasibility. At the end of the invent phase, a concept is selected and the last phase, implement, commences. During the implementation phase, the novel concept is further validated, and overall risks are more deeply explored as innovators develop their strategy and business planning activities before a project launch. Strategy development is an in-depth process involving multiple elements: intellectual property strategy, research and development strategy, clinical strategy, regulatory strategy, quality management, payment strategy, market strategy, and sales and distribution strategy. Furthermore, business planning involves developing an operating plan and financial model, strategy integration and communication, funding approaches, and commercialization pathway.

Value-specific teaching elements implemented into the Stanford Biodesign innovation process

Designated faculty members with expertise in health economics and technology assessment lead the value specific elements of the Biodesign Innovation process. Value focus begins early in the Biodesign process. Bootcamp, which occurs at the start of the Biodesign Innovation fellowship, includes an accelerated project practice run and daily lectures in a chosen clinical area. The concept of value is introduced in bootcamp, before clinical needs finding. As the process advances, the concept of value is explored more deeply. It begins with introductory lectures about the structure of the healthcare system, healthcare financing, and its current challenges in addition to outcomes assessment and methods of cost-effectiveness analysis. Subsequent workshops include reviewing and discussing technology case studies, group exercises developing cost-effectiveness models, and detailed introductions to reimbursement mechanisms. Throughout, emphasis is on providing fellows with resources and data they can use in their future careers, beyond the fellowship.

Value screening occurs at multiple times throughout the Biodesign process, adding components appropriate to the stage of development. Value assessment adds an additional screening layer to the needs filtering stage of the Biodesign process. As soon as need statements are established, the innovation teams will define strict criteria that their solution will need to fulfill to be viable. These criteria include a maximum cost per outcome improvement criterion long before any solution arises from the teams' brainstorm.

During the first phase of the Biodesign process—needs identification—health-economic value teaching focuses on value exploration. The clinician innovators attend value workshops, prepare value deliverables, and present them to faculty. The early-stage deliverables during needs screening include but are not limited to:

1. **Market analysis:** Market analyses for value include an understanding of the clinical need and specifically the patient population based on published incidence and prevalence data. Market analysis segments the market into subpopulations and finds the best realistic target market for a given need.
2. **Stakeholder analysis:** Stakeholder analysis includes a more detailed characterization of the impact of a new solution on various stakeholders, including patients, society, payors, and providers. It involves identifying the decision makers, those who decide whether a given concept is adopted into the care pathway, and influencers, those who surround decision makers and affect adoption decisions.
3. **Treatment landscape:** Treatment landscape analysis for value includes an in-depth look at all available treatments for various clinical and conceptual options. It also involves a literature review of existing health technology assessments related to the clinical need. Ideally, those assessment and underpinning cost-effectiveness models have similar populations or outcomes as the need under consideration. This review helps to expose gaps in the currently available treatments, information gaps in amount of value added or cost-related limitations, and helps to identify relevant clinical and cost metrics in a given indication. The cycle of care, which follows the patients through their interactions with the healthcare system, gives a clear view into the burdens, benefits, and quality of life that patients experience.
4. **Reimbursement landscape:** The reimbursement landscape analysis for value identifies the costs related to a population. It is also important advice for following the path of money and the stakeholders it affects. For example, a single disease process may involve multiple reimbursement codes over a specified period; this is relevant to payors because it provides information for upfront and long-term costs. (Table I)

The outcomes of the value estimates provide additional guidance to the fellows as they screen their final sets of identified needs in order to select the most promising needs to tackle during the subsequent Invent phase.

As solutions for the identified needs are developed and evaluated, fellows are guided to further refine their initial value estimates and work toward a further quantified actual value proposition. To analyze the value of a new technology's expected clinical outcome, teams first review published health technology assessments of existing solutions. A review includes a look at the outcomes evaluated, the population referenced, and potential gaps in the evidence. These are compared against the population and outcomes in the need statement. Then, the expected clinical outcome of the new technology is incorporated into a new cost-effectiveness assessment and compared with the gold standard of care. Finally, the health economic value proposition highlights the overall impact to patients, payers, and providers; identifies knowledge gaps; and assesses a plan to address pending questions, required further validations, and future risks. (Table II).

In parallel to health-economic value teaching, the notion of commercial value is introduced by a separate group of faculty members who support the implementation phase of the fellowship. The commercial value exercises begin with sizing the market, evaluating estimated revenue and cost of goods, risk assessment, and exit opportunities. Teams create a development plan, risk reduction plan, and funding plan and present these to center faculty. We acknowledge that without commercial value, promising technology will rarely be brought to market, regardless of the strength of its health economic value. Conversely, demonstration of health economic value strengthens the commercial value of emerging technologies.

In conclusion, as healthcare and surgery-specific costs are increasing, so is the momentum for a better understanding of value and the impact new treatment approaches and technologies have on stakeholders. In the Stanford Biodesign Innovation process, our curriculum has evolved to make value a cornerstone of the process. The value parameters of the innovation are established even before the actual solution is invented, and technologies that fail to meet the established value criteria are systematically discarded during the screening phase. Early incorporation of value estimates allows innovators to construct meaningful value-driven solutions with potential to become a viable business. It also allows innovators to view cost-effectiveness assessment as an opportunity for innovation in the field and as a deterrent to more expensive tools that offer marginal benefit to the healthcare system. In summary, it is possible to design new medical devices that are useful to patients, decrease overall healthcare costs, and develop enough stakeholder value to create sustainable businesses.

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Fig 1.
Biodesign Innovation fellowship process.

Table I

Examples of questions asked when assessing value

Question	Application
Is there a cost gap in the current solution landscape?	Less costly solutions that provide the same outcome add value
What effect on patients would a given solution provide?	An incremental increase in cost that at the same time is associated with meaningful improvement in patient outcome may be justified and worthwhile
How large is the potential market?	A need may not be a viable business if the potential revenue is too small

Table II

Sample rating scale for the objective factor: potential to add value

Rating	Description
4	Positive clinical benefit with major cost savings.
3	Positive clinical benefit with incremental cost savings.
2	Positive clinical benefit with no effect on cost.
1	Positive clinical benefit that increases cost.

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