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The Impact of Disruptive Innovations in Orthopaedics

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Abstract The US healthcare system is currently facing daunting demographic and economic challenges. Because musculoskeletal disorders and disease represent a substantial and growing portion of this healthcare burden, novel approaches will be needed to continue to provide high-quality, affordable, and accessible orthopaedic care to our population. The concept of "disruptive innovations," which has been studied and popularized by Harvard Business School Professor Clayton Christensen, may offer a potential framework for developing strategies to improve quality and control costs associated with musculoskeletal care. The introduction of mobile fluoroscopic imaging systems, the development of the Surgical Implant Generation Network intramedullary nail for treatment of long bone fractures in the developing world, the expanding role and contributions of physician assistants and nurse practitioners to the orthopaedic team, and the rise of ambulatory surgery centers are all examples of disruptive innovations in the field of orthopaedics. Although numerous cultural and regulatory barriers have limited the widespread adoption of these "disruptive innovations," we believe they represent an opportunity for clinicians to regain leadership in health care while at the same time improving quality and access to care for patients with musculoskeletal disease.

Introduction

The cost of delivering health care in the United States has become one of the most important public policy issues of the 21st century. The percentage of the US gross domestic product (GDP) that has been consumed by health care has grown from 5% in 1960 to a staggering 16% in 2007 [3]. According to latest projections by the Congressional Budget Office, unless drastic measures are undertaken to control healthcare spending in the United States, total national spending on health care will claim more than 30% of the GDP by 2035 and approximately 50% by 2082 [8]. Although the problem is clearly multifactorial, many health policy analysts have pointed to the adoption of new and advanced healthcare technologies as one of the primary drivers of cost [11]. The United States leads the world in biomedical research, and we have shown we can develop the most sophisticated care to tackle the most complex medical problems. However, our ability to deliver care effectively and efficiently to all who need it is woefully inadequate as evidenced by the high number of un- and underinsured citizens and our low ranking in measures of public health relative to other developed countries [22]. Thus, both the future health and viability of the US economy and its population are intimately related to the thoughtful and responsible adoption of new healthcare technologies.

Given past utilization rates and future demographic trends, the field of orthopaedic surgery can expect to be particularly impacted by this impending economic crisis. According to national healthcare statistics, musculoskeletal

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disorders and disease are the leading cause of disability and account for more than half of all chronic conditions in people over the age of 50 [26]. During the period 2002 to 2004, over 83 million Americans reported one or more spine conditions, and 42 million Americans reported arthritis and joint pain [19, 26]. This resulted in an increase in ambulatory physician visits for musculoskeletal care from 426 million in 1996 to 1998 to 508 million in 2002 to 2004 as well as a 69% increase in total non-MD ambulatory care visits over that same time period [26]. The economic impact of these trends is substantial. In 2004, the sum of direct and indirect expenditures for the burden of musculoskeletal ailments was $849 billion, or 7.7% of the GDP [26].

Moreover, in the next 20 years, the estimated increase of 35 million North Americans over the age of 55 will further amplify the burden of musculoskeletal disease [5]. Nearly 50% of inpatient procedure volume is driven by individuals over the age of 65, and it is estimated that by the year 2030, close to 20% of the US population will have entered this age cohort [27]. Compounding the demographic trend of an aging baby boomer population, this unique cohort in American history has higher expectations of the healthcare system than any generation before them.

Although the future of the American healthcare system is wrought with both demographic and economic challenges, neither need prove insurmountable. In his research on "Disruptive Innovations" in health care, Harvard Business School Professor Clayton Christensen and his colleagues provide valuable insight into one possible strategy to address this challenging, seemingly intractable problem [7]. This article presents the basic principles of "disruptive innovations," documents their precedence in and relation to the healthcare system, and provides specific examples from the field of orthopaedic surgery. In our concluding remarks, we address the inherent cultural and regulatory barriers to adoption of these "disruptive innovations" and offer some possible strategies to overcome these obstacles.

Disruptive Innovations

In his book, "The Innovator's Dilemma," Christensen defines disruptive innovations as "cheaper, simpler, more convenient products or services that start by meeting the needs of less-demanding customers" [6]. According to Christensen's research, disruptive innovations arise in every industry. Although the dominant players in a particular market sector focus on improving the functionality of their products or services to meet the needs of the most sophisticated customers at the high end of the market, they often miss the simpler, more convenient, and less costly alternatives initially designed to appeal to the least demanding customers at the low end of the market. Over time, the simpler (frequently technologically inferior) products and services get better and are eventually able to meet the needs of the vast majority of consumers.

Sustaining innovations are those products and services marketed toward consumers at the higher end of the market. To remain leaders in their field, industries invest in research and development to create a progressively more sophisticated product, which is characterized by a steadily increasing trajectory of technologic improvement (Fig. 1, top solid line). There are numerous examples of sustaining innovations in orthopaedics such as alternative hip replacement bearing surfaces, computer-assisted surgical navigation tools, total disk arthroplasty, locking plates, and bone graft substitutes. Although these new technologies represent important developments that may advance the field of orthopaedics, expand the indications for orthopaedic procedures, and improve patient outcomes, they do not necessarily address the needs of the majority of our patients nor do they help address the problems of limited accessibility and affordability of musculoskeletal care.

Consumers' ability to absorb or use the technologic advances of any innovation is finite (Fig. 1, area between the dashed lines). Furthermore, the pace of sustaining innovation nearly always outstrips the ability of consumers to absorb the improvements in functionality. This creates the potential for the introduction of disruptive innovations that start by meeting the needs of the least demanding consumers at the low end of the market (Fig. 1, bottom dashed line). The performance trajectory of these

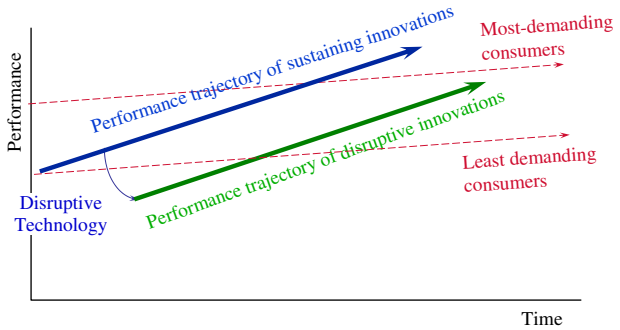

Fig. 1 The performance trajectory over time of disruptive versus sustaining innovations is shown. The area between the dashed lines outlines the rate of improvement consumers can absorb over time. The pace of sustaining innovation nearly always outstrips the ability of customers to absorb it, thereby creating the potential for the introduction of disruptive innovations. The progress of these disruptive innovations is shown by the bottom solid line. (Reprinted with permission from Christensen CM, Bohmer R, Kenagy J. Will disruptive innovations cure health care? *Harv Bus Rev.* 2000;78:102–112, 199.)

disruptive innovations has a distinct but similar vector of technologic improvement compared with sustaining innovations (Fig. 1, bottom solid line). Over time, the functionality of these technologies improves, and eventually, they are capable of meeting the needs of the vast majority of consumers.

Christensen goes on to argue that the "phenomenon of overshooting the needs of the average consumer and creating the potential for disruption quite accurately describes the current situation faced by the healthcare industry" [7]. Sustaining innovations such as emerging technologies, specialist physicians, and academic teaching hospitals constantly strive to improve their functionality to address the needs of the sickest, most complex patients with the most demanding healthcare problems. No one would argue that these entities are contributing to the progress in the field of medicine. However, in a world of limited healthcare resources and a nation where the most medically complex patients make up a minority of the population, it could be argued that our focus should be redirected toward identifying and developing disruptive innovations. This could start by addressing the needs of less medically complex patients but over time could be used to facilitate higher-quality, more convenient, more accessible, and less costly care to the majority of healthcare consumers in the United States.

The field of orthopaedics is constantly undergoing rapid development through ongoing basic science and clinical investigation. Currently, the focus of most biomedical researchers and the pharmaceutical, medical device, and biotechnology industries is disproportionately centered on sustaining innovations, because of organizational structures and financial incentives. For these reasons, the impact of disruptive innovations on the future of orthopaedics and the health care of the nation can only be realized with a change in perspective and a reallocation of healthcare dollars.

In the next sections, examples of disruptive innovations in four areas of orthopaedic care delivery illustrate various manners in which they may impact the healthcare system. In "Diagnostics", we focus on the introduction and popularization of the mini-fluoroscan as a means of facilitating and increasing access to real-time imaging. In "Surgical Techniques and Technologies", the Surgical Implant Generation Network (SIGN) intramedullary nail is analyzed as a "low-tech" treatment option to improve the level and access of orthopaedic fracture care in the developing world. The expanding role and contributions of physician assistants (PAs) and nurse practitioners (NPs) to the orthopaedic team is the topic of the discussion on disruptive innovations in "Care Processes." Finally, in "Healthcare Delivery Systems", we analyze the various ways in which institutions have attempted to implement the paradigm of "patient-centered care" by modifying existing programs and care delivery models, focusing specifically on the rise of ambulatory surgery centers.

Diagnostics: Point-of-service Radiology: the Mini-fluoroscan

Mini-fluoroscans, or mini C-arms, are mobile fluoroscopic imaging systems designed for point-of-service, real-time images that have the potential to increase access and decrease costs in the delivery of high-quality orthopaedic care. They are gaining popularity in operating rooms, emergency departments, and physician offices because of their mobility, simplicity of use, lower cost, and lower-dose radiation compared with their full-size counterparts. Clearly, they do not currently offer the same image quality or functionality that full-scale fluoroscopy units or digital radiography equipment can provide, and they would not be appropriate for use in many complex procedures such as pedicle screw placement or open reduction internal fixation of a long-bone fracture. However, technologic advances have enabled these devices to provide adequate image quality for less complicated interventions such as evaluating the alignment of a distal radius fracture after closed reduction, allowing dynamic evaluation of small joint stability, or assessing the adequacy of reduction and hardware placement in the operative treatment of certain fractures.

As a disruptive innovation, mini-fluoroscans offer the ability to reduce the costs associated with using radiology technicians and radiologists while at the same time increasing the autonomy of the orthopaedic surgeon to obtain and interpret his or her own radiographs. In addition, the ability to obtain real-time images cuts down on the cumulative time and money spent waiting for conventional radiographs to be obtained, processed, and then either printed or uploaded onto a picture archiving and communication system. As the technology reliably improves such as image resolution and cordless foot pedals, it is expected that the indications for use of the mini C-arm will increase.

Currently, there are two types of mini C-arm units available in the United States: the Fluoroscan (Hologic, Inc, Bedford, MA) and the Xitec XiScan (F&M Control, SL, Vitoria, Spain). In a study comparing the mini-fluoroscan with a conventional mobile C-arm on its ability to maintain image quality while (1) delivering the lowest possible radiation exposure to both patient and physician; and (2) minimizing operator effort and inconvenience, the authors of the study rated the mini C-arm as "acceptable" in both categories [10].

Ideally, increased use of mini C-arms could result in improved patient outcomes and increased autonomy of the orthopaedic surgeon while reducing the need for radiology technicians to operate conventional fluoroscopy units, thus

lowering overhead costs for hospitals and surgery centers. The mini C-arm allows orthopaedic surgeons, emergency department physicians, and nonphysician providers to obtain fluoroscopic images, view the images in real time on a monitor, save and retrieve them later, or have a printout immediately available during the closed management of fractures. With the increased volume of patients presenting to physician offices, urgent care clinics, and emergency departments and the high use of plain radiography, the ability to substitute the use of the mini C-arm for the use of conventional fluoroscopy and digital radiography could lead to reliable cost savings and a decreased burden on the healthcare workforce.

Fluoroscan, a division of Hologic, Inc, illustrates the natural progression of disruptive innovations to a technology sector and specifically within a single company. Within a year of expanding their product line by introducing the Premier mini C-arm to their already established conventional C-arm market, the success of the Premier resulted in the discontinuation of its larger, standard-sized C-arm. Hologic executives attribute the success to the user-friendly interface of the mini C-arm and the advent of a proprietary beam alignment technology called Laser Aiming Device (LAD) [23]. The LAD enables the user to position the desired part of the anatomy in the center of the imaging field when the input surface of the image intensifier is obscured by drapes, arm boards, or other objects present in the operating room. Currently, the company is focusing on improving their product by making the system even easier to use and streamlining system housekeeping functions like image storage and transfer. This example illustrates how a relatively simple technology that was originally inferior in functionality improved over time and was eventually able to meet the needs of most mainstream consumers, thus displacing its higher functionality predecessor (sustaining innovation) for certain indications.

Surgical Techniques & Technology: SIGN (Surgical Implant Generation Network) System to 'Create Equality of Fracture Care Throughout the World'

The SIGN system was developed in 1999 to address the orthopaedic needs of the developing world and represents a surgical technique and technology as a disruptive innovation. Its founder, Dr Lewis Zirkle, explains the SIGN intramedullary nail was founded to "create equality of fracture care throughout the world" [25]. Rather than incorporating the newest technologic advancements or design modifications to address the needs of the higher end of the fracture care market, the nail was specifically designed to be "low tech," easy to use, and inexpensive to manufacture. Specifically, the SIGN system relies on hand drills and reamers as well as a rigid slotted jig for placement of interlocking screws. This response to the recognized lack of access to fluoroscopy and reliable power instrumentation in many countries in the developing world represents the way in which a disruptive innovation can increase access to treatment. Currently, approximately 40,000 SIGN nail procedures have been performed in over 140 programs in 40 countries [25].

In addition to a surgical technique adapted for a resource-poor healthcare system, the SIGN system itself was developed to be inexpensive to manufacture, highly versatile, and widely available. A set of 100 nails, complete with the instrumentation, is sold for an initial cost of $20,000. The nails themselves can be used for the humerus, tibia, and femur and inserted either in antegrade or retrograde fashion. Furthermore, the philosophy behind the SIGN system is to provide not only equitable, but sustainable fracture care. As such, a replacement nail and the interlocking screws are sent free of charge for each one that is used as long as the treating surgeon systematically reports the details of the clinical case, implants used, and postoperative radiographs on the SIGN web site's surgical database.

There are two published, peer-reviewed journal articles on clinical and radiographic outcomes after treatment with the SIGN nail system. One manuscript reviews the short- to midterm results of the SIGN nail for treatment of open tibia fractures in Kathmandu, Nepal, whereas the other reports on a consecutive series of patients who were treated with SIGN nails for extremity fractures in Nigeria [12, 24]. Both studies report a high degree of clinical success with a low incidence of complications. In Nepal, Shah et al. were able to demonstrate that 86% of (31 of 36) open tibia fractures healed within 6 months with only an 8% infection rate [24]. Similarly, Ikem and colleagues reported a mean time to union of 3 months, no missed interlocking screws, and a low complication rate. In their series of 40 patients, there were two cases of superficial infection, one interlocking screw failure from osteoporotic bone, and two delayed unions [12].

Like all disruptive innovations, the SIGN intramedullary nail system is not a static entity, but rather is evolving into other areas of fracture care. Recently, Dr Zirkle developed a SIGN system for internal fixation of hip fractures that does not rely on power instruments or fluoroscopy, which is called the SIGN hip construct. The first clinical case in which this system was used occurred at Wazir Akbar Khan Hospital in Kabul, Afghanistan, in a patient who sustained an intertrochanteric hip fracture. The translation of the SIGN surgical technique and instrumentation from long bone fractures to hip fractures clearly demonstrates the manner in which the performance trajectory of a disruptive

innovation can improve over time and begin to meet the needs of more demanding consumers (Fig. 1, solid bottom line).

Process of Care: Physician Assistants and Nurse Practitioners—Colleagues, Not Competitors

The increased role of physician assistants (PAs) and nurse practitioners (NPs) in orthopaedic surgical practice is an example of healthcare providers as a disruptive innovation, because they are able to help facilitate increased access and lower costs associated with delivering high-quality orthopaedic care. Although the establishment and development of the first formal PA and NP educational programs and professional organizations occurred in the mid-1960s, it was not until the 1980s and 1990s that there was a rapid expansion of PA and NP training programs. At that time, healthcare legislation was revised to reduce barriers to use PA and NP services in a variety of healthcare settings. HMOs recognized the important roles of PAs and NPs in controlling costs, and restrictions on resident duty hours spurred employment and postgraduate learning opportunities in hospital inpatient settings [18]. Twenty-three percent (11,500) of the estimated 50,000 clinically practicing PAs work in surgical specialties or subspecialties, and there are currently 5000 PAs employed in the field of orthopaedics in the United States [1].

Christensen et al. have noted that many of the most potent disruptive innovations in health care achieved success by "enabling a larger population of less-skilled people to do in a more convenient, less costly setting things that historically could be performed only by expensive specialists in centralized, inconvenient locations" [7]. For PAs and NPs in orthopaedics, common responsibilities include taking evening and weekend calls as well as emergency department coverage, performing admission history and physical examinations, first-assisting in the operating room, providing patients with preoperative information and postoperative instructions, and performing dressing and cast changes [13]. Many of these tasks and roles that used to be performed by surgeons are clearly within the capabilities of certified PAs and NPs and for a fraction of the cost. Moreover, according to the Medical Group Management Association (MGMA), PAs and NPs often generate revenue that more than covers their compensation. MGMA collects data annually comparing PA compensation with gross charges. According to 2002 data, for PAs in surgical practices, the employer pays 32 cents for every dollar of charges generated [17]. This cost savings is experienced both at the practice and national level. As of January 1, 1998, Medicare pays PAs 85% of the physician fee schedule, which also holds true for first-assisting during surgery. For a surgical procedure, this translates to approximately 14% of the primary surgeon's fees (ie, 85% of physician first assistant fees, which is 16% of the surgeon's fees) [1].

When an appropriate level of responsibility is bestowed on the PA or NP, quality of care is not sacrificed. In fact, studies of patient satisfaction have shown a high level of satisfaction with care provided by PAs and NPs. In 1994, the Federal Advisory Group on Physician Assistants and the Workforce concluded that published research since the profession began consistently found a high level of patient acceptance. Furthermore, a comprehensive 1995 to 1996 Kaiser study evaluating patient satisfaction with PAs, NPs, certified nurse midwives, and physicians in a managed care setting concluded that "patient satisfaction with interpersonal care appears to depend on communication style and not on type of provider" [21]. With the anticipated changes in demographics in the coming decades, it can be expected that PAs and NPs will play an increasingly important role in the orthopaedic team by assuming a larger share of the nonoperative aspects of the orthopaedic patients' care, thus allowing orthopaedic surgeons to focus on the surgical management of musculoskeletal disease.

Healthcare Delivery Systems: The Rise of Ambulatory Surgery Centers

Although technological advancements and the expanding role of ancillary staff may contribute to improved access and care, the greatest opportunities to improve the healthcare system as a whole and the care provided to the population is to focus on and modify the healthcare delivery systems currently in place. Recently, there has been increased awareness that the current hospital system in the United States fails the individual patient in many regards as a result of the fragmented provision of care by multiple providers in a myriad of settings. In response to this, there has been an emphasis on patient-centered or patient-focused care as a low-technology solution to the existing problems. Single-specialty hospitals and ambulatory surgery centers (ASCs) have consistently enjoyed high patient volumes and high satisfaction rates, in part because of their ability to deliver focused, efficient, high-quality patient-centered care. In a recently published study, Cram and colleagues reported that even after adjusting for numerous important facility and patient characteristics such as bed size, teaching status, and patient comorbidities, specialty orthopaedic hospitals delivered higher-quality care to orthopaedic patients than their general hospital counterparts [9]. In response to this, general hospitals have had to modify their service lines and implement operational efficiencies in an attempt to compete for orthopaedic

patients seeking high-quality, convenient, accessible care. As noted by Christensen et al., the basis for competition for many less complicated procedures such as elective orthopaedic surgery has changed to reward reliability, accessibility, convenience, and low cost rather than higher functionality [7].

Ambulatory surgery centers satisfy the criteria for a disruptive innovation in the field of care delivery in that they are a cheaper, simpler, more convenient alternative to hospital operating rooms, and they were initially designed to appeal to the low end of the market. An ASC is a facility that by definition provides surgical treatment that does not require hospitalization. These facilities were initially tailored toward healthier patients requiring minor elective procedures. Orthopaedic subspecialties amenable to ambulatory surgery include arthroscopy, sports-related injuries, hand, some spine as well as foot/ankle procedures, and the list is expanding.

Many of the initial ASCs struggled after their debut in 1972 as a result of inadequate reimbursement and the need to establish themselves in the eyes of investors as a high-quality, profitable investment. After 1982 and the approval of Medicare reimbursement for ASCs, there has been substantial growth in the number of ASCs in the United States. Today there are more than 4000 ASCs throughout the United States compared with 275 in 1980 and 1450 in 1990 [2, 14]. From 1996 to 2003, the number of ASCs increased by 50%, from 2425 to 3646, whereas the number of hospital-based outpatient surgery centers dropped by 16% [20]. One of the primary reasons for the success of ASCs when compared with hospital-based outpatient surgery centers is their profitability. The Pennsylvania Health Cost Containment Council reports that free-standing ASCs have an average net margin of 12%, whereas hospital outpatient surgery centers are on average barely profitable at 2% [20]. These differences in profitability have led to payment reforms that have limited payment for ASCs to 65% of the payment for hospital-based outpatient surgery centers for the same procedures [16]. These types of misguided payment reforms incentivize less efficient care and threaten the future viability of ASCs to deliver high-quality, cost-efficient care.

The literature supports the fact that increased volume and profits have not come at the expense of quality of care. In fact, the American Association for Accreditation of Ambulatory Surgery Facilities, in its ongoing effort to improve patient care, has developed an Internet-based quality improvement and peer review program to analyze outcomes for the surgery centers it accredits. Each surgeon must report all unanticipated sequelae, and at least six random cases are reviewed by an accepted peer review group biannually. In a study conducted over 2 years (2001 to 2002), one unanticipated sequelae occurred in every 299 procedures (incidence of 0.33%), and a death occurred in one in 58,810 procedures (0.0017%), which was comparable whether the procedure was performed in an accredited ambulatory surgery facility or a hospital-based surgical facility [15]. Thus, it appears that ASCs, rather than being static entities, are constantly innovating, streamlining, and incorporating technologic advances in surgical devices, techniques, and anesthesia protocols to expand the conditions for which same-day surgery is safe and appropriate.

Reasons for Nonadoption: Barriers to Progress

Disruptive innovations in health care, in theory, offer lower cost, more efficient and convenient alternatives while maintaining, if not improving, the quality of care provided to patients. Therefore, it might seem unusual that there would be any resistance to their adoption. Yet as Christensen aptly notes, "healthcare may be the most entrenched, change-averse industry in the United States" [5]. From physicians to hospitals, health plans to implant manufacturers and regulators, it appears many stakeholders in the US healthcare system support the status quo to maintain their positions and profits. Although no one would blame the fact that most healthcare stakeholders feel a keen sense of defensiveness to protect their piece of an ever diminishing pie, without thoughtful, voluntary sacrifice, we risk losing control of how our piece is divided. It is at these crossroads specifically where providers can regain some control of the practice of medicine. The rise of managed care, changes in reimbursement rates from third-party payers, and the diffusion of new technologies to the market have intensified "turf wars" between the different professional guilds of medical practitioners. Disruptive innovations, some would argue, are only stoking the flames, because they allow procedures to be performed more efficiently in a more convenient location by providers who had previously been unable to provide such a service. In orthopaedic surgery, examples of "turf wars" include the ongoing battle with radiologists over the use of in-office diagnostic imaging and conflicts with podiatrists and physical therapists over the scope of their practice. These disputes are provider-centric conflicts that consume valuable resources and energy that could be redirected to enhance the value of care we provide by increasing quality and reducing costs.

Hospitals, by virtue of their size, associated overhead, and their large investments in the latest sustaining technologies, are similarly wary of disruptive innovations, because they may threaten their long-term financial viability. The rise in ASCs and single-specialty hospitals have shown investors and physicians alike that high-quality care

can be provided with a much higher return on investment when facilities are patient-oriented, care delivery and operations are streamlined, and physicians and personnel are well integrated. Clearly, general hospitals are at a distinct disadvantage when it comes to "competing" for profits with standalone ASCs and single-specialty hospitals, because the burden of the uninsured and underinsured falls squarely on the shoulders of the former and the scope of practice differs greatly between the various healthcare delivery systems. However, comparisons can and should be drawn between the greater operating efficiencies of the ambulatory surgery centers as compared with hospital-based outpatient surgery centers. The margin differentials that exist between these two delivery systems cannot be explained simply by the patient population cared for or services provided. Although it may be true that ASC's are guilty of "cherry picking" patients, an analysis of the systems in place in these facilities may provide valuable lessons to improve the efficiencies of the hospital-based outpatient surgery centers. Unfortunately, it appears many hospitals are ill-equipped to compete in today's flexible, highly competitive healthcare delivery market.

Commercial health plans and other third-party payers, with their strong focus on profit margins, would seem to be an ally of disruptive innovations in that these technologies hold the promise of providing cost savings without sacrificing quality of care. However, commercial payers only reimburse for procedures that have been clinically validated, and many disruptive innovations, by virtue of being recent entrants to the market, do not yet have peer-reviewed research to support their efficacy compared with so-called "gold standard" treatment interventions. By labeling many new potentially disruptive procedures as "investigational," private insurers stifle growth and innovation that could lead to higher-quality, lower-cost care in the long run.

The rise in direct-to-consumer advertising of hip and knee replacement implants, primarily by implant manufacturers, but also by hospitals and surgeons, to gain a more competitive position in the lucrative and expanding arthroplasty market also poses a formidable institutional barrier to the adoption of disruptive innovations. It is the sustaining innovations that currently fuel the research and development of the orthopaedic device manufacturers such as alternative bearings for use in THA, computer-assisted surgical navigation tools, and new suture fixation devices. Although these devices have the potential to improve patient outcomes, they are consistently introduced into the market at a substantial cost premium and before validation of their clinical benefit and cost-effectiveness through well-designed, prospective clinical studies. Patients, as consumers, are shielded from the costs of orthopaedic implants and are often presented with misleading information about the benefits of particular products, which in turn may lead to inappropriate demands for newer, more costly, unproven technologies, strain the physician-patient relationship, and potentially contribute to the rising cost of health care [4].

Regulators, as opposed to physicians, care delivery systems, and third-party payers, have no financial incentive to resist the diffusion of disruptive innovations. Although originally established to protect both the consumer and society from unforeseeable risk as well as enforce the standards established by physicians, regulatory bodies often indirectly curb the diffusion of disruptive innovations by protecting and enforcing the status quo, which happens to be on the side of sustaining innovations. One of the main obstacles to diffusion of disruptive innovations stems from a dearth of published research demonstrating safety and efficacy. The lengthy and cumbersome FDA approval process for investigational devices and the bureaucratically complex HIPAA regulations are two key examples of how regulators indirectly impede the diffusion of disruptive innovations. Additionally, the enforcement of stringent intellectual property laws has the unintended consequence of limiting the introduction of generic drugs and device alternatives.

Discussion

The US healthcare system is clearly in crisis, and current strategies have proven inadequate. Many healthcare institutions and healthcare technologies have overshot the needs of most patients with nonlife-threatening conditions who require elective surgical treatment such as many orthopaedic patients. As Christensen et al. have noted in their work, the market for simple, elective surgical procedures no longer rewards higher functionality, but rather rewards convenience, accessibility, low cost, and reliability [7].

In this article, we have applied the concept of disruptive innovations popularized by Christensen to the field of orthopaedics to illustrate examples in which simpler, cheaper alternatives have improved access of care, increased patient satisfaction, and empowered clinicians to provide higher-quality, more convenient and efficient care to their patients. Although we chose to focus on the specific examples of disruptive innovations described, there are many other potential examples related to musculoskeletal care delivery, including calcium phosphate cement for the treatment of distal radius fractures in the elderly, musculoskeletal ultrasound, and "medical tourism."

One of the defining characteristics of a disruptive innovation is a performance trajectory that allows it to eventually meet the demands of more sophisticated consumers. Each of our examples has the potential to

continually evolve, improve, and thereby become "more disruptive" over time. Specifically, the technology underlying the mini-fluoroscans may improve to the point that the image quality achieved is comparable to that of conventional C-arms. Furthermore, although a number of the larger C-arms now are able to create fluoroscopic computed tomography reformats for three-dimensional detail, one could imagine that the mini C-arms may incorporate this feature in the years to come. This would allow for an expansion of current indications such as evaluation of complex, intraarticular fractures by these smaller imaging machines. Additionally, less expensive radiographic printers may be developed to allow for point-of-service printing of formal radiographs, thereby obviating any dependence on the radiology department.

In regard to increasing the role of PAs and NPs, these so-called "midlevel" providers have become an integral part of most orthopaedic practices, functioning as primary care musculoskeletal providers and thus allowing orthopaedic surgeons to focus on the surgical management of musculoskeletal disease.

Similarly, ASCs will continue to grow their market share as surgeons and anesthesiologists collaborate to develop perioperative protocols that allow for more complex procedures to be performed as "same day surgeries" without compromising safety (eg, improving preoperative education, including the proper use of assistive devices, providing appropriate preoperative education to patients and their families, and discharging patients home with indwelling pain catheters).

The sustaining orthopaedic innovations that are repeatedly introduced into the marketplace will continue to benefit our patients and advance the field of orthopaedics. To date, health care in general and the field of orthopaedic surgery in particular has focused a disproportionate share of resources and effort on the problems of a medical minority. To improve the overall health of the nation, efforts and resources should be redirected toward technologies that improve access and tackle issues of affordability to address the needs of the majority. Although it would be naïve to believe all of the ills of the healthcare system could be reversed simply by the development and diffusion of disruptive innovations, not actively attempting to identify and cultivate them will lead us further down our current path toward unsustainable healthcare inflation and an ever increasing gap between the health care we are capable of delivering based on technologic innovation and the health care we are able to deliver based on limited resources. Moreover, the concept of disruptive innovations offers the opportunity for clinicians to regain leadership in health care by working together with other healthcare leaders to deliver higher-quality, more convenient and accessible cost-effective care to our patients.

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