Higher Integrity Health Care
Evidence-Based Shared Decision Making

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Corruption of the Healthcare Delivery System

Two recent books[1,2] have added to the body of work[3–6] describing how the pharmaceutical industry has influenced medical research in its favor. By selective reporting, targeted educational efforts, and incentivizing prescriber behavior, the industry also has a profound impact on the way medicine is practiced. The medical device industry, promoting advances in procedural and diagnostic arenas, has not yet had the spotlight so carefully focused on it, but any future examination is likely to reveal similar influence. Many companies walk a thin line when it comes to providing free equipment and offering training when promoting the use and uptake of novel technologies.[7] In both industries, the interests of patients often take second place to marketing.

The accounts in Goldacre's and Gøtzsche's books cast serious doubt on the governance of current healthcare practice. In addition, billions of dollars are invested in direct-to-consumer advertising and the manufacture of consumer interest in healthcare services, either by creating new disease labels, so-called disease mongering,[8] or by promoting the use of drugs to address spurious risk predictions. This has become particularly noticeable given the recent promotion of drugs to reduce cholesterol, control blood pressure, and more recently, prevent bone loss, where in many circumstances, there is increasing debate about the appropriate thresholds for pharmaceutical intervention for these conditions.[9]

Many have spotted the problem. Physicians and patients tend to assume that newer and more technologically advanced care means better care.[10] The practice of medicine has also been heavily influenced by efforts to lower diagnostic thresholds, thereby intervening more often, without paying attention to the increasingly small level of benefit, or to the substantial potential harms.[11–13] In 2013, the first international conference was held on the theme of overdiagnosis: >300 researchers, clinicians, and policy makers attended, and future conferences are scheduled.

How can these challenges be overcome? Can we find a path for medicine that has a higher level of integrity? How might we achieve health care that is based on sound scientific evidence, where practitioners inform and involve individuals, respecting the issues that matter most to patients?

How Could Medicine Become More Open, Transparent, and Respectful?

We think there are 5 significant problem areas that need to be tackled. First and foremost, unsatisfactory research processes and a lack of transparency lead to an evidence foundation that is too weak for clinical practice. Second, there is low-quality evidence synthesis, based on incomplete, poorly appraised data. Third, the evidence is difficult to interpret by those who need it, mostly because the data are seldom rendered relevant to the decision facing clinicians, and little, if any, thought is given to making the evidence intelligible to patients. Fourth, measurement and accountability systems remain insufficiently effective at modifying clinical behavior: other, often financially motivated, incentives seem to override efforts to encourage patient-centered care. Fifth, there is an unrelenting effort made to manufacture consumer demand for healthcare, especially in developed economies such as the United States, using direct-to-consumer advertising and many other forms of consumer influence. These problems act in synergy to create a system where healthcare is increasingly commodified and profit driven, and where both clinicians and patients feel marginalized and frustrated. The Table summarizes these issues. We now consider them in more detail and, in each case, suggest a path to the delivery of higher integrity healthcare.

Problem 1: A Weak Research Foundation That Lacks Transparency

There are a multiple examples where the failure to disclose the known, yet unpublished, harms of new drugs have led to significant adverse events, even patient deaths. Gøtzsche[2] lists how Pfizer agreed to pay $2.3 billion as settlement in 2009 for illegally promoting 4 drugs (valdecoxib, zisprasidone, linezolid, and pregabain). He cites the fines and settlements of other well-known companies as examples of the extent of the problem: Novartis, $423 million in 2010 for illegal marketing of a drug for epilepsy; GlaxoSmithKline, $3 billion in 2011 for illegally marketing drugs for off-label use. These are just a few examples: the list is extensive and sobering. One of most recent problems was the failure of GlaxoSmithKline to include safety data about rosiglitazone (Avandia) to the Food and Drug Administration, a drug for diabetes mellitus withdrawn in Europe in 2010 because of

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Table. Problems Blocking the Path to a Higher Integrity Healthcare System AQ8

Underlying Problem	Path to High-Integrity Health Care
A weak research foundation that lacks transparency	
Study conclusions can be influenced by selection of design, population, and end points.	Regulators overseeing drug and device trials should ensure that designs meet broad public interests
Failure to release research data leads to incomplete assessment of harms and benefits.	Enhance the integrity of clinical research by requiring protocol registration and data transparency, see All-Trials (http://www.alltrials.net/)
The problem of publication bias, where negative results are unpublished, while positive results are promoted, often using ghostwriters	Ensure that articles are written by the named authors and financial contributions openly declared
Low-quality evidence synthesis	
Evidence synthesis is often incomplete and of low quality	Ensure synthesis methods are transparent and robust by adopting rigorous processes, for example, GRADE (http://www.gradeworkinggroup.org/)
Many clinical guidelines are influenced by the commercial interests of expert contributors	Establish methods to improve the integrity of clinical guideline production
Evidence that remains inaccessible to those who need it	
Limited availability of scientific evidence in formats that are accessible to clinicians and patients	Create evidence-based tools that allow patients and clinicians to collaborate, for example, Option Grids and Issues Cards (http://www.optiongrid.org/ and http://shareddecisions.mayoclinic.org/decision-aids-for-chronic-disease/diabetes-medication-management/)
Ineffective performance measurement and accountability	
Payment and delivery systems create incentives to do too much or do too little and fail to encourage meaningful choice.	Design systems that reinforce the need to respect choices determined by the informed preferences of patients
Clinicians, health systems, and policy makers make decisions assuming they understand the preferences of those they serve	Ensure that the informed preferences of patients guide decision making at the level of policy and health system design
What matters most to patients is too often left unexplored	Meaningful, practical measures that collect, analyze, and provide data about the preferences and experience of patients
Unempowered patients	Patients requesting digital recordings of clinical encounters
Manufacturing consumer demand	
Direct to consumer advertising exaggerates benefits, minimizes harms, and promotes overdiagnosis	Engage stakeholders to establish better standards for dissemination of information to consumers
Media misses opportunity to help consumers make wise choices	A more skeptical media could help consumers learn how to make wiser choices

GRADE indicates Grading of Recommendations Assessment, Development, and Evaluation.

cardiovascular deaths. As commentators have said, pharmaceutical companies seem to view such penalties merely as the price of doing business.

The difficulty of obtaining research funding for comparative effectiveness studies is directly related to the prominence of industry-sponsored trials: finance dictates the activity. Another unresolved problem is how to prioritize the focus of research funding, particularly when budgets are scarce. The problems of greatest concern to patients are often left uninvestigated, with emphasis given to research that expands market share. Some efforts have been made to address this issue. The James Lind Alliance remains a lone pioneer in this area.[14] Equally problematic is publication bias, where results of trials that fail to demonstrate an effect remain unpublished, yet trials with favorable results are swiftly published and promoted. The use of freelance writers to write research articles, so-called ghostwriting, where authorship is credited to leading opinion leaders in the field, has also been exposed widely.[1]

Solution

There is growing recognition of the limitations of study design. Regulators should move forward to address them by requiring trials to compare against the best current therapy rather than against placebo and to measure outcomes that matter to patients instead of using selected surrogate outcomes. Although hard won, significant progress has already been made toward more research transparency. Building on the first major call for trial registration that was made in 1990,[15] the AllTrials campaign has galvanized opinion in this area.[16] AQ9 The goal of the campaign is to improve the integrity of clinical research, requiring the registration and publication of trial protocols, making it possible to track studies that have not reported results. Access to the data would also enable secondary analysis and verification. The campaign has had significant impact and regulators have taken notice of the increasing demand for more transparency.

Ghostwriting is a more difficult problem to tackle. The pressure to publish leads many academic researchers to accept arrangements that compromise their integrity. High-quality journals do require declarations of authorship and competing interests by authors, but verifying such statements is difficult. Where trials are funded by a company with an interest in the results, it seems reasonable to require much greater scrutiny. Research outputs should have prominent warnings where the trial design, management, and analysis were not done independently of a company who stood to profit by the outcomes.

Problem 2: Low-Quality of Evidence Synthesis

Good evidence synthesis should be the bedrock on which clinical guidelines are developed. Yet, the development of clinical practice guidelines has become an industrialized, often sponsored process.[17] Multiple guidelines exist on the same clinical topic, often making different recommendations. These guidelines are frequently produced by expert panels convened by specialty-based organizations. As Moynihan et al[18] have shown, linkages to pharmaceutical companies are commonplace. These types of guidelines have been criticized because their evidence synthesis is often incomplete, leaving them vulnerable to bias.

Solution

One of the most significant developments of the past few decades has been the development of high-quality evidence synthesis, best illustrated by the work of the Cochrane Collaboration. The principles of complete, transparent, rigorous synthesis have also been replicated by some other institutions, where conflicts of interests are made transparent and minimized where possible. Clinical guidance produced by institutions such as National Institute for Health and Care Excellence in the United Kingdom is a good example, where processes are transparent and published. Recently, the Grading of Recommendations Assessment, Development, and Evaluation working party has established methods to asses the quality of such reviews.[19] The Grading of Recommendations Assessment, Development, and Evaluation methods are now adopted by >70 organizations worldwide. Guideline developers should describe how the work was funded, and all those involved should have publically available declarations of all their financial and intellectual interests. There is increasing interest in evidence synthesis that might draw on crowdsourcing methods, reducing the major duplication of effort in this area and resulting in tools that have much wider audience reach.[20] In a world where science is moving toward the principles of open-source data collection and transparency, the potential to derive a global consensus on the effect of healthcare interventions becomes tantalizingly possible.

Problem 3: Evidence That remains Inaccessible to Those Who Need It

The first 2 problem areas address evidence sources, specifically the research process and how to ensure comprehensive, rigorous data synthesis so that the messages are accurate and robust. However, solving these 2 issues will never be enough without addressing the final mile of the delivery pipeline. The final destination of high-quality evidence has to be the clinical encounter where care is decided and delivered. Good evidence is only useful when it is understood by clinicians and patients and used to make good decisions. We think this final mile has been neglected and needs urgent attention. Of course, clinicians need better access to high-quality summarized evidence. Yet, we see the need to go much further. Patients also need access to the evidence and in ways which have been designed to ensure their involvement in decisions. AQ10 Evidence that involves patients in decision making leads to improved outcomes, leading to increased policy interest in how to best sustain patient-centered care.[21] We think it is possible to develop tools that support collaboration and deliberation, 2 key activities of shared decision making.[22]

Solution

The solution is to redesign the tools for use by patients. However, despite good evidence synthesis, publishing high-quality guidelines achieves little unless practitioners are motivated to consider them carefully and in collaboration with patients. The advice in guidelines always applies to populations of patients—the interpretation of evidence so that decisions are made with respect to individual patients is the key to effective practice.[23] Shorter tools help. We have seen some progress in AQ11 this direction, but it has been painstakingly slow.

The term shared decision making is now widely recognized, yet also often misunderstood. The term refers to a process where a clinician and a patient make a real effort to understand what is important, each to the other. Information is shared and preferences are elicited. Many think that shared decision making is about providing patient decision aids, tools such as DVDs or websites, that provide information to patients. These tools are, of course, helpful; they provide high-quality information (Stacey et al[21]). However, there is little evidence that distribution alone is sufficient, there needs to be effort made to engage patients in meaningful dialogue. In addition, efforts to implement these tools have met significant barriers, so reliance on tools alone is unlikely to be a route to success.[24]

There has been recent interest in tools that are shorter and designed to be used in clinical encounters. Their goal is to provide a catalyst for providers and patients to have different kinds of conversations, stimulating collaboration and deliberation, using concise summaries, based on the highest possible quality synthesis of evidence. Examples are Issues Cards[25] and Option Grids.[26,27] By designing tools that focus on stimulating dialogue with patients, they become shorter and easier to use. Clinicians also appreciate having short summaries that provide comparative information about treatments, information that otherwise is difficult to find. More work is needed to evaluate their impact, but these point-of-care tools seem to offer a clear path ahead for evidence-based shared decision making. Ensuring that these tools are of high quality, and as unbiased as possible will be a high priority, as indicated in the Affordable Care Act.[28]

Problem 4: Ineffective Performance Measurement and Accountability

In many developed healthcare systems, payment and delivery systems create incentives to do too much and fail to encourage meaningful choice. Rising healthcare costs within developed and developing countries threaten both public and private budgets. The evidence that between 20% and 30% of current US healthcare spending is wasted[29–32] contributed to the sense of both crisis and opportunity that motivated US healthcare reform. It has become clear to those who work to reform the care delivery systems that existing measurement systems fail to ensure sufficient accountability. Measuring volumes while not paying attention to quality leaves patients vulnerable. Currently, clinicians, health systems, and policy makers

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make decisions assuming they understand the preferences of those they serve. It has become clear that the issues that matter most to patients are too often left unexplored, and we have neglected the adoption of measures that value the informed preferences of patients. There has been interest in the use of patient reported measures, but progress toward the use of such data to improve systems is slow. The patient's voice goes largely unheard.

Solution

Two broad initiatives have emerged. One is focused on payment reform, and included bundled payments and accountable care organizations,[33] intended to reward providers for improving care and lowering costs. The other is focused on advancing performance measures so that patients and others can judge the value of care along important dimensions such as patient reported outcomes, such as improved function, quality of life, and meaningful engagement in decision making.

Considerable progress is being made in the implementation of payment reform, although it is not yet clear whether these initiatives will lead to significant and sustained reductions in healthcare costs. There is much less evidence that measurement systems can assess whether clinicians inform, elicit, and integrate patient preferences when building care plans. Developing measures that can assess patient-centered care in a practical, reliable, and sustainable way in routine clinical settings has eluded the efforts of researchers to date. It remains difficult to collect valid data from patients about their experience of care. Patient reported measures are often administered many weeks after the relevant encounter, and response rates are too low to be reliable. Patient reported measures could have an important part to play in performance measurement if more data were available about their validity and reliability.[34] In summary, existing measurement systems do not yet provide a means of ensuring that practitioners are patient centered. Linking these forms of metrics to payment reform will be critical.[35]

Given the lack of patient centeredness, it is important to note the emergence of a phenomenon that could make a significant contribution to change. Often out of frustration with the care they have received, some patients have decided to use smartphones, or other devices, to record clinical encounters, sometimes covertly, assuming that permission would be denied if they were to ask. There are many reasons why patients might wish to record encounters, ranging from wanting to listen again to the encounter to gathering evidence that could be used in a court of law. Clinicians, when they become aware of covert recording by patients, have reacted in a negative way, calling it a violation of trust.[36]

However, organizations that indemnify clinicians have adopted a different approach. During the past 5 years, medical defense organizations have issued guidance saying that patients have the right to record clinical encounters, and that they do not need the consent to do so. It is, they say, equivalent to a highly accurate form of note keeping. They also add that it would be much more acceptable if patients openly recorded the encounters, and that clinicians and their organizations should accept that digital recordings of clinical encounters will become part of practice. Adopting a permissive attitude is the most recent policy of some medical defense organization. Some commercial organizations have started to offer services to record clinical encounters.

Perhaps some healthcare organizations will decide to adopt AQ12
the idea of recording clinical encounters? This would mean that the content of medical practice would be accessible for review and assessment. It may be a large data set, but the possibility emerges of examining the quality of these encounters, assessing how practitioners informed, involved, and sought the preferences of the patients. We may not yet have ability to analyze these issues efficiently, but perhaps it is only a matter of time before systems arrive that could automate this assessment.

Problem 5: Manufacturing Consumer Demand

To maximize the potential profit from the commodification of health it helps to grow the market, to generate more customers, irrespective of whether this provides additional value to them as individuals. The most obvious way in which this is done in the United States is by direct-to-consumer drug advertisements. In the United States, pharmaceutical companies spent roughly $4 billion in 2011 on direct-to-consumer marketing in addition to ≈$14 billion promoting drugs to prescribers in the same year.

There are also efforts known as disease mongering, where new illnesses are created, such as the notorious problem labeled as the restless legs syndrome,[37] or female sexual dysfunction.[8,38,39] Another effective way of increasing the market is to lower diagnostic thresholds, expanding the number of worried consumers. An effective way of modifying thresholds is to influence the production of clinical practice guidelines. Moynihan et al[18] analyzed to what extent experts on guideline panels had close ties to relevant pharmaceutical interests. Searching publications from 2000 to 2013, the authors found 16 articles proposing changes to the definition of 14 common conditions. Of the 16, 10 lowered the diagnostic threshold for disease, expanding the proportion of the population at risk or diagnosed. The 8 articles that recommended lower diagnostic thresholds and wider definitions of abnormality had panel members with ties to companies that would benefit from the broadened definition. None of articles that advocated wider definitions of disease explored the potential harms to patients of more testing or additional treatment. By enhancing the assumption, commonly held by patients and by the popular media, that more healthcare equates to better care, lowering disease thresholds generates more customers. Whether it relates to blood pressure, cholesterol levels, bone density, by reducing the number who can be called normal, we widen the at risk pool and therefore, the number in need of testing or treatment.

Solution

We do not envision an easy solution to these issues. The public would be rightly skeptical about efforts to curb the ability to provide information to consumers. Nevertheless, stakeholders could be better engaged to develop standards, trusted sources of health information, and shared decision making

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would ensure this transparency at the level of individuals. A more skeptical media help consumers be wary of hype that over promises. Without some ability to monitor the quality of information given by commercial organizations, to check veracity and assess the potential to do more harm than good, we risk manufacturing inappropriate demand for interventions that have marginal benefit at best, and at worst, high costs and harm that could be avoided.

Conclusions

We have highlighted 5 major problems, set against a background of obvious corruption. There is a lack of research transparency and a low quality of evidence synthesis. This is not an ideal foundation for high-quality clinical practice. Moreover, even if the synthesis is competent, most evidence remains inaccessible and presented in formats that are difficult to translate into effective communication about harms and benefits. Clinicians report the evidence to be inaccessible, so patients have even less chance of making sense of research when facing important decisions. Accountability systems have failed to measure performance. We do not know when healthcare decisions are guided by sound interpretations of the evidence and whether patients are engaged in this process. Rather, we observe that in the United States, in one of the most highly developed healthcare systems, consumer demand for healthcare is manufactured and manipulated, driving up cost, waste, and harm.

Solutions to these problems are visible but will be difficult to introduce unless there is a much wider recognition that healthcare has become less about well-founded, trusted relationships between healthcare professionals and patients. Rather, it looks more like a profit-driven service industry, where commercial interests have influenced the value chain. Reversing this trend requires attention to generating real value for patients, namely, ensuring they get the care they need, and no more; the care they want, and no less. Shared decision making offers a sustainable system solution, if based on high integrity, excellent evidence synthesis and clinicians committed to collaborating honestly with patients.

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