Interferon-based testing for tuberculosis as a disruptive innovation

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Abstract

People often assume that the most significant barrier to improved health care, including tuberculosis (TB) control, is technological. However, in many cases complex social networks of provision are organized around older technologies. Even after an important innovation arises, there remain a number of barriers that are essentially social in nature that act to sustain the status quo if not addressed. Such barriers include the way costs are partitioned between different players, personnel allocation, sample collection, instrumentation, as well as broader social concerns such as fear of stigmatization among those within the screening population and preserving the interests of public health agencies to identify and track cases throughout treatment. In the case of tuberculosis, the interferon-based assay for TB antigenic response meets the technological threshold, however social elements include consideration of the way costs and services are distributed between employers, public health, Medicaid/Medicare, private insurance and the individual being tested. In order to realize the full promise of this new assay, greater attention must be given to these systems aspects of care.

Disruptive Technologies

Much is said about disruptive technologies (or disruptive innovations) in the literature, however these references are often vague and the nature of the disruption is typically undefined. We have previously identified two primary classes of disruptive innovations: low level disruptions and high-level disruptions (Best & Khushf, 2006).

Low level disruptions are technological innovations that are introduced to the market in a form that underperforms the dominant technologies in use, but because they are cheaper when they are introduced, they meet some market niche. In time, as the technologies are perfected and developed they can completely displace the dominant technologies. Low level disruptive innovations defy prediction. Initially one might assume that the interferon-based TB assays follow this pattern. There are claims of an overall lower cost for screening using these assays, and iterative improvements in the assays over time have raised these technologies to a point of competitiveness. However, Mantoux testing and the array of services that follow a positive test don't really constitute a competitive market entity as it is normally described in this literature, and the systems barriers for introducing the assays are formidable.

High level disruptions are also technological in nature, but here the defining characteristic is that their use depends upon the implementation of new systems. In contrast to low level disruptive innovations, the disruptive aspects of these technologies may be anticipated, and future use is determined by the activities that restructure older systems. Examples of high level disruptive innovations include the electric grid, railroads, and automobiles. Because of the complexity of the system for TB control and elimination, the introduction of interferon-based screening for TB will pose challenges that will require reconfiguration at multiple levels. Thus this innovation seems to fit the model for high-level disruption well.

Distribution of Costs for TB Screening within the System

Although costs for tuberculosis skin testing (TST) are often perceived to be relatively low, the estimated cost for the screening phase of tuberculin skin testing was estimated to be between $41 and $362 per health care worker (HCW) when performed by the hospital, and between $176 and $264 per HCW when performed by the health department (Lambert et al, 2003). This did not consider the cost of follow up testing and treatment for positive cases. The majority of costs for TST screening were associated with personnel, training, and time taken off for placement and reading of the TST. By contrast, costs associated with QuantiFERON-TB Gold® (QFG) testing would be confined to phlebotomy and lab costs. Lab costs would be significantly higher for QFG (approximately $100 vs <$10 for TST supplies).

Since specificity is higher for QFG testing, there will be significant savings in follow-up costs as false positives are avoided. The relative savings associated with QFG testing will depend upon the characteristics of the population screened. Among inmates in a county jail, the frequency of positives was nearly double for TST compared with QFG (9.0% vs 5.4%)(Porsa et al, 2006). Assuming that the difference in positive rates is primarily a reduction in false positives, there would be significantly reduced system costs for interferon-based screening using QFG.

In our hospital, costs were initially estimated to be just $3-$5 for TST screening, 20x to 30x less than expected for interferon-based testing. Because the costs for TST are typically embedded in a more complex employee health system where the personnel costs are already in place and budgeted, the cost to the system for TST appeared to be far lower than actual costs. Likewise, downstream savings associated with follow up of positives due to more efficient screening are realized by a different institution (state health department), and would escape consideration by decision makers considering the burden of increased laboratory costs. In addition to immediate costs for screening and follow up, due consideration must be given to iatrogenic costs associated with therapy, lost work time, and a variety of more nuanced social costs (e.g. stigmatization). These issues are compounded by the way costs and services are distributed between employers, public health, Medicaid/Medicare, private insurance and the individual being tested.

Systems Disruption and System Issues Related to TB

The advantages of using a screening test with higher specificity, elimination of the need for follow up visits, and reducing the iatrogenic burden associated with TB screening have attracted a lot of attention and support for the use of interferon-based screening for TB. In recognition of the complex integration of services within the extant TB system, care should be given to the identification of potential barriers in the funding and delivery of services, with special attention paid to the interplay between various actors within the system. To consider interferon-based assays from the perspective of a high-level disruptive technology, attention should be paid to potential social and economic barriers in order to proactively develop solutions to minimize disruptions in funding, personnel, and other elements of the system infrastructure.

Conclusion

People often consider the most difficult barriers to improved health care, including tuberculosis control, to be technological. However, health care delivery systems are complex social networks, and issues such as the distribution of costs, budget appropriations, identification and allocation of personnel, preferences of health care users, social perceptions of burdens and benefits, the definition of disease, and historical roles of system actors require integrated adjustments to achieve buy-in from multiple and diverse stakeholders. From this view, the technological development of a superior screening tool is necessary but is not sufficient on its own to bring about the spectrum of changes required to maximize benefits. While there may be an overall reduction in costs associated with QFG testing, hospitals and other providers might incur increased costs (and have reduced profit), and some private and public insurers might refuse to bear costs that would normally be borne by public health agencies. If these systems issues are not addressed, we might remain locked in to older technologies of TB control.

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