Commercialization of Quality

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The value of diagnostic imaging largely resides on the ability to visualize and identify abnormalities in the image(s) acquired. This ability is enabled in an image of sufficient resolution, field of view, and contrast differentiation, namely an image of sufficient image quality for the diagnostic task at hand. The value of the diagnostic imaging service depends on images and image-producing devices that convey significant diagnostic content. Image devices can find commercial success when they reliably provide images of superior image quality versus competing products; however, products of “sufficient” image quality are often purchased when products offering superior image quality come with a premium price. To date, products and services affording superior quality assurance or quality control at a premium cost or additional expense have found challenging and limited commercial success. This tendency may be changing. With an increasing emphasis on efficient, appropriate, and cost-effective care delivery, the tools needed to attain and maintain superior imaging services are quickly becoming necessities.

The vendors producing devices and services for the diagnostic imaging industry participate in this market to make a profit. Any new product and service these vendors consider for development and commercialization must undergo a business assessment to understand and forecast the potential profit contribution it may offer to the company¹. This assessment will include many factors including but not limited to the costs of bringing the product or service to market (development, regulatory status/filing, packaging, distribution, installation), market viability² (positioning versus competitive products and prices, legislative and reimbursement environment, estimated time to regulatory approval), and market acceptance and

adoption (target market identification, size and unit volume opportunity, clinical/administrative proof statements, peer acceptance, and advocacy). All of these business costs must be weighed against expected unit sales, selling price, and subsequent profit margin over the expected life of the product. Accordingly, products and services not seen as potentially profitable are very rarely brought to market. The exception is typically found if a vendor believes bringing a product or service to market may position then as an “industry good Samaritan,” but this tactic is difficult to quantify and thus justify in the “go/no go” decision matrix.

The realities of the marketplace have shown that the perceived value of superior image quality has its limits. While a particular vendor’s modality may offer capabilities and features that may extend and enhance the diagnostic content of its images, the crucible and scrutiny of the purchase process may obviate these advantages. If the inclusions to create the superior image result in a higher selling price, this difference is subject to scrutiny. If a somewhat lower-priced unit providing “adequate” image quality can perform the same exam, generate the exact same fee for the exam, and thus revenue to the department, what is the bottom-line justification for the superior, yet more expensive, system? In today’s medical business environment, many administrative committees, perhaps over the advocacy of the physicians (radiologists), will opt for the lower-cost option based solely on the bottom-line impact to the institution.

Within the context of a business assessment, quality products and services have been problematic for vendors to justify. There has been no additional reimbursement available to providers using quality systems to enable a purchase justification through direct revenue increase and no penalties if quality systems are not utilized. The adherence to MQSA standards and reporting requirements in mammography currently represents the exception. Further exception is noticed in mammography with additional reimbursement available for the use of CAD as it is perceived to improve quality through accuracy.

¹ Cooper [1]

² Yankelovich [2]

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Interestingly, this regulatory requirement may be viewed as the emerging trend rather than the current clinical exception. With the emerging mandated requirements for dose reporting in CT, we may envision a similar, broader evolution in quality monitoring for CT imaging.

Quality reporting often requires additional work effort. The necessary documentation and follow-up require time and personnel resources. Despite some automated data capture systems, staff hours are needed to assure compliance and to review findings. Peer review in essence necessitates a second reading of the image study, and repeat of inadequate exams involves patient recall, staff and facility resources, and of course, additional time.

That is not to say vendors have not deployed quality systems. If a vendor foresees the integration of a quality system giving their product or service a competitive advantage, they may justify its inclusion as a means of increasing the product's sales volume. The track record of this approach is by no means assured. While it may make for a perceived advantage during the sales process, the additional quality systems may not be ultimately utilized due to the penalties (time, personnel) discussed. Also, development of a quality system in the absence of industry-wide standards or requirements often dictates a proprietary system native and limited to that vendor's products, thus limiting market potential to a percentage of their installed base and future unit sales. This limited market can be the critical factor in a business assessment. A leading computed radiography (CR) product vendor's integration of an automated image quality assessment system in their CR products may serve as an example. A considerable investment was made in research and development of a sophisticated application that could report and even correct common image quality factors in CR imaging. It was foreseen to enable significant improvement in image consistency, virtually eliminating repeat exams and potentially saving money and improving efficiency. However, as this pioneering effort would only work with this vendor's CR devices and the data communication was only possible with the vendor's PACS, a very constrained number of customers might be potential purchasers of the system. While automated, human work effort and time is also needed to translate the insights gained into superior clinical practice. Unfortunately, this service has not been offered commercially to date.

Times Are Changing

It appears we may be entering a time when greater appreciation and value will be realized for implementation and use of QA/QC initiatives. The implementation of the Health Insurance Portability and Accountability Act in 1996 and the Health Information Technology for Economic and

Clinical Health (HITECH) Act in 2009 established requirements for security and privacy of electronic health records. HITECH specifically mandates the use of electronic health records partly towards the goal of attaining usable data to analyze, gain evidence, and provide efficient and effective care of a consistently high quality. Failure to implement the quality systems needed to assure compliance could result in monetary penalties. The Centers for Medicare and Medicaid Services (CMS) relying on the infrastructure of these electronic health records is fostering Quality Measures. CMS defines Quality Measures as "tools that help us measure or quantify healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable and timely care."³ Proposed Quality Measures to be implemented in 2014 are now published for public consideration and comment. Many organizations, including the National Quality Forum (NQF), are working with CMS on the development and implementation of quality standards. NQF believes "performance standards can be used by institutions, providers, and healthcare consumers to:

- Create reliable, comparative performance information on which consumers can rely to make informed decisions about their care;
- Ensure practitioners and provider organizations are held accountable for the quality and efficiency of their performance; and
- Support quality improvement activities."⁴

CMS has implemented reduced/denied reimbursement for certain hospital-acquired conditions (Deficit Reduction Act 2005) and, beginning in October 2012, hospital readmissions within 30 days of discharge (Affordable Care Act of 2010)⁵. To avoid these punitive measures, information systems can be used to analyze patient cohorts and quality systems used to maintain and document best practices.

Underpinning these current and likely future government actions is the attempt to reduce costs. Towards this end, also included in the Affordable Care Act were new rules to improve care coordination for Medicare patients under a structure called Accountable Care Organizations (ACOs). "ACOs create incentives for health care providers to work together to treat an individual patient across care

³ Centers for Medicare and Medicaid Services web site, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/index.html>

⁴ National Quality Forum web site, http://www.qualityforum.org/Show_Content.aspx?id=119

⁵ Medicare Program, Hospital Inpatient Value-Based Purchasing Program, Final Rule, Federal Register, vol. 76, no. 88, May 6 2011

settings—including doctor’s offices, hospitals, and long-term care facilities.”⁶ Rather than a penalty, the Medicare Shared Savings Program will reward ACOs using quality care standards to lower growth in health care costs. Accordingly, a goal of any organization participating in an ACO is to utilize the most appropriate and effective resources and reduce unnecessary procedures. The development and utilization of Evidence-Based Medicine, defined as “integrating individual clinical expertise with the best available external clinical evidence from systematic research”⁷ is being encouraged to drive this effort.

Within this changing environment, radiology services will be challenged to demonstrate their appropriateness and value in care delivery. Radiology must also use evidence-based principals to provide the most appropriate exam with the greatest diagnostic content. Radiology interpretations will need to reduce ambiguity and provide greater diagnostic clarity within the context of the patients’ treatment plan. Without these values, radiology may be viewed as a cost center within the ACO environment. Best practices will need to be analyzed, refined, and utilized to attain the operational efficiencies needed. Accordingly, systems to collect, analyze, present, and report operational and clinical performance to assure compliance through quality become a necessity.

Summary

Without overriding financial imperatives, the commercial marketplace for products and services enabling quality improvement, quality assurance, and quality control has been limited in health care. Companies serving this industry have

had a difficult time finding business justification to bring these products to market. However, government initiatives in the past 6 years attempting to reduce health care costs are placing an emphasis on better, more appropriate, and more effective health care delivery through evidence-based medicine. Incentives, penalties, and reimbursements for providers serving Medicare and Medicaid patients are being implemented or altered to encourage this adoption. Within this new environment, quality systems become vital tools in managing optimal operations, and thus, a new commercial marketplace is rapidly evolving for vendors to develop, promote, and profitably sell quality assurance and quality control products and services. With a viable, growing, and competitive market, radiologists, technologists, and radiology administrators may look forward to having a wide choice of quality tools to help them make their departments an invaluable resource in a changing health care delivery system.

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⁶ Healthcare.gov web site, <http://www.healthcare.gov/news/factsheets/2011/03/accountablecare03312011a.html>

⁷ Sackett et al. [3]