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Adopting Identification Standards in the Medical Device Supply Chain

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ABSTRACT

The U.S. Food and Drug Administration has recently mandated that medical device manufacturers adopt Unique Device Identification (UDI) standards on their medical devices. The benefits that UDI brings to hospitals and patients is relatively obvious, including inventory transparency, product safety, product equivalency, business intelligence. However, adoption by manufacturers, who face the mandate, has been slow in part because the benefit to them is not as readily perceived. This study focuses on the incentives, barriers, and benefits that medical device manufacturers perceive in UDI adoption. This study seeks to understand which adoption pressures are driving manufacturers to act, and attempts to gauge the benefits to manufacturers from UDI adoption. Through survey methods, the evidence suggests that medical device manufacturers implement UDI largely as a response to the coercive and normative pressures they face. There continues to be a high level of uncertainty regarding the return on investment for the medical device manufacturers, particularly from the late adopters.

KEYWORDS

Healthcare, Institutional Theory, Supply Chain Management, Technology Adoption, Unique Device Identification

INTRODUCTION

The establishment of standards within an industry is essential for innovation and collaboration, whether it be technology standards, nomenclature standards or process standards. In fact, one of the key objectives of professional associations is to establish and enforce standards across the organizations that operate in that profession or industry. Diffusion and adoption of standards continue to be an area of interest due to the diversity of outcomes and cases observed across many industries and eras. This research builds upon the vast literature of standards adoption and diffusion by specifically examining a case of product identification standard diffusion in the medical devices industry.

In health care, effective management of medical devices is a significant contributor to the clinical success and hospital profitability. Medical devices management involves hospital administrators, physicians, patients, and the medical device suppliers (Burns, Housman, Booth, & Koenig, 2009; Young, Nyaga, & Zepeda, 2016). The proliferation and complexity of medical devices stress the need for a mature and standardized system to track and manage them both within an organization and across organizations. Many studies have demonstrated that the proper implementation of universal product identification can significantly improve supply chain performance and reduce risks (Ozelkan & Galambosi, 2008; Sodero, Rabinovich, & Sinha, 2013).

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In the medical devices industry, a standardized coding scheme has been recently established by the United States Food and Drug Administration (FDA). The Unique Device Identification (UDI) standard is an alpha-numeric code that consists of two segments: A device identifier and a production batch identifier (Department of Health and Human Services, 2013). This code can then be cross-referenced in public databases and systems of other organizations consistently.

Having a standardized labeling system carries potential benefits to all organizations in the medical devices supply chain (The Brookings Institution, 2015). Medical device manufacturers can use UDI to track inventories being stored or transported around the globe. Healthcare providers can improve medical record documentation, more easily search for product alternatives, and have easier access to information about clinical use and safety (Wilson & Drozda, 2013). Intermediaries, such as distributors and group purchasing organizations can utilize these standards to minimize search costs and transaction efficiency (Pheney, 2014). However, a major challenge has been to assimilate the medical devices supply chain towards this standard: Convince manufacturers to use UDI in product packaging and convince hospitals to invest in the infrastructure to track and make use of UDI data (Daniel, McClellan, Gardena, & Deak, 2014).

Background About UDI in the Medical Devices Industry

Serious attention has been given to UDI after the topic was raised by the FDA in its *Amendments Act of 2007*. A 2012 ruling proposed a phased implementation of the UDI system over seven years, starting with the most critical medical devices, such as implantable devices, and eventually moving to commodity-type items. In September of 2013, the FDA's UDI rule was published (Department of Health and Human Services, 2013). This rule set a schedule for medical device manufacturers to have a standardized label, both human– and machine-readable, on every medical device package distributed in the U.S, with some exceptions. Additionally, labelers must submit medical device information to a centralized database: The FDA's Global UDI Database (Department of Health and Human Services, 2013). While health providers are highly encouraged to scan and cross-reference UDI labels, they are under no regulatory obligation to do so.

Many manufacturers consider UDI to be most beneficial to distributors and providers, struggling to see the return on investment for their own organizations even though the FDA's mandate targets manufacturers (Pohl & Nachtmann, 2011). The distributors and healthcare providers have hesitated to adopt the data standards into their own information systems. Without regulatory pressures coercing them to make use of UDI standards, health providers prefer to weather the uncertainty and await a higher level of upstream UDI diffusion before investing. This situation has been described as a prisoner's dilemma, where both sides would be better off by investing in UDI technologies and standards, but neither side is willing to risk a wrong first move (Conway, 2012). Even as adoption of UDI by manufacturers is increasing, many appear to adopt UDI standards out of compliance with regulation, without capitalizing on the potential efficiency gains (Kroupnik & Moretti, 2013).

Research Motivation and Questions

The issue of standards adoption is a topic of importance and interest to any industry or line of business, whether it is establishing standards on screws and bolts used in the automotive industry, wire ports in the computer industry, or plumbing parts in the construction industry. Insights about this topic can refine and extend theories in technology or standards adoption. The classic two-stage diffusion model (Tolbert & Zucker, 1983), suggests that technical pressures drive early adoption and institutional pressures drive late adoption. Subsequent studies find little evidence that adoption motives predict early versus late adoption (Kraatz & Zajac, 1996; Sherer & Lee, 2002). UDI presents a good case study to apply past theories about standards adoption due to its well-defined timeline and easily observable adoption pressures on stakeholders.

In this study, we examined how early versus late adoption correlate with the adoption pressures and outcomes experienced by organizations. Second, we explored the extent that institutional pressures

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