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Co-creation of market expansion in point-of-care testing in the United States: Industry leadership perspectives on the community pharmacy segment

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ABSTRACT

Background: Point-of-care testing (POCT) is a specialty of laboratory medicine that occurs at the bedside or near the patient when receiving health services. Despite its established clinical utility and consumer demand in the community pharmacy, the implementation of POCT within this setting has remained modest for a variety of reasons. One possible solution to this problem is the concept of co-creation — the partnership between consumer and manufacturer in the development of value for a service or device. Objective: Using the theoretical underpinning of co-creation, this study aimed to investigate perceptions of point-of-care-testing (POCT) industry leadership on the community pharmacy market in the United States to uncover reasons for limited implementation within community pharmacies.

Methods: Participants were recruited for this study through the use of snowball sampling. A series of semi-structured interviews were conducted with the participants via telephone. Interviews were recorded, transcribed, and entered into a qualitative analysis software program to summarize the data. Results: Five key themes were uncovered: gaps in understanding, areas of positive impact, barriers to implementation, facilitators of implementation, and community pharmacy — a potential major player. Conclusions: Through uncovering gaps in perceptions, it may be possible to leverage the U.S. pharmacy industry's size, potential for scalability, and ease of patient access to further patient care.

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1. Introduction

Point-of-care testing (POCT) is a specialty of laboratory medicine that occurs at the bedside or near the patient when receiving health services. In the community pharmacy, typical examples of POCT are lipid panels, A1c, streptococcus, and influenza and are usually tested from patient saliva or <5 mL of blood (typically from a finger stick via a lancet device). A common theme of the success of the POCT market is the linking of test result to rapid treatment at the point-of-care. Consequently, POCT market development has centered around hospitals and medical clinics where providers are able to quickly act on results. ^{1,2} Although a logical fit, these settings have experienced only modest POCT implementation success. ^{3–7} Parallel to the growth of the use of POCT in hospitals and medical offices was the expansion of POCT into the over-the-counter (OTC)

market. A striking difference between hospitals and medical offices, where demand for POCT was provider-driven, the OTC market demand was driven by the consumer and their desire for convenient and quick health information. This importance of consumer-driven demand to the future success of POCT is further emphasized by the fact that recent data places glucose self-testing devices at a 70% share of the total POCT market. 2

Likewise, over the past several years, the concept of "retailization" or "consumerism" of health care has taken hold in the U.S., resulting in large retailers entering and partnering in health care. The message being sent by consumers is one of the value of accessibility, convenience, and cost. Importantly, these retail clinics, or convenient care clinics, such as The Little Clinic and the MinuteClinic, have not been shown to encourage higher utilization rates over traditional health care settings, an often cited concern with this growing U.S. trend. Taken together, the concept of POCT located within a retail health clinic offers a new level of convenient, accessible care.

Community pharmacy in the U. S. finds itself at the intersection

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of POCT consumer products (glucose monitors, fertility, etc.) and the growing "retailization" of health care trend. In fact, the current retail health care industry is dominated by large retail pharmacy operators. One reason for this may be that community pharmacies are found approximately 5 miles from 95% of the American population. 11 POCT technology in the U. S. community pharmacy has origins that begin with the passage of the Clinical Laboratory Improvement Amendments (CLIA) in the late 1980s. 12 Early use of POCT was limited to fasting glucose and lipid measurements, typically as part of health fairs or screening events, rather than an integral part of care delivery at the pharmacy. The use of POCT further evolved as changes in legislation allowed for POCT to be used to treat patients, as well as to screen. For example, pharmacists are demonstrating their impact on such acute infectious diseases as influenza and strep throat by using models that involve legal collaboration between prescribers and pharmacists to immediately test and treat for acute diseases under collaborative practice agreements (CPAs).^{13,14} High patient interest and satisfaction with these service models of pharmacist-provided POCT have also been established. 15,16 Pharmacies are now the fourth leading category of CLIA-waived facility. 12 Of note, the use of CLIA-waived POCT for infectious diseases has been suggested as a viable service provided within community pharmacy workflow because of the ability to immediately provide treatment under a protocol between prescriber and pharmacist. 17 Despite its established clinical utility and consumer demand in the community pharmacy, the implementation of POCT within this setting has remained modest for a variety of reasons. One such identified barrier is that device designs historically were intended for the workflow, patient demands, and other setting-specific factors unique to hospitals and medical offices. Development of POCT devices produced specifically to the unique needs of the community pharmacy may be useful in overcoming this barrier.

One possible solution to this problem is the concept of cocreation. This idea was first introduced in 2004 by Prahalad and Ramaswamy and defined as "the joint creation of value by the company and the customer; allowing the customer to co-construct the service experience to suit their context." ¹⁸ In short, co-creation is the partnership between consumer (customer or business-tobusiness) and manufacturer in the development of value for a service or device. 18 Research has established that organizations in industries undergoing rapid technological evolution are more capable of sensing opportunities associated with technological shifts when they use principles of co-creation. ¹⁹ Furthermore, these organizations are better at overcoming "constraints of existing knowledge, rigid routines, and financial dependencies" when involving the customer in the development of the product or service. 19 To aid in bridging the void between provider (POCT industry) and consumer (retail community pharmacy) a qualitative study was developed to determine initial talking points to guide the cocreation process. The study has two phases. The purpose of this paper is to present the findings of this initial phase, which aimed to determine the perceptions of POCT industry leadership on the retail community pharmacy market in order to explore reasons for the slow rate of implementation of POCT in community pharmacies by utilizing the theoretical underpinning of co-creation. The second phase of the study will gather perspectives of community pharmacy leadership.

2. Methodology

2.1. Study design

This qualitative, exploratory study to examine POCT leadership perspectives employed techniques based upon grounded theory²⁰

to examine perspectives of the study's participants. This approach "uses a systematic set of procedures to develop an inductively derived grounded theory about a phenomenon". Although this study stops short of arriving at theory development, the basic approach of grounded theory was used to generate themes grounded in the data. Semi-structured interviews were conducted with POCT industry leaders to generate data relevant to the research question, and then an inductive approach was used to systematically analyze the data to search for patterns and identify emergent themes. To ensure the rights and welfare of human subjects involved in this research were protected, the Institutional Review Board (IRB) at the university where the researchers are employed reviewed and approved this study.

2.2. Methods

2.2.1. Participants

Participants were recruited for this study through the use of snowball sampling, an established strategy in qualitative research to recruit participants from a population that may be difficult to access.²² The principal investigator (PI) obtained an initial list of industry professionals in leadership positions within the POCT manufacturing industry from a national POCT conference organizer. He began contacting these industry leaders, inviting them to participate in the study while also asking each one for contact information of another potential participant, and continued the process until reaching a point of saturation, where no new concepts were emerging from the data. Holding a high level position of employment in the POCT manufacturing industry (e.g., CEO, founder, marketing director, etc.) was the only inclusion criterion for participation. A total of 10 participants were recruited and interviewed for this study. No honorarium or other incentive was provided.

2.2.2. Data collection

An initial draft of the interview questions was developed internally based upon the PI's discussions with key opinion leaders in POCT. The group reviewed two iterations of the interview protocol before revisions were finalized. The final interview protocol included 3 domains of inquiry, encompassing questions about the participant's organization and his or her role in it, views on the current community pharmacy market segment, and perceptions of POCT and the community pharmacy segment in the future (Table 1).

Table 1 Interview protocol.

Category	Questions
Company strategy, vision, and business environment (Who are you?)	What is your role at this organization? What does your organization do? What is your organization's vision or future direction? What is your customer value proposition? What is your organization's view of the pharmacy segment of the POCT market? What has lead to that view?
Current pharmacy segment thoughts/perceptions	Do you have experience selling POCT in the pharmacy segment? Can you expand on that? Do you have experience working with the pharmacy segment to sell your product? Can you explain this further? Does the demand for POCT products in the pharmacy segment come from the pharmacist or the corporation? Why do you think that?

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