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Development of a Market Entry Strategy for an Innovative Blood Testing Device

A Case Study on DeDx

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Abstract

This thesis explores the research question "*What would a feasible market access strategy for an innovative at-home blood testing device in the United States look like?*" as a case study on the company DeDx. DeDx is a company based out of Berlin, Germany, creating an at-home blood testing device for a complete blood count (CBC) with differential so patients can do blood tests from the comfort of their homes. The thesis evaluates the theory on the elements of a market entry strategy for an at-home blood testing device in the U.S., including the blood testing market, remote patient monitoring (RPM) market, insurance and reimbursement, funding, medical device distribution methods, doctor/clinician and hospital/clinic acceptance, and patient acceptance. Then, qualitative research was performed with semi-guided interviews with doctors/clinicians and hospital/clinic administrators or managers in the U.S. The analysis used an abductive approach to combine theory and qualitative research aspects to create a market entry strategy for DeDx. This approach led to the recommendation that DeDx keeps its target population as oncology patients receiving outpatient chemotherapy. Additionally, DeDx should run thorough and diverse pilot studies to gain traction amongst the medical community. As a reimbursement scheme, DeDx should use the RPM CPT codes to reimburse the device by either distributing the device through RPM companies by selling or licensing to them, or by selling the device directly to clinics to use in their own RPM programs. They should also sell the device directly to clinics to distribute to patients as they see fit.

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1 Introduction

The world of technology is constantly growing because of innovations. Some innovations will become the next big thing, while others will never reach the market. As a startup, having a well-developed market-entry plan is crucial to the survival of the product at hand. No matter which industry, it is essential to research and develop these plans to reach the product's highest potential.

This thesis is a case study on DeDx, a medical technology startup based out of Germany. This thesis will dive into the company, the background and theory of the industry, and research on the industry to ultimately answer the question: "*What would a feasible market access strategy for an innovative at-home blood testing device in the United States look like?"*

1.1 About DeDx

Dedx U.G. is a medical technology startup based out of Berlin, Germany. Iris Wing-To-Lam, Tim Landgraf, and Leo von Lojewski founded the company and entered DeDx in the Company Register in September 2022. DeDx received funding from the German government's EXIST grant and support from the Berlin Institute of Health and the Charité – Universitätsmedizin Berlin. In addition, DeDx completed the 4C Accelerator Tübingen, an accelerator for med-tech startups focused on commercialization, certification, clinical studies, copyright, and regulation, as well as the German Accelerator, which focuses on international expansion, saving resources, and receiving mentoring.

DeDx is creating an at-home blood testing device for patients to perform their routine blood tests from the comfort of their own homes. DeDx's device is an in vitro diagnostic (IVD) product designed to measure complete blood count (CBC) with 5-part white blood cell (WBC) differentials, and platelet counts through microfluidic, optical, and deep learning technologies. The device works by the patient doing a finger stick poke and collecting blood drops from their fingertip with a microfluidic cartridge. The patient then inserts the cartridge into the optical device for imaging. The images are then uploaded to the DeDx servers for machine-learning-based analysis and blood cell counting. Lastly, the device will send the results to the patients' clinicians seamlessly and flag any serious adverse events for immediate

medical attention. Overall, the device is designed to be easy to use, low cost, and deliver results quickly.

DeDx is still in the early stages but is taking the proper steps to work toward FDA approval and enter the U.S. market. The at-home blood testing market is not saturated; currently, there is only one at-home blood testing device in the U.S., known as Athelas Home. DeDx plans to use this device as their predicate device for the FDA 510(k) application. However, this device only tracks white blood cells, neutrophils %, and absolute neutrophil count (ANC) (Athelas Incorporated, 2023), not red blood cells like DeDx does in addition to the others. Other competitors of DeDx include point-of-care blood testing machines and the gold standard laboratory blood testing equipment.

DeDx currently has a primary target population of cancer patients receiving outpatient chemotherapy. Most outpatient chemotherapy patients must get a blood test before each chemotherapy administration to ensure they maintain a safe blood count. There are currently 650,000 patients receiving outpatient chemotherapy in the United States alone each year (Centers for Disease Control and Prevention, 2022). Technology advancements have allowed monitoring to move outside the clinic or hospital with remote patient monitoring (RPM). In oncology, many devices are being integrated into care and clinical trials, but most of these remote devices focus on activity, sleep, and heart rate (Kroloff, Ramezani, Wilhalme, & Naeim, 2022). DeDx can tap into this market and provide at-home blood monitoring that no other companies offer. Though DeDx has identified potential in the oncology market, it would still like to explore the market potential in other medical specialties.

DeDx's current market strategy is, after receiving FDA approval, to start selling the device to contract research organizations (CROs) in the U.S. to help promote and support decentralized clinic trials. Decentralized clinic trials are becoming increasingly popular thanks to the help of telemedicine, telehealth, and RPM. While selling to the clinical trials market, DeDx also plans to enter the oncology care market in the U.S. The best strategy to enter the U.S. oncology care market is the focus of this paper, as ideas for market entry have been formed but must be investigated with research. Lastly, some years later, after receiving the CE mark, DeDx will sell to CROs in Germany and then to the German oncology care market.

1.2 Research Rationale and Question

The healthcare industry is dynamic and constantly changing due to innovations. One field in health care that is changing and growing is the field of remote patient monitoring (RPM). Patients can monitor their basic health, chronic conditions, or severe illnesses from the comfort of their homes. They can take their temperature, blood pressure, and blood glucose levels and relay their results to a doctor virtually. Some advantages of RPM are the ability to monitor patients continuously, cost reduction in hospitalization, reduced hospitalizations, and improved efficiency in healthcare services (Malasinghe, Ramzan, & Dahal, 2017, p. 57). One standard test that RPM systems still need is blood testing devices.

Blood tests are a universal practice, specifically complete blood counts (CBC) measuring red blood cells, white blood cells, and platelets. These counts are essential for monitoring overall health, diagnosing medical conditions, checking on medical conditions, and checking on the progress of medical treatments (Foundation for Medical Education and Research, 2023). A CBC can help identify conditions such as anemia or leukemia and monitor blood count changes due to medical conditions or medicines that commonly affect blood count (Foundation for Medical Education and Research, 2023), for example, monitoring patients with schizophrenia on the drug clozapine which can lower WBC counts.

DeDx is working on a solution to bring CBC blood testing to the patient's home. After FDA approval, DeDx must have a strong market entry strategy prepared to ensure that the product is positioned well in the market and has the best chance of success. DeDx has completed basic research on the U.S. market and has had many expert conversations with oncology patients, oncologists, and a few insurance experts in the U.S. Through this research and expert conversations, several potential market entry strategies have been identified. However, more information is required to determine the most feasible method. DeDx has identified a need in the oncology field, but other medical markets need to be further investigated and identified.

Since medicine is a field of high accuracy, doctors and patients are concerned with new technologies because they expect an accurate and trustworthy diagnosis (Pan, Ding, Wu, S. Yang, & J. Yang, 2018). This is another crucial detail for DeDx to

consider when creating a market entry strategy because they not only have to consider how to get doctors and patients to accept the device, but they must also consider how the product will change the workflow of current blood testing methods and overall care. In addition, the best distribution method is critical to identify as this will impact the decision on a reimbursement strategy and if it makes sense to set up a reimbursement pathway. Ultimately, this decision will also affect the marketing and sales strategy. The market entry strategy can significantly impact the product's success, so it is essential to evaluate and choose the most appropriate option carefully.

Therefore, this paper will explore the research question: *What would a feasible market access strategy for an innovative at-home blood testing device in the United States look like?*

1.3 Research method

The theoretical research in this paper comes from articles in highly ranked business and medical journals such as *International Entrepreneurship and Management Journals, The International Journal of Production Research, Public Health and Surveillance, Cancer, Journal of Medical Internet Research, and MIS Quarterly*. The articles used were written in the last ten years (2013-2023) and had an impact factor above 1.5 or are in the VHB highly ranked journals list with a rating of A+, A, or B. The theoretical research also came from expert conversations DeDx has previously completed with clinicians, patients, insurance companies, and financial experts. For the practical portion of this paper, a qualitative study was completed, performing online interviews via Microsoft Teams with two critical stakeholders in the blood testing industry: Doctors/clinicians and hospital/clinic administration or managers. The interviews took place with a guided/semi-structured approach, and the transcripts were coded manually using the software MAXQDA to highlight common themes and ideas. They were then analyzed through an abductive approach, which combines aspects of the theories and new data to develop a market entry strategy.

1.4 Key Findings and Theoretical Contribution

Aspects of the theory and research were brought together with an abductive approach to create a market entry strategy for DeDx to enter the U.S. oncology care market. Four main points were identified for the market entry strategy: target population,

doctor/clinician, hospital/clinic, and patient acceptance, reimbursement, insurance, and payment strategies, and device distribution. The theory and research confirmed that the target population for the DeDx device should be oncology patients receiving outpatient chemotherapy. In addition, the study showed that pilot studies, ease of use, reimbursement strategies, and integration with EMRs would be crucial for the acceptance of the device amongst the healthcare community. The best reimbursement strategy identified for DeDx was doing RPM reimbursement by selling or licensing the device to established RPM companies. The best direct sales option identified was selling directly to clinics or hospitals. These reimbursement and payment strategies go hand-in-hand with the distribution strategies of selling or licensing the device to established RPM companies and selling it directly to oncology clinics and hospitals to distribute the devices to patients as they see fit or adding them to their own RPM programs.

1.5 Structure of Thesis

This thesis will consist of four parts. First, in the theory portion of the paper, the basics of the U.S. medical technology market, specifically blood testing and RPM, will be discussed. Then, the existing facts and theory of factors affecting the entry to the U.S. blood testing market, including U.S. insurance and reimbursement, medical technology funding, medical device distribution, patient technology acceptance, and doctor/clinician and hospital/clinic technology acceptance, will be discussed. The second section is the methods and analysis section explaining the interview groups, the process of finding the interviewees, conducting the interviews, and the interview questions. In addition to explaining how the data was collected, this section also explains how the qualitative data was analyzed. The third section of this thesis is the interview results, highlighting common themes and individual opinions. Lastly, the fourth section consists of a discussion and conclusion, first walking through a recommended market access strategy using an abductive approach bringing together the theory and research results. The section will then discuss other potential market access strategies, study limitations, and further research recommendations.

2 Theory

The theory section of this paper aims to provide a conceptual framework that informs the research question and findings. Scholarly articles from the following highly

ranked business and medical journals were used to build the theory portion of this paper: *International Entrepreneurship and Management Journals, Journal of Economic Perspectives, The International Journal of Production Research, Public Health and Surveillance, Cancer, Journal of Medical Internet Research, Journal of Clinical Oncology, Trends in Biotechnology, Advances in Wound Care, The American Journal of Public Health, Journal of the International Society for Telemedicine and EHealth, Telemedicine and e-Health, BMC Medicine, and MIS Quarterly*. Additionally, documents from the U.S. Census Bureau and the Center for Diseases Control and Prevention and expert conversations by DeDx with oncologists, patients, and insurers were used to build a theory on potential market entry strategies for DeDx's innovative at-home blood testing device. The articles used in this section were written in the last ten years (2013-2023) and came from journals with impact factors above 1.5 or are listed in the VHB highly ranked journals list with a rating of A+, A, or B. The expert conversations referenced were conducted in the year 2022. They were completed by me during an internship with DeDx, by the founder of DeDx, Iris Wing-To-Lam, or by the global consultancy company, Fyr Hub.

2.1 U.S. Medical Technology Market

The U.S. medical technology market is a complex market that is rapidly evolving with a wide range of products, services, and technologies designed to improve the health outcomes of patients. Several factors, including advances in research and technology, demographics, and consumer expectations, drive the market. Some products and services include medical devices, diagnostic tests, telemedicine services, and electronic health records. As DeDx is a medical device, specifically an in vitro diagnostic (IVD) device, the medical device market is vital for them to pay attention to. In 2021, the medical device market in the U.S. was valued at 226 billion U.S. dollars and is expected to reach over 312 billion U.S. dollars by 2027 (Stewert, 2022).

2.1.1 Blood-Testing Market

Blood testing is a common practice globally. Blood tests can be as simple as testing for one thing, such as cholesterol or glucose, but they can also check for more complicated things, such as infectious diseases. Blood tests most commonly occur at

a lab, clinic, or hospital, apart from certain types of monitoring, such as blood glucose monitoring, that can easily be tested at home.

Most blood test devices are also known as in vitro diagnostic (IVD) devices. “In vitro diagnostic, (IVD) tests—which use blood, saliva, and other human samples to detect the presence or risk of certain diseases—are a pillar of modern medicine” (the PEW Charitable Trusts, 2021). IVD devices include devices such as blood glucose monitors and laboratory tests such as cancer screenings, blood type identification, and tests for COVID-19. In 2015, the IVD market in the U.S. had a market size of 8.7 billion U.S. dollars and is forecasted to be worth 13 billion U.S. dollars in 2023 (Stewert, 2017). The DeDx device is part of this growing market since the device is considered an IVD device, as the patient’s blood is used to perform the test.

In DeDx’s target population of oncology patients receiving outpatient chemotherapy, blood testing plays a significant role in patient care. According to several oncologists and patients in expert conversations with Iris Wing To Lam and me, DeDx’s target population of oncology patients receiving outpatient chemotherapy receive blood tests before every treatment, and many patients receive tests at least weekly. In the expert conversation I had on August 17th, 2022, with an oncology Physician’s Assistant (PA) based in the U.S., the PA stated that their patients on active intensive chemotherapy might even receive blood draws for lab testing two to three times a week. A U.S. patient stated in an expert conversation with Iris Wing To Lam and me on October 4th, 2022, that even on their weeks off chemotherapy, it was still necessary for them to go in and get their blood drawn and tested to be sure their blood count was still at safe levels.

As mentioned, DeDx has completed a competitor analysis and constantly scans for new competitors in the market. There are currently no at-home blood testing devices for CBC in the United States. Athelas Home is DeDx’s closest competitor in the U.S. and can measure WBC, percent neutrophils, and ANC (Athelas Incorporated, 2023) but cannot measure red blood cells and platelets. Large laboratory companies may play a role in the reason that the at-home blood-testing market is unsaturated, but the research on this theory is limited. Besides Athelas Home, other competitors in the blood-testing market include the gold standard lab equipment, which occupies most

hospitals and clinics, and point of care (POC) (with the point being the doctor's office) blood tests.

2.1.2 Remote Patient Monitoring (RPM) Market

RPM is a practice that is becoming more and more common, especially after the rise of COVID-19. The design of RPM systems is to retrieve a variety of physiological data from patients, including electrocardiograms (ECGs), electroencephalograms (EEGs), heart rate, respiratory rate, pulse oximetry, blood pressure, body temperature, and blood glucose levels (Malasignhe et al., 2017). RPM devices can be contact or non-contact devices including thermometers, blood glucose monitors, and smart watches. A study by Hayes et al. (2022, p. 388) found that the most common RPM intervention type was smartwatches or mobile health/applications, at 23.85%, followed by cardiac implant devices or heart monitors, at 14.37%.

RPM is commonly used amongst different patient groups, such as patients with chronic illnesses, mobility issues, post-surgery patients, neonates, and elderly patients (Malasignhe et al., 2017). The data collected from RPM devices helps to decentralize the focus from the provider-centric facility-based healthcare model to care where a patient may be (Patel et al., 2023). This can be crucial for patients that live in more rural areas, further from medical facilities. For example, in the oncology field, Onega et al. (2017), in a 2017 study, showed that 14% of the U.S. population lived more than 180 minutes in travel time from a National Cancer Institute parent or satellite facility.

In a RPM study on cancer patients that had COVID-19 by Pritchett et al. (2021, p. e2198), they discovered a significant reduction in hospital admission rates that was directly attributable to RPM enrolment. In addition, they discovered that though visits to the emergency department occurred at a comparable rate among the patient's using RPM and those not using RPM, there were fewer admissions for those that were enrolled in the RPM program (Pritchett et al., 2021, p. e1298). Though this study was focused on cancer patients infected with COVID-19, many areas in cancer care could also benefit from remote patient monitoring, such as "patients returning home after hospital discharge who are at high risk for symptom toxicity, and following oncologic surgery" (Daly et al., 2021, p. e1282).

2.2 Factors Affecting Entry to the Blood Testing Market

Many factors influence entry into the blood testing market in the U.S. and many players are involved in the blood testing market, including laboratory testing companies, device manufacturers, and healthcare providers. Today, a healthcare professional does most blood testing in a laboratory or POC testing (with the point of care being a doctor's office or hospital). In addition to the current blood testing practices and competitors in the market, many different aspects of the medical field must be considered when trying to put a medical or IVD device on the market. These aspects include understanding reimbursement schemes, funding in medical technology, medical device distribution methods, patients' acceptance of new devices and methods, and doctor/clinician acceptance and hospital/clinic acceptance.

2.2.1 Insurance and Reimbursement in the U.S.

The U.S. has many different forms of health insurance ranging from federal programs, such as Medicare, to individual private insurance companies. Private coverage includes employment-based plans, which are provided through employers or unions, direct-purchase plans, which involve a customer purchasing coverage directly from an insurance company or a federal or state marketplace, and TRICARE, which is coverage for uniformed service members (U.S. Census Bureau, 2018, p. 1). Public coverage in the U.S. includes Medicare which is a federal program helping with health care costs for those 65 and older or under 65 with disabilities, Medicaid which are individual state-run programs including Medicaid and the Children's Health Insurance Program (CHIP), and CHAMPVA or VA which is Civilian Health and Medical Program of the Department of Veterans Affairs, and also includes care provided by the Department of Veterans Affairs and the military (U.S. Census Bureau, 2018, p. 1).

According to the U.S. Census Bureau (2018, p. 2), the census in 2018 revealed that in the U.S. "8.5 percent of people, or 27.5 million, did not have health insurance at any point during the year.". In addition, "In 2018, private health insurance coverage continued to be more prevalent than public coverage, covering 67.3 percent of the population and 34.4 percent of the population, respectively" (U.S. Census Bureau, 2018, p. 2).

Though the federal U.S. insurance programs remain uniform nationwide, the state programs such as Medicaid change state-by-state, and same with private insurance. The same private insurance company may have completely different coverage from one state to the next. Insurance plans differ from state to state, and so do their reimbursement plans. Insurance companies individually determine how much they will reimburse for products and services, as no coverage is the same. However, although insurance companies plans and coverage differ, they often still use the same common procedural terminology (CPT) codes and healthcare common procedure coding system (HCPCS) for billing. They use these codes to ensure proper and uniform billing, though the reimbursement for each code can be different depending on the insurance company.

In an expert conversation by Fyr Hub with an Insurance Company Former Vice President (VP) in the U.S. on April 22nd, 2022, the Former VP supported this point that not everything will be covered by insurance. They stated that just because the FDA has approved a device and it seems "good," it may not always be covered by insurance. They shared that insurers are looking for valid medical literature and looking at the number of studies, the number of patients, the sources of the studies, and if it shows improved outcomes versus traditional treatments. Therefore, DeDx will have to plan studies to prove a clinical benefit to convince insurers to cover and reimburse the costs of the device for patients.

In another expert conversation by Fyr Hub with a Director of Global Innovation at a Global Insurance Multinational Company (MNC) in the U.S. on April 21st, 2022, the Director of Global Innovation shared that being successful in terms of insurance coverage takes building personal connections with people in the insurance industry. They stated that startups must find the right insurance companies by identifying what matters to them and then building a strong personal connection to improve chances of progressing a collaboration with the company. This could be important to DeDx, as they may need to negotiate with insurance companies at some point, and identifying insurance companies that, for example, cover many oncology patients, could be beneficial.

2.2.1.1 Blood Testing Reimbursement

Blood testing costs in the U.S. are highly variable depending on what setting tests are done in, and reimbursement for these tests highly ranges based on insurance coverage. For example, Medicare Part B (medical insurance) patients usually pay no money for routine and necessary blood tests when a doctor or provider orders them (Medicare.gov, 2023). However, the costs are only covered if the laboratory meets Medicare requirements. According to the quarter 1, 2023, Medicare Clinical Laboratory Fee Schedule, the rate for a CBC with differential WBC count is $7.77 and has the CPT code of 85025 (CMS.gov, 2023). This code and price do not include the fee a clinic or lab may charge for a blood draw. The DeDx device would not qualify under this code as this code is only for CBCs performed within a laboratory.

Medicaid reimbursement for blood testing differs state by state; there is no set national price for Medicaid. Private/commercial health insurance prices also greatly vary. Patients with private insurance could have most of the test covered and pay only a few dollars, or little to none will be covered and patients will pay thousands of dollars. Some companies do home-blood testing in which the patient can take a sample of their blood and send it to a lab, or a phlebotomist or nurse comes to the patient's house and draws their blood for them and then sends it to the lab. The coverage for these tests also ranges and highly depends on the insurance company and plan.

In several expert conversations with patients completed by Iris Wing To Lam and me in August, September, and October 2022, patients in the U.S. stated that their blood testing costs are covered by their insurance. Additionally, each of these patients stated they were covered by private insurance.

DeDx completed an analysis of 94 hospitals, labs, and clinics in the U.S. in July 2022 to see what a CBC generally costs. This analysis showed that the average price for a CBC, without taking insurance into account, between hospitals and labs/clinics was $101.53, while the average for hospitals was $145.94, and the average for labs/clinics to be $24.54. The prices not only ranged based on whether it was a hospital or a lab but also by the state. These prices were also taken without including the price of the blood draw fee. Generally, a blood draw fee can add an extra $10-20.

One goal of the DeDx device is to lower the patient's out-of-pocket costs while lowering the cost the insurance companies must pay for testing.

2.2.1.2 RPM Reimbursement

Innovations in general, but especially for remote patient monitoring, are severely restricted by constraints on reimbursement (Daly et al., 2021, p. e1282). Reimbursement for RPM has become more common since the rise of the pandemic; however, it is not available at scale across the U.S. healthcare system (Kelley et al., 2020). Medicare uses codes maintained by the American Medical Association called Current Procedural Terminology (CPT) codes to bill the payers of the service for RPM. Medicaid and most private or commercial insurance companies usually follow the suit of Medicare, meaning they also all usually use the same CPT codes for billing that Medicare does. This allows patient costs to stay low and the physician's office to be reimbursed for the service. The CPT codes for RPM are shown in Table 1, along with the average RPM reimbursement rates for 2023, according to Lamboley (2023) and Tenovi (2023).

As mentioned, when doctors bill these RPM codes to Medicare, Medicaid, or private insurance companies, the clinic is the party that is being reimbursed. In most cases, the patients' costs would be covered, and the doctors would bill the insurance companies for the RPM services, and the insurance companies reimburse the clinic for those services. This allows the clinics to gain a return on investment (ROI) when investing in RPM devices. An example of how revenue is generated with these codes and payment prices is shown in Table 2. In this example, a yearly total of $186,000 could be expected to be generated if 100 patients were enrolled in the RPM program. If the DeDx device is priced at $850, the investment cost for 100 devices would be $85,000, plus $20 per test cartridge; we would assume each patient takes at least four tests a month, meaning a minimum cost of $80 per patient per month, or $8,000 total per month. This would give a total cost of investment of $189,000 in the first year, and the offices or hospitals would generate $186,000 from RPM reimbursement the first year (and each year following). Therefore, in the first month of the second year, the office or clinic will be generating a profit from the RPM reimbursement. In this example a positive ROI would be generated in year 2 of using RPM. However, this example calculation does not consider the need to purchase additional RPM devices,

such as thermometers, to reach 16 physiological readings over 30 days. If a practice must purchase additional RPM devices, the ROI will decrease in the first years and take longer to generate a positive ROI.

Table 1

Medicare RPM CPT Codes

RPM CPT Codes		
Code	**Description**	**Average Reimbursement Rate**
CPT 99453	Initial set-up and patient education on equipment (a one-time fee)	$19
CPT 99454	Supply of devices, collection, transmission, and summary of services to clinician. Must include at least 16-days of monitoring physiological data in a 30-day period	$49
CPT 99457	Remote physiologic monitoring treatment management services by clinical staff or QHCP* first 20 minutes of RPM services over 30 days	$48
CPT 99458	Remote physiologic monitoring services by clinical staff for an additional 20 minutes of RPM services over 30 days	$39
CPT 99091	Collection and interpretation of data by physician or QHCP*, 30 minutes minimum	$53

Note: This table shows the CPT codes for RPM practices set up by Medicare and the average reimbursement rate according to Lamboley (2023) and Tenovi (2023).
*QHCP – qualified health care professional

Table 2

Revenue on RPM Example

Code	**Reimbursement Rate**	**Monthly Reimbursement Total Based on 100 Patients**
CPT 99453	$19	$1,900
CPT 99454	$49	$4,900
CPT 99457	$48	$4,800
CPT 99458	$39	$3,900
	Monthly Total	$15,500
	Yearly Total	$186,000

Note: Table 2 shows an example of how much a physician's office or hospital could be reimbursed for RPM services based on 100 patients being enrolled. Code 99091 was excluded from this table as it cannot be billed in combination with Code 99457.

Medicare will reimburse RPM, however, Medicaid will not always, and not all private or commercial insurers will reimburse RPM. In the study by Hayes et al. (2022, p. 388), they identified that "Of the state Medicaid programs in the United States and the District of Columbia, 36 (70.58%) programs have a Medicaid policy for some level of RPM reimbursement as of 2021. However, 28 of these 36 (77.8%) programs have some restrictions in their Medicaid policies on RPM reimbursement." The restrictions include things such as limiting the types of providers that can prescribe reimbursable RPM, the service and facility type, the settings in which RPM can be billed, such as by a home health agency only, limiting the health conditions that can be reimbursed for RPM, and the requirements of the device such as being FDA approved or not (Hayes et al., 2022, p. 389). However, Medicaid is just one type of insurance reimbursement. In the study completed by Hayes et al. (2022, p. 390), out of the 399 total documents reviewed, none specifically addressed the RPM reimbursement policies among commercial insurers in any U.S. state.

In theory, for DeDx to be reimbursed as an RPM device, it will need to be part of an RPM system. This could occur by adding it to an already existing RPM system or by creating an RPM system on its own with other devices. Since the RPM codes require at least 16 days of physiological readings and, in general, blood tests do not need to

be done every other day, then it may be best to pair the DeDx device with another device, such as a thermometer to ensure the patient can achieve 16 days of physiological readings in a month. Suppose a hospital or clinic already has an RPM program that they run independently. In that case, the DeDx device may be easily added to their RPM program if it matches their data transmission mode (via WIFI, Bluetooth, etc.). If a hospital or clinic runs a RPM program through a specific RPM company, then DeDx could join a RPM company by licensing or selling the device to the RPM company. If the device is in demand by doctors and patients, then this could be an attractive selling point for these RPM companies as they would have a device that other RPM companies do not have, setting them apart.

If DeDx can join or create a RPM system, then DeDx will be available for reimbursement to all Medicare patients (in which RPM is declared necessary for their care), some Medicaid patients, and some patients covered by private insurers. With limited information existing on how many and which private insurers cover RPM and under what conditions, it is hard to say how many patients covered by private insurance would have the device available to them as part of a RPM system.

2.2.1.3 Medical Device Reimbursement

How patients pay for medical devices ranges in the U.S., and so does the cost. In some cases, offices will provide their patients with devices, while other times, insurance will cover a portion or all the cost of medical devices, and in other cases, patients must pay out-of-pocket for devices if their insurance does not cover the entire cost or any of the cost. While CPT codes are primarily used to identify medical services and procedures by health care professionals, HCPCS codes identify products, supplies, and services not in those CPT codes (CMS.gov, 2023). This includes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside of a healthcare setting (CMS.gov, 2023). Though these codes are used for billing, they are distinct from coverage and payment (Nusgart, 2013, p. 577).

DeDx could benefit from an HCPCS code if they sell through device distributors to ensure a code for the patient's insurance companies to be billed with; however, this process is not straightforward. The Centers for Medicare and Medicaid Services

(CMS) issues new HCPCS codes, however the Pricing Data Analysis and Coding (PDAC) determines appropriate HCPCS codes through a verification process (Nusgart, 2013, p. 578). Some products may fall under an existing HCPCS code, while others may be unique and need a new code. In this case, PDAC would verify that a new code is needed, and CMS would evaluate and decide whether to create a new code (Nusgart, 2013, p. 578). In DeDx's case, due to its uniqueness and price, the product would almost certainly need a new HCPCS code. Products such as at-home blood glucose monitors with strips and continuous blood glucose monitors have HCPCS codes, but no products with HCPCS codes are similar to DeDx's product. DeDx's closest competitor, Athelas Home, does not have an HCPCS code. The Athelas One, Athelas's first version made for point-of-care use, was deemed not suitable for an HCPCS Level II code by CMS and was recommended to seek guidance on HCPCS Level I codes (CPT codes) (Centers for Medicare and Medicaid Services (CMS), 2020). If DeDx chooses to distribute the device and cartridges through medical suppliers, then an HCPCS code will be necessary for the suppliers to bill insurance, such as Medicare Part B, to cover the product (Nusgart, 2013, p. 579).

Additionally, HCPCS codes can only be applied for after a minimum of 3 months of sales following FDA approval. Sales information such as total number of devices sold, the dollar amount of sales broken down by Medicare, Medicaid, and private insurance will need to be provided to prove there are enough sales to create an HCPCS code for the product (Nusgart, 2013, p. 581). Though the codes are standardized throughout the insurers, the coverage is not standardized.

Without a HCPCS code, it would be difficult for DeDx to sell this device through medical suppliers as the patients would not always be reimbursed since the suppliers would have no code to bill the insurers with. Having patients pay out of pocket is an option but not ideal. Patients can submit claims for medical devices not covered by their insurance policy, however, there is no guarantee that the claim will be approved.

2.2.1.4 Patient Transportation Reimbursement

Patient transportation is one of the most significant burdens that many patients face. In an expert conversation by Fyr Hub with a U.S. medical oncologist on April 14th, 2022, the oncologist shared that transportation is one of their patient's most prominent issues and that they often depend on others to drive them to and from appointments. A gastrointestinal (GI) oncologist also shared in an expert conversation with Fyr Hub that some of their patients must travel between 60 to 100 miles to appointments. In another expert conversation by Fyr Hub with an Insurance Company Former Global VP in the U.S. on April 22nd, 2022, the Former Global VP stated, "If you are not convenient to that facility, if you are an hour away, two hours away – which is not unusual in America – where you are traveling that far into a cancer center, it can be a tremendous burden, physically, financially, and emotionally on the patient and their family to have to do that monitoring." They shared that their company did not cover transportation, though more companies were pushing to do so, and more employers are looking for plans that cover transportation for sick individuals.

In another expert conversation by Fyr Hub with an Associate Director at an Insurance Company in the U.S. on April 22nd, 2022, the Associate Director stated that their insurance company covers transportation costs as an additional patient benefit. The company uses this as one of its selling points for remote patients and other patients that often need transportation.

In the U.S., nearly 3.6 million individuals forego or delay medical treatment due to barriers in nonemergency medical transportation (NEMT) (Rochlin, Lee, Scheuter, Milstein, & Kaplan, 2019, p. 472). Nonemergency medical transportation is transportation to and from medical services (National Academies of Sciences, Engineering, and Medicine, 2018) and therefore includes getting to and from appointments for blood testing. According to the National Academies of Sciences, Engineering, and Medicine (2018), U.S. states must assure NEMT for Medicaid services; however, since Medicaid programs differ from state to state, coverage also differs. In addition, they state that Medicaid beneficiaries struggle with the resources to afford transportation to medical appointments and often have long travel times (National Academies of Sciences, Engineering, and Medicine, 2018).

One of DeDx's goals is to decrease transportation time and costs for patients and insurance. Moving blood tests to the home setting reduces the need for patients to travel to the clinics as often. This gives patients more time to do what they enjoy or allows them to continue resting at home rather than going to a clinic. The DeDx device reducing transportation costs could be a selling point for insurance companies that cover transportation costs as it can reduce the amount of money that they spend on transportation for their cancer patients.

2.2.2 U.S. Medical Technology Funding

Medical technology in the United States can be funded through several channels, including government grants, private investments, venture capital, and corporate partnerships. Medical technology companies can apply for grants from government agencies such as the National Institutes of Health (NIH) (U.S. Department of Health and Human Services, 2023), the Small Business Innovation Research (SBIR) program (SBIR, 2023), and the National Science Foundation (NSF) (America's Seed Fund, 2023). These grants provide funding for research and development activities related to medical technology, such as preclinical trials, clinical trials, and regulatory approval. DeDx will not need to complete clinical trials but will need to complete performance tests and regulatory approval.

Like other industries, private investments are another way medical technology companies gain funding in the U.S. This includes funding from private investors, such as angel investors and venture capitalists. Private investment can provide significant funding for research and development activities and help scale operations. Private funding could be necessary for DeDx as they are still developing their prototype and need to continue researching and developing the components of the device. A third option for funding is venture capital. As usual, venture capital firms invest in medical technology companies with high growth potential. These firms provide funding in exchange for equity in the company, with the expectation of a ROI when the company goes public or is acquired by another company. DeDx is also in contact with a venture capitalist in the U.S. negotiating investment terms and partnership terms. One last way medical technology companies access funding in the U.S. is through corporate partnerships, which means partnering with established corporations in the healthcare industry. These corporations can provide funding,

expertise, and resources to support research and development and bring a new product to market. DeDx has a mentoring partnership with Roche and has had conversations with other big healthcare corporations but has yet to make any other official partnerships or receive funding from these corporations.

As previously mentioned, DeDx is a medical technology that functions using a microfluidic cartridge. The cartridge holds the patient's blood and is inserted into the DeDx machine for blood analysis with deep learning. Microfluidics is a rapidly growing field with a wide range of potential in healthcare. In 2013 the market was estimated at $1.6 billion and was expected to reach between $3.6 and $5.7 billion by 2018 (Volpatti & Yetisen, 2014, p. 347). Therefore, in addition to working in the growing medical device and RPM market, DeDx is also working in the growing microfluidics market.

2.2.3 Medical Device Distribution Methods

The distribution of medical devices varies greatly depending on the type of device, but this section will focus on distribution methods for IVD and similar devices. Looking at DeDx's closest competitor, Athelas Home, they have changed the distribution method of their at-home blood testing device since they first entered the U.S. market. Initially, the Athelas Home device was known as Athelas One. Their original business plan was to have doctors lend the device directly to patients, or they could buy it through the Athelas website. The device did not have an HCPCS code but would submit claims for coverage on behalf of the customer to their insurers. Since their founding in 2017, this business model has changed. Athelas Home is now sold as part of an RPM system, and the device cannot be bought separately. Athelas's RPM system consists of a blood pressure monitor, glucometer, weight scale, pill tracker, an app for patients, and an app for doctors (Athelas Incorporated, 2023). In addition, Athelas also has nursing staff to review incoming data, and they provide billing services. This model is similar to what DeDx has been considering as a distribution method. As mentioned in the RPM reimbursement section, DeDx could partner with existing RPM companies, add their device directly to RPM systems run by hospitals or clinics, or make their own RPM system.

Another option could be selling the device through medical device suppliers. This is how some IVD devices, such as blood glucometers, are sold. This would likely require creating an HCPCS Level II code for the DeDx device. As mentioned in the medical device reimbursement section, there may be better routes for DeDx, but it is an option. This route depends on whether CMS will approve the device and cartridges as an HCPCS Level II device. This route does have some benefits. For example, DeDx will not have to deal directly with customers, and the medical device suppliers will take care of their sales. However, with this distribution route, DeDx will still need to prioritize talking and creating professional relationships with doctors, clinics, and hospitals, as they will need to prescribe the device to patients for this distribution route to be successful.

Another potential distribution method is selling directly to hospitals or clinics to have them distribute the device to their patients as they see fit. This method would allow DeDx to bypass third-party distributors and sell their products directly to medical facilities such as hospitals or oncology clinics. This would give DeDx control over the sales process, including pricing, marketing, and customer service, and remove the fees that distributors may charge. Clinics and hospitals would buy the device as a one-time investment (and purchase more if/when needed), then they can continuously buy new cartridges. Then the clinics or hospitals would be free to add this device to their RPM programs or give it to patients that need extra monitoring. DeDx must prove that the clinic or hospital will have an ROI to do this method. ROI from buying RPM equipment will differ for every clinic based on various factors, including the cost of the equipment, the number of patients being monitored, and reimbursement rates, as previously discussed. Table 2 can be referred to again as it shows an example of the amount of money an RPM program can generate in a year using CPT codes for reimbursement. RPM equipment can provide benefits that help with revenue for clinics or hospitals by increasing the number of patients being monitored, reducing readmissions, and improving patient outcomes. In addition, for clinics, it can reduce the need for in-person visits, which can save in-office costs by reducing staff needed or the number of lab tests needed in the office.

2.2.4 Doctor/clinician and Hospital/Clinic Technology Acceptance

Doctor or clinician and hospital or clinic acceptance is crucial when putting any medical device on the market. Some are more accepting of new technologies, while others are hesitant. With digitization and RPM, some healthcare professionals fear an increase in workload and handling and responding to alerts from these systems (Maguire et al., 2020), which is a reason why most RPM companies, in addition to dealing with the devices, also have staff viewing the readings and working on the billing. In addition, with the medical field requiring such high accuracy, some doctors fear new technologies as they want to ensure an accurate and trustworthy diagnosis for their patients (Pan et al., 2018, p. 5802). If the doctors are hesitant to prescribe a new product to a patient or do not trust test results from a particular device, the doctors or clinics will not recommend the device for patient use.

Another issue that comes with doctors, clinicians, clinics, and hospitals accepting the device for use is the interconnectivity of the device. "Most clinical organizations communicated to SMEs that they wanted everything to be integrated into their electronic medical record (EMR) to minimize workflow disruption. However, it becomes highly burdensome for SMEs to seamlessly integrate into EMRs across health institutions because most institutions have distinct, noninteroperable EMRs" (Kelley et al., 2020, p. 10). DeDx has also identified this as a concern in previous expert conversations they have completed with healthcare professionals. For example, in an expert conversation by Fyr Hub with a GI oncologist on April 19th, 2022, the oncologist shared that it would be crucial for the device to be integrated into their EMR. Several oncologists also expressed the burden of having another application to view the results of the DeDx device and how much easier it would be to have the blood test results sent directly into their EMR. In these expert conversations, some oncologists also mentioned the extreme importance of a highly accurate device and would want to see proof of its accuracy and how it compares to the gold standard testing equipment. Tests to prove the device's accuracy will already be done when applying for FDA approval. However, DeDx must consider that some medical professionals will only consider it a usable product they would want to add to their workflow once it has been tested and received FDA approval.

Additionally, ensuring that the device will benefit doctors and that they express interest in the device is vital. In two expert conversations by Fyr Hub with a U.S. medical oncologist and a GI oncologist on April 14th and April 19th, respectively, the oncologists expressed interest in the DeDx device but also expressed concern for the device. They both expressed that a CBC may not be enough to determine if treatment should continue, and they see a benefit in also having a comprehensive metabolic panel (CMP) in order to detect how their kidneys and livers are functioning before determining whether or not to proceed with treatment. This question of whether a CBC is enough is an important point that will be further explored with the research of this thesis.

Though there may be reasons doctors, hospitals, and clinics may be reluctant to start using new technologies, there are also many reasons for doctors, clinicians, clinics, and hospitals to want to adopt a device such as DeDx's. For example, an oncology workforce shortage and many administrative burdens delay the necessary care patients need (Patel et al., 2023). The DeDx device can help with the shortage by moving in-clinic blood tests to patients' homes. This would allow clinics to use the nurses or phlebotomists needed for those blood draw appointments to work on other tasks and with patients that need immediate care. In oncology clinics, the chemotherapy and other drug administration processes can be entirely disrupted and delayed due to blood tests. As more patients need blood tests, especially on the day of their appointment, it can cause additional delays for other patients there and causes an increased workload for medical assistants, nurses, and lab technicians (Liang, Turkcan, Ceyhan, & Stuart, 2014, pp. 7185-7186). The DeDx device can move some of the required blood testing out of a clinic to a patient's home, allowing a clinic to need less workforce, reduce staff workload, and reduce care delays. DeDx is a digitized device, and digitized capabilities can reduce the clinician's administrative burden and free capacity to provide timely care to cancer patients (Patel et al., 2023).

Another reason doctors, clinics, and hospitals may be more willing to accept a device to use is the benefit it provides of improving the patient's health or care treatment. Concerning RPM devices, in the Macguire et al. (2020, p. 8) study on symptom management of patients with malignant pleural mesothelioma, the doctors

recognized "that, by remotely monitoring symptoms on a daily basis, they had a much more detailed picture of the individual's symptom experiences over time, which could positively inform decision making and selection of supportive care interventions." In theory, with more frequent blood testing in the comfort of a patient's home, cancer patients' blood count could be more closely monitored, allowing doctors to alter regimens as needed. It can also inform patients earlier if they need to go to the hospital or take any actions due to a low or decreasing blood count.

2.2.5 Patient Technology Acceptance

In addition to doctor/clinician and hospital/clinic acceptance, patient acceptance is crucial for the market entry of the DeDx device. If the patients do not feel capable of using the device or do not understand the purpose of the device, then the patients will be more reluctant to use the device. In an expert conversation by Fyr Hub with a U.S. medical oncologist on April 14th, 2022, the oncologist shared that one of the main things to aid the accuracy and reliability of a patient-operated result is the comprehension of the patient and the ease of doing the test. The device must be simple and easy to use for the patient.

One factor that plays a role in patient acceptance is the doctor's acceptance. For example, "The incentive and recommendation of one's physician have been shown to play a pivotal role in enrollment in preventive health care services (such as vaccination) and in using the Internet as a resource for medical information" (Cimperman, Brenčič, Trkman, & Stanonik, 2013, p. 787). Though the DeDx device is not a preventive health service, this emphasizes that a doctor's recommendation is important for patients in healthcare. If a doctor advises a patient that they believe an in-lab test is better in some way or that they will not accept the results of the at-home test, then patients will not use the device because they trust their doctor's opinion. Especially when working with high-risk patients such as cancer patients, they could be more concerned about mistakes because a mistake could cost them their life.

In addition, with new medical technology, its connectivity must be considered for patient acceptance of the device. For example, "Appalachia is also home to some of the most rural and difficult-to-access communities in the United States. Although

these communities may benefit most from telemedicine and remote care, broadband access and adoption remain among the lowest in the country" (Aronoff-Spencer et al., 2022). So, areas that could immensely benefit from remote devices and care, such as rural areas, may not be able to receive care in that way due to the broadband access of that area. Therefore, the device's connectivity, whether by Bluetooth, Wi-Fi, or cellular connection, is vital for DeDx to consider.

DeDx has completed several expert conversations with oncology patients, all of whom have expressed the desire for a device such as this one and the ability to draw their own blood and run the tests from home. One patient's spouse, in an informative conversation with me on August 10th, 2022, claimed it would have been convenient to have an at-home blood testing device as their spouse would not have had to go to work an hour late or leave an hour early to go to the clinic and complete a blood test during the labs opening hours. Another patient, in an informative conversation with me and Iris Wing To Lam on October 4th, 2022, said that there were some days she did not feel like getting out of bed due to the extreme side effects of her chemotherapy treatment and being able to do her pre-treatment blood test from home would have allowed her to stay more comfortable at home rather than having to get up, get dressed, and drive to get one simple test and return home.

3 Methods and Analysis

When selecting a research method for my research question (*what would a feasible market entry strategy for an innovative at-home blood testing device in the United States look like?*), I considered the information collected in expert conversations completed by DeDx and Fyr Hub before my research period and the theoretical contribution to formulate questions to give the most information possible surrounding the research question. This section explains the steps, research methods, and analysis used to build a market entry strategy.

3.1 Interview Methods

This research is strictly qualitative data. It is primary data I collected through interviews in February and March of 2023. This study has two interview groups: U.S.-based doctors/clinicians (oncologists and general practitioners) and U.S.-based hospital or clinic administrators or managers.

There are several reasons why these two interview groups were chosen. For one, doctors and clinicians are some of the most knowledgeable people in the healthcare system. They care for patients, prescribe them medications and devices, refer them to other doctors, work with patients based on their insurance, and overall have a strong influence on the use of products in healthcare. Doctors and clinicians can give insights into their workflow, including blood testing in their current healthcare setting, acceptance and recommendations of new products, working with patients' insurance, and more. Hospital and clinic administrators can also give an inside look at the workflow of clinics, acceptance of new products, how a new product could change their workflow or patient experience, partnership experiences and opportunities, and working with insurance companies. Overall, these two groups can give insights into more than direct patient care.

There were six doctors/clinicians interviewed with the job titles of Professor of Medicine and General Internal Medicine and Student Health Doctor, Family Physician and Practice Owner, Medical Hematologist and Oncologist, Associate Professor of Internal Medicine and Medical Oncology, Assistant Professor of Hematology/Oncology, and Hematologist. Five hospital/clinic administrators or managers were interviewed with the job titles of Hospital Administrator for Population Health, Vice President of Laboratory Services for the Hospital System, Clinic Coordinator, Clinic Manager, and President of the Hospital System. Interviewees were found in a variety of ways. Some interviewees were found via LinkedIn by searching job titles such as clinic manager, hospital manager, clinic administrator, hospital administrator, oncologist, and general practitioner. Other interviewees were found via personal connections and recommendations. Lastly, interviewees were also found via cold emails to clinics and hospitals, clinic and hospital administrators, and medical professors that teach general medicine or oncology/hematology.

The age of participants was asked, but there were no age, race, gender, or other restrictions except for the previously mentioned job titles. Interviewees were only considered for interviews if they were practicing medicine in the U.S. or were based at a hospital or clinic in the U.S. Interviewees' locations were collected, and they were from several states in the U.S., including Michigan, Virginia, Ohio, Illinois,

Arizona, and Massachusetts. Table 3 gives an overview of the interviewee numbers in the order in which they were interviewed, job titles, and location so it can be used for reference throughout the results and discussion of the thesis.

The interviews took place with a guided/semi-structured approach through video calls via Microsoft Teams. Conducting the interviews via Microsoft Teams was the best option because the participant's locations were all over the U.S., and I was based in Munich, Germany. All participants participated with their cameras on, except one who faced the camera the opposite way. I formulated a set of questions to guide each interview group and based each interview on the person I interviewed. The questions were open-ended, which allowed interviewees to share their knowledge to whatever extent they could or felt comfortable doing. Some questions were eliminated if they did not seem relevant to the interviewee, the interviewee had already answered the question within the scope of another question, or the interviewee expressed that they did not have the knowledge or ability to answer the question. If the interviewee had more knowledge and experience on the subject, more questions were added. Interviewees were also allowed to ask questions and share anything else they felt fitting at the end of the interview. Interviewees were informed at the start of the interview that their information would be kept confidential and that nothing they said would be attributed to them in this thesis without their permission. Therefore, the data has been anonymized, and no names, ages, genders, or the employers of interviewees will be shared. Interviewees were also informed that they could stop the interview at any point if they pleased. Interviewees were asked before the interview if they agreed to be recorded and have the conversation transcribed as we spoke, which all agreed to. Each interview took 15-40 minutes, depending on how much information the interviewee was willing or able to share. Interviews were listened to again immediately following the interview, and the transcripts were edited to ensure accuracy.

Table 3

Interviewee Data

Interviewee number	Doctor (D) or Administrator (A)	Job title	Location
1	D	Professor of Medicine at a Medical University, General Internal Medicine Practice and Student Health Practice	Chicago, Illinois
2	D	Family Physician, practice owner	Jackson, Michigan
3	A	Hospital administrator for population health	Charlottesville, Virginia
4	D	Medical Hematologist and Oncologist	Rochester Hills, Michigan
5	D	Associate professor of Internal Medicine and Medical Oncology at Medical University	Colombus, Ohio
6	A	Vice President of Laboratory Services for Hospital System	Farmington, Michigan
7	A	Clinic Coordinator	Grand Rapids, Michigan
8	A	Clinic Manager	Phoenix, Arizona
9	D	Assistant professor at a Medical University and Hematologist/oncologist	Worcester, Massachusetts
10	D	Hematologist at a Cancer Institute	Lansing, Michigan
11	A	President of Hospital System	Farmington, Michigan

3.2 Interview Questions

The interview scripts and the sets of guide questions for both groups can be found in Appendices A and B respectively. For the doctors/clinicians interview group, questions were asked about care pathways, mostly about monitoring, patient types, frequency of testing, the use of RPM, technicalities of using an at-home blood testing device, and how such a device could be implemented in their clinic or a clinic. For the clinic/hospital administrators or managers, questions were asked about using RPM, the usefulness of an at-home blood testing device, current blood testing methods, and the implementation of such a device in their clinic/hospital or a clinic/hospital. Additional questions were added or removed based on the interviewee's knowledge. Interviewees were also allowed to contribute any extra comments, stories, or knowledge they had in and out of the context of the question.

3.3 Method of Analysis

After completing all the interviews for each group, the transcripts were analyzed to collect data. First, each transcript from each group was reread to pull out the main ideas and summarize each interview. Then, each transcript was uploaded to MAXQDA, a qualitative analysis software, and reviewed again more carefully to start coding different themes and categories found in the interview transcripts. The transcripts were coded by combining an inductive and deductive approach. The inductive part of the coding was creating an initial coding framework based on the interview questions, the theory research, and the research question. The initial coding framework consisted of the codes blood testing, remote patient monitoring, insurance and reimbursement, medical device distribution methods, doctor/clinician and hospital/clinic acceptance, and patient acceptance, shown in Figure 1. These codes were kept in mind when coding the interview transcripts, but other themes and new codes and sub-codes were created to reduce bias and code as much information as possible, which is the deductive approach. All interviews were read through 5 times to ensure thorough and correct coding. The final coding framework with subcodes is shown in Figure 2 (See Appendix C for a sample of the coded segments from the transcripts).

Figure 1

Initial Coding Framework

Note: Figure 1 shows the initial coding framework for analyzing the research.

Figure 2

Final Coding Framework with Subcodes

Note: Figure 2 shows the final coding framework after analyzing the transcripts to find common themes amongst interviewees.

4 Results

In this thesis, I employed a qualitative research approach to investigate a feasible market entry strategy for an innovative at-home blood testing device in the U.S. The codes shown in Figure 2 were created using the data collected in the interviews. In this section, the results from each of those coded sections are presented and explained.

4.1 Blood Testing

The subject of blood testing was a focus in both interview groups, with guide questions about the workflow and need for blood testing in the interviewee's healthcare setting. This information is crucial for DeDx to understand as a blood testing device. What the current practices are, the patient and clinician journeys, and the workflow of blood testing are all critical to understand because the DeDx device may change the patient and clinician journeys and workflow of blood testing.

4.1.1 Blood Testing Info

Several interviewees gave general information about blood testing, including the cost of blood tests. Interviewee 6 shared that a CBC with a WBC differential in the Medicare catalog costs $7.77. However, this is the charge for the test alone and does not include the charge for the blood draw. Interviewee 7 shared that their partner lab gives them the lowest price for testing, which is the Medicare price of $7.77, but in the end, they pay around $45 per test due to the cost of the blood draw.

4.1.2 Frequency of CBCs

Regarding the frequency and need for CBCs, general practitioners and those at general clinics expressed that most patients receive a CBC once per year (Interview 2; Interview 7). On the other hand, oncologists expressed that their oncology patients receiving chemotherapy have a CBC done right before each treatment, and often at least once a week, some patients more and some patients less, depending on their therapy regimen (Interview 4; Interview 5; Interview 9; Interview 10).

Interviewee 4 expressed a unique opinion that having a CBC done daily would be ideal for some of their patients. Interviewee 10 had a different opinion, sharing that

even with an at-home machine, they wouldn't increase the number of CBC's done to more than the hospital standard of two or three times a week.

4.1.3 Is a CBC enough

One concern of DeDx is whether testing just a CBC will be enough for oncologists to make medical decisions for their patients, such as if they should receive their treatment, stop their treatment, or seek immediate medical attention. When asked whether CBC is enough for monitoring, several interviewees stated that they often test more than just CBC. They often run at least a comprehensive metabolic panel (CMP) and other tests depending on the disease. Two of the interviewees in general care shared that they would be more interested in the device if it also ran a CMP (Interview 2; Interview 8). All five oncologists interviewed mentioned that being able to test kidney and liver function with a CMP would be ideal in addition to the CBC (Interview 1; Interview 4; Interview 5; Interview 9; Interview 10). Emphasizing this idea, interviewee 10 stated, "If you could do it, the chemistry panel, then that would be, you know, golden" (Interview 10).

Though many interviewees stated that they like to see more than just a CBC, Interviewee 4 stated that a CBC with differential would be enough to decide if a patient can receive chemotherapy. Additionally, it could determine if a patient with a fever needs to go to the hospital for emergency care due to the possibility of neutropenia (Interview 4). On the other hand, Interviewee 5 shared that a toxicity assessment is crucial to patient care and that "2 to 5 % of our population, a CBC is all we would want" (Interview 5).

4.1.4 Lab Locations

The last main point interviewees touched on about blood testing is lab locations. Lab locations and lab proximity to patients are important for DeDx to understand, as one goal of DeDx is to cut down transportation time and patient costs. Therefore, interviewees' information about lab locations can help DeDx understand where patients receive their lab work. Out of the six interviewees that shared information on their lab locations, four stated patients could get their lab work done anywhere (Interview 3; Interview 5; Interview 6; Interview 10), while two stated that they have

in-house labs in which most patients get their blood work done at (Interview 4; Interview 8).

4.2 Patient Care

One important subject to gain insights on out of these interviews was the patient care pathways in both oncology and general practice. These pathways are important to understand, because it is important to further understand how the DeDx device could fit into oncology, and if it could fit into general practice.

4.2.1 Common Monitoring

Some interviewees shared some things that are monitored more often for some patients than what they usually check at yearly check-ups. For example, Interviewee 2 shared that they often monitor A1C, especially for people with diabetes. Additionally, patients on Coumadin are often monitored at least monthly to ensure their health and safety (Interview 2). Interviewees 4 and 9 also supported that patients on Coumadin are often monitored more frequently, though those are not tests they are running on the patients themselves; cardiologists usually run them.

4.2.2 General Care Pathways

In addition to sharing values that they commonly monitor in general care, some interviewees also shared more about the care pathway for their patients, particularly about blood testing. For example, Interviewee 8, from a general care clinic, talked in further detail about what blood testing is like for their general patient population, which consists of patients of age 65 or older. They shared that patients get their blood drawn at their practice, and the blood at the end of the day is then taken to a third-party lab for processing, and the third party then sends the results via fax. They explained that this could be a very cumbersome process since they cannot run the tests in the office. In addition, they also mentioned the anxiety and stress many patients feel from driving through traffic, getting to the practice, and waiting to see a doctor.

4.2.3 % of Patients Receiving Chemotherapy

As previously stated, DeDx currently has a primary target population of oncology patients receiving outpatient chemotherapy. Therefore, to learn more about oncology

care, oncologists interviewed were asked how many of their patients receive chemotherapy. Interviewee 4 stated that most of their oncology patients receive chemotherapy, Interviewee 5 estimated between 60-70%, Interviewee 9 estimated 70% or more, and Interviewee 10 estimated 75%.

4.2.4 Chemotherapy Care Pathways

The oncologists interviewed also gave insights into their care pathways for chemotherapy patients. Interviewee 1 shared a unique care pathway that no other oncologist mentioned. They shared that their healthcare system has urgent centers staffed by oncology nurses to keep their oncology patients out of the ER and in a place where specialists can handle them.

Interviewee 4 shared their practices care pathway as follows: "They come in, they get blood work, they see the doctor, and they have chemotherapy all in the same day. We have them, again, trying to limit the amount of time that they have to come into the office, wait in the office. So, we do that all at once. Now if they are getting weekly CBC they don't necessarily see the doctor. They just come in once a week and they just come right to lab. They get their lab drawn and they go. You know that takes all of 5 minutes." They also shared that at other institutions, patient care and labs do not occur in the same location or necessarily on the same day, forcing patients to make multiple stops for their appointments and lab draws. Interviewee 10 confirmed this statement by sharing their patient's usual care pathway: "So what it usually looks like is. The patients come in one to two days before their treatment, get their labs drawn, then come back. You know, a day or two later. Get their treatment and then, depending on what their therapy is, have to come in again for lab results."

4.2.5 Challenges to Chemotherapy

Additionally, the oncologists interviewed shared the most significant challenges they face regarding chemotherapy. Interviewee 10 supported the mission of DeDx by stating that the biggest challenge is monitoring blood counts and receiving them promptly to allow for interpretation before treatment. On the other hand, Interviewee 5 stated that they do not have many challenges in general when it comes to monitoring their patients. However, they stated they have concerns regarding monitoring, such as watching the renal function, electrolyte imbalances, and

cytopenia's in patients receiving more intensive regimens. Other challenges that interviewees faced were related to patient knowledge. Interviewee 4 shared that one challenge they believe the patients face is knowing whether they need to go to the hospital if they have a fever and said that a device like DeDx could help patients see if their blood counts are low or normal and help decide whether to stay home or make their way to the hospital. Additionally, Interviewee 9 shared that they believe the biggest challenge for patients is understanding how chemotherapy affects their health, not just in terms of cancer but their overall health.

4.2.6 Patient Transportation

Another challenge many interviewees mentioned was patient transportation to and from appointments. Interviewee 11 mentioned when they worked in a more rural area, that some patients would have to drive three hours to the nearest hospital and would have to find this transportation themself. However, it is not just tricky for patients living in rural areas to get transportation to and from appointments. Interviewees 4, 7, 8, and 9 also all shared that they have patients that struggle with transportation. Interviewee 9 underpinned the fact that not just rural patients struggle with transportation to appointments by stating, "We serve like the population in the inner cities, so a lot of poor people do not drive, and they have to rely on other forms of transportation, family, friends, and um some subsidized transport to the city or the state, so that can be kind of a hurdle for patients to come in." Interviewee 8 shared that they solve patient transportation issues through their contracts with Uber, Lyft, and Google to provide easy and paid-for transportation for their patients. Again, these interviews support that patient transportation can be challenging to arrange and burdens many patients. This is just one of the issues DeDx is trying to tackle by moving patients' blood testing to their homes.

4.2.7 RPM vs. In-person Appointments

Most of the interviewee's practices are based more on in-person visits than telemedicine visits, and some shared their views on in-person visits versus doing RPM. Interviewee 1 shared a story of identifying a patient's heart attack because of the patient's wife elbowing him to tell the truth when asked about chest symptoms and that that could not have been done with RPM. They also shared that there are things that the "experienced clinical eye and understanding of the patient" can

identify that AI and RPM cannot address. Interviewee 10 had a different view and supported telemedicine and RPM by sharing that having lab results before appointments, which an RPM device would allow, makes an appointment easier as they do not have to look up the patient's labs and can view it before. Additionally, they shared that the DeDx device could allow for more telemedicine visits for their patients that live a further distance away.

4.3 Current RPM Practices

Though the RPM field is growing, not all medical practices have adopted RPM. Since DeDx is a RPM device and has the option to follow an RPM reimbursement scheme, it is important to identify what interviewees are already monitoring and how they monitor, as well as identify who is not using RPM, why they are not using RPM, and if they would be interested in using RPM. Many interview guide questions asked about current RPM practices and the willingness to use RPM.

4.3.1 No RPM Currently

As stated, interviewees were asked whether they use any RPM at their office, clinic, or hospital. Five interviewees stated they currently do not use any RPM (Interview 4; Interview 5; Interview 6; Interview 9; Interview 10), and Interviewee 2 stated they only use RPM with 3 or 4 patients in total. Four of these interviewees are oncologists working with DeDx's target population, while the other two work in general care.

4.3.2 What is Currently Monitored with RPM

Though five interviewees were not running any RPM, the other six interviewees stated they did run some RPM. This ranged from running RPM through a program to having a handful of patients monitor a few things independently and reporting it to the doctors. The primary physiological reading tracked with RPM by the interviewees was blood pressure with a blood pressure cuff (Interview 1; Interview 2; Interview 3; Interview 8), blood sugar with finger pokes or continuous glucose monitors (Interview 1; Interview 2; Interview 8), and weight with a scale (Interview 2; Interview 3; Interview 8). In addition, several interviewees mentioned the monitoring of international normalized ratio (INR) with an INR device (Interview 1; Interview 2), while others also measured blood oxygen levels with a pulse oximeter (Interview 1), temperature with a thermometer (Interview 3), volumes of air breathed

with a spirometer (Interview 3), EKGs with an echo stethoscope (Interview 3), home screenings for colon cancer (Interview 8), and congestive heart failure with CardioMEMs (Interview 11). As expected, RPM monitoring and devices can range from practice to practice, which these interviewees showed.

4.3.3 Receiving Results

How results for RPM devices are received also ranges from practice to practice. Interviewee 11 shared that the results are usually sent via Wi-Fi-connected devices directly into the hospital's EMR. Interviewee 1 shared that their patient's results are sent directly into their EMR via Bluetooth-enabled devices, and Interviewee 3 shared that 80% of their patients with RPM devices have their results sent directly into their EMR via Bluetooth-enabled devices, and the other 20% have non-Bluetooth enabled devices and self-report results. Interviewee 2 stated that their patient's results are received via fax or email to the practice. Interviewee 8 stated that their patients must text or call in their results. It is crucial to understand how doctors, clinics, and hospitals currently receive their RPM results because DeDx needs to plan further the connectivity of their device and how results will be shared, which is also crucial for device acceptance from all parties involved.

4.3.4 RPM Device Distribution

Distribution and sales of RPM devices also range based on the clinic and the RPM program. Some practices standardize their RPM equipment, while others allow patients to choose and purchase their own devices. Interviewees 1 and 3 stated that their RPM devices are standardized for all patients using RPM, and they provide the devices to their patients. This allows them to standardize care in their RPM program and give all their patients equal access. On the other hand, Interviewee 8 stated that their patients could choose their own devices and must also purchase them on their own.

4.3.5 RPM Companies

Practices can run RPM programs independently or through companies that specialize in RPM and help with devices, billing, and more. Interviewee 3 was the only interviewee who ran their RPM program with an outside RPM company. All other interviewees with RPM ran their RPM program through their clinic or hospital.

4.3.6 Adding a Device

For DeDx, it is important to consider how these programs are run and how devices are added to RPM programs. When asked how difficult it would be to add a new RPM device to their program, Interviewee 3 said, “Once you have your platform established and you are working with a company that knows what they are doing, adding a peripheral device is not a big deal.” They explained that adding a device just takes time. Interviewee 11 shared that when adding a new device to their RPM system, it must go through specific processes and meet certain qualifications, such as ensuring it reaches their cyber security standards. Additionally, when asked about billing for their RPM program, interviewees 3 and 11 stated they use the RPM CPT codes set by the AMA to bill for RPM. In contrast, most other interviewees were unaware and not using the RPM CPT codes.

4.3.7 Current Benefits to RPM

Practicing RPM can result in various benefits for both the practices and the users. When asked about the benefits of their current RPM practices, Interviewee 3 stated: “In the hospital, you are not only looking at your basic revenues, your ED, your clinics, your specialty clinics, your inpatient stays, but you also have to evaluate your risk, your cost avoidance, your risk avoidance and any cost-saving measures that you can potentially manage as part of the continuous improvement process and quality.” They then shared that their hospital readmission rate was nearly 19%, and within six months of starting their RPM program, they decreased the readmission rate by 5% and have not struggled with readmission rates since the start of their RPM program. Interviewee 11 supported this point by sharing that a primary benefit of RPM is keeping patients out of the hospital, in addition to cutting down on travel time for patients and the number of visits and the fact that they can still bill for RPM. Since no at-home CBC devices are currently on the market, DeDx could further increase the benefits of RPM mentioned by cutting travel time and the number of visits specifically for blood tests.

4.4 Insurance, Reimbursement, and Payment Methods

Insurance, reimbursement, and payment methods are critical factors for market entry for medical devices and proved to be important to many interviewees. Creating a plan to make the device available to as many patients as possible is essential. This

includes investigating how insurance could cover the device, whether clinics or hospitals have the desire to invest in devices, and overall, how the device will be made financially available to patients.

4.4.1 Insurance and Payments

Interviewees expressed reimbursement and affordability is a crucial point for them and their patients Interviewee 1 simply stated, “I want devices which are affordable”, and shared that their health system would not be interested in a device that cuts out a large chunk of their poorer patients. This point relates directly to doctor, hospital, and clinic acceptance as well, because if the device is not available to all types of patients, they may not support the device in their healthcare setting, and without their support, the device’s market entry will be more difficult. In addition, Interviewee 5 expressed the concern that, “We have to jump through many hoops to get insurance coverage and payment.” Insurance coverage in the U.S. is not always straight forward, and a well-thought-out plan is necessary.

In the U.S., there is a broad spectrum of insurance coverage. Interviewees proved this point by sharing the estimated insurance coverage of their patient populations. Interviewee 7's practice only takes the uninsured as they are a non-profit that provides free health care to the uninsured. Interviewee 8's patients are all on Medicare, but some have supplemental insurance packages through private insurers such as Humana and Cigna. Interviewees 3, 6, and 10 stated they have large mixtures of insurers, from Medicare to Medicaid, Veterans Affairs, and private insurance. Interviewee 2 stated that most of their patients have commercial insurance but that most of their patient visits in a day-to-day setting are covered by Medicare or Medicaid. Interviewee 4 shared that among their several practices, the one in a large inner city is primarily Medicaid-covered patients. In contrast, their practice in the suburbs is mostly commercial insurance or Medicare and almost no Medicaid. Interviewee 9 also worked in a large inner city and shared that their patients are half Medicare and Medicaid and half commercial insurance. Lastly, Interviewee 5 estimates their patients to be 60% commercial insurance and 40% Medicare or Medicaid.

When specifically talking about the DeDx device and payments with interviewees, interviewee 4 stated that even with an at-home device, there needs to be a billing process to pay doctors for viewing and interpreting results. Interviewee 9 shared the same idea, "We have to kind of evaluate the needs and then figure out how that time is spent and how much time is needed and who will be being paid for that time." These statements, therefore, support the idea of RPM, as the CPT code pathway for RPM devices allows clinics and hospitals to be reimbursed for the time they spend viewing, interpreting, and relaying results to patients.

4.4.2 RPM CPT Code Pathway Feedback

Interviewees were asked about the RPM CPT code pathway to see what they thought about it and if it is a pathway, they could see their clinic or hospital using. Interviewees 3 and 11 stated that they already use this set of CPT codes for their RPM practices. On the other hand, Interviewee 8 shared that they are unfamiliar with the CPT codes for RPM and that they predominantly use ICD-10 codes, in which Medicare gives them a lump sum of money for each patient based on their ICD-10 codes. The other interviewees running RPM were unfamiliar with and not using the CPT codes for RPM. The interviewees not running RPM were also unfamiliar with the CPT code pathway, but Interviewees 4, 9, and 10 said they could see such a pathway being used in their clinics.

The RPM CPT code pathway requires 16 physiological readings in 30 days. With this pathway, a leading question that needed to be addressed was if 16 blood tests in 30 days are too much, and if so, what else could be added to reach those 16 physiological readings? Interviewee 9 supported the idea that this might not be the best pathway with just a blood testing device by stating, “You know, I am not, under any circumstances, especially my patient group, I am not doing 16 tests a month.” Emphasizing this point, they also stated, “I cannot imagine there will be 16 different time point blood tests, but you could incorporate like a vital sign monitoring.” Interviewee 10 expressed the same idea that other vitals, such as temperature, could be helpful. They said temperature could be useful as it could allow patients to know if they are neutropenic and need to go to the emergency room when their temperature is taken in addition to their blood count. These results support that the DeDx device

should be combined with another type of physiological reading if planning to use the RPM CPT code pathway to reimburse the device.

4.5 Product

At the beginning of the interviews, I explained to interviewees the product that DeDx is working on and gave a general description of how the device works. Many interviewees expressed interest in the device and were excited to learn more. Additionally, interviewees had the chance throughout the interviews to share any competitors they know of, what target populations they believe this device is fit for, product concerns, benefits they could see the device bringing, how they would want to receive results, and how the device could be distributed to patients.

4.5.1 Competitors and Other Solutions

Interviewees were asked if they could identify competitors of an at-home CBC device. The main competitors DeDx has previously identified are Athelas Home and POC hematology analyzers. No interviewees expressed knowledge of Athelas Home or expressed that they considered POC hematology analyzers as a competitor. Supporting this statement, Interviewees 2, 4, and 9 stated that they do not know any competitors. On the other hand, some interviewees identified competitors other than Athelas Home or POC hematology analyzers. For example, Interviewees 1, 5, and 8 shared that one growing competitor is home draws, when medical staff or home nurses go to a patient's home, draw their blood for them, and take it to a lab to test.

Though the competitor of home nurses was identified, the DeDx device provides benefits that home nursing cannot. Interviewee 1 supported this statement by stating, "So if you are making an argument, you might say we can get real-time value and real-time results which are within 10 or 15 minutes and know where you are as opposed to waiting for the visiting nurse to collect it, drop it off to the lab, drive, get stuck in traffic, etcetera, etcetera."

4.5.2 Device Interest

The idea of at-home blood testing has sparked interest with many medical professionals and patients with whom DeDx has had conversations. Many interviewees also showed this interest. Interviewee 4 exclaimed, "When I heard

about this, I just thought oh wow!" Interviewee 8 showed interest by stating, "I do think patients would really, really benefit at least in my population, 65 plus from at-home blood testing." Interviewee 9 shared, "If we can kind of troubleshoot all the other aspects and make it user-friendly and safe and seamless that will integrate with our electronic medical record, that would be something I would be interested in." Interviewee 10 summarized their interest well: "To have that being able to be done at home would be fantastic." Lastly, Interviewee 11 expressed the opportunity they see and how an at-home blood testing device could help them reach their goals by stating, "But yeah, I would see opportunities there. I think, like I said, if we can do more from remote, especially people with chronic diseases, to keep them out of the hospital, that is our goal."

On the other hand, the DeDx device may not benefit all patient groups and all practices. Interviewee 5 highlighted this point by stating, "I'd say 2 to 5% of our patients could benefit." Interviewee 2 also hit on this point by stating, "Each of the three providers, we probably have close to 10,000 patients, I would imagine we, probably would not have more than 10 at a time on it though." This interviewee was a family practitioner, and another interviewee, an oncologist, expressed that the target group of at-home blood testing would likely not be general medicine (Interview 1; Interview 2).

4.5.3 Target Populations

DeDx plans to focus on the target population of oncology patients receiving outpatient chemotherapy. During initial evaluations, DeDx decided general medicine would likely not be a target market for this device. This idea was further explored and confirmed during the interviews. Though some medical specialties would not benefit as much from an at-home blood testing device as others would, some patient groups could still reap the benefit from at-home blood testing. Several interviewees expressed that the oncology market would be a good market for this device and should be the primary market (Interview 1; Interview 2; Interview 4; Interview 5; Interview 6; Interview 8; Interview 9). However, other markets were identified by interviewees, including hematology patients, such as patients with anemia, patients with GI bleeds, rheumatology, patients whose medications have been changed, patients that need post-appointment monitoring, and pre-operation and post-operation

patients (Interview 1; Interview 2; Interview 3; Interview 4; Interview 5; Interview 6; Interview 7; Interview 8; Interview 9; Interview 11). In addition to ill patients, some patients could benefit from at-home testing for other reasons. For example, busy patients and those with families could benefit from an at-home device (Interview 8) or patients that do not like needles (Interview 6).

4.5.4 Ease of Use

One focus of DeDx is ensuring an easy-to-use product. This was a topic brought up by several interviewees. Many interviewees mentioned that the device needs to be as easy to use as possible to prevent misuse of the device (Interview 1; Interview 2; Interview 4; Interview 6; Interview 9; Interview 10). Interviewee 1 gave insights and suggestions to ensure this happens, such as making sure any graphics or instructions are run through by people of all literacy levels and testing the device with people of all literacy levels.

4.5.5 Product Concerns

In addition to the ease of use, many professionals have raised other concerns about the DeDx device. For example, Interviewee 11 mentioned that it could be hard to ensure that patients are compliant and draw their blood when they are supposed to. Interviewee 1 also touched on the concern of patient compliance by stating that the target population of cancer patients is a population that is sick, tired, exhausted, and confused, which could cause problems with compliance and results. On another note, there are concerns about how results will be received. For example, Interviewee 3 explained that if the device cannot integrate with their EMR, then it is not a device they would be interested in. In addition, Interviewees 1 and 5 shared that they have technical concerns with the device, emphasizing that it needs to be just as accurate and reliable as the gold-standard lab equipment.

Interviewee 1 explained another concern with the issue of platelet clumping and how it can affect results. Additionally, Interviewee 10 stated there is a risk of infection, especially for patients not in the cleanest environments. Interviewees 4 and 6 said they are concerned about quality control and ensuring the devices are calibrated and working correctly for all patients. Lastly, the most common concern interviewees brought up is the reimbursement issue. Interviewees 1, 4, and 9 all expressed this

concern by stating it must be determined how these results will be monitored and how doctors will be reimbursed or paid for that, while Interviewees 5 and 10 stated their biggest concern is the cost and who will bear the burden of it.

4.5.6 Benefits

On the other hand, the DeDx device has the potential to bring many benefits to practices, doctors, and users, as blood tests can be crucial for care. Interviewee 4 emphasized the importance of blood tests for patient care by stating, "We always say for us that is like the fifth vital sign." The most common benefit identified by interviewees was keeping compromised patients out of the hospital or busy draw sites (Interview 3; Interview 4; Interview 6; Interview 10; Interview 11). Interviewee 6 underpinned this benefit by stating, "The last thing you want is someone who is immunocompromised going into a draw site and interacting with other people."

Other benefits identified by interviewees are that a device like this would allow for more monitoring, real-time results, and increased telehealth opportunities (Interview 1, Interview 10, Interview 11). Interviewee 2, a family physician, mentioned that in general practice, a device like this could be beneficial, allowing lab work to be done before a patient's appointment. A benefit DeDx previously identified is that this device could help with medical staffing shortages by decreasing the number of in-lab or in-office blood draws. Interviewee 8 confirmed this benefit by sharing that they face issues with staffing and that for their practice, the DeDx device could cut down the number of blood draws phlebotomists have to do in their office daily and cut down the overall stress of their phlebotomist. They mentioned that decreasing the number of lab draw appointments could also allow time for other in-office tasks.

4.5.7 Receiving DeDx Results

A significant topic DeDx has been investigating is how to deliver the results of the device to clinicians. The most favorable option DeDx has identified is integrating the device results with EMR systems. The interviews revealed that EMR integration would be the ideal situation to receive results from the DeDx device, as all but one interviewee stated that they use an EMR system. Interviewees 3, 4, 5, 6, 9, and 11 all stated that they use the EMR platform Epic. The other EMRs varied; Interviewee 7 uses a small EMR made for small practices called Practice Fusion, Interviewee 8's

company has built its own EMR, and Interviewee 10 uses an EMR platform called Cerner. In contrast, Interviewee 2 still uses paper records but wants to transfer to EMR within the next year. Interviewees 4 and 9 also shared that not only having the results integrated into their EMR would be the ideal situation, but that they would like to get a notification of the results so they are aware their patient has taken the test and can review their results.

As a second option, though not the most favorable, DeDx also considered sending results from the DeDx device via email to clinicians. Most interviewees expressed that receiving results via email would not be the most favorable for a few reasons. Interviewee 4 shared that their practice emails are used for administrative communication and are not patient directed; therefore, receiving results to their email would not be ideal. Interviewee 9 stated that receiving results in their email would create a burden on the doctors to check their emails in a timely fashion, which cannot always be done due to time constraints. They also expressed concern by saying that if they were on vacation or had a day off, it would be a burden to be responsible for checking their email for their patient's results.

Further rejecting the idea of results being sent via email, Interviewee 10 expressed concern about confidentiality issues if results are sent in an email and the fact that their blood test results can be critical and could get lost in an inbox. On the other hand, just one interviewee leaned the opposite way as Interviewees 4, 9, and 10. Interviewee 5 stated that their practice could be flexible, and emails with results could be sent to their clinical staff.

4.5.8 Distribution of DeDx

One plan DeDx needs to solidify for the market entry strategy is how the device should be distributed throughout different types of healthcare systems. Options DeDx has explored include practices distributing directly to patients with or without RPM programs, patients purchasing or renting the device through medical suppliers or distributors, or partnering with labs. Interviewees 1, 3, and 11 mentioned that before any system would make the device broadly available for distribution, they would start with a pilot study, and after pilot studies are completed, it will be easier to implement the device in a healthcare setting. Several interviewees supported the idea

of practices distributing directly to patients with or without RPM programs by saying that they could see their clinics or hospitals investing in devices and sending them home with patients as needed (Interview 1; Interview 2; Interview 4; Interview 5). Interviewees 1, 3, and 4 emphasized that if their practice were to invest in the devices, they would want to know if they would have a return on their investment. Interviewee 5 supported the idea of a sales method in which patients are reimbursed and purchase the device through medical supply companies or rent the devices through medical supply companies. Interviewees 6 and 11 supported the possibility of partnering and distributing the device through labs with the idea that the labs can explain to a patient how to use the device and then send the patient home with the device. Interviewee 6 shared that a lab partnership would allow the laboratories to be involved and not lose revenue to the DeDx device.

4.6 Pilot Studies

Pilot studies are crucial for any medical device or pharmaceutical product. These studies can prove clinical benefits and ROI and increase sales and device acceptance. Several interviewees supported this by mentioning that DeDx should run pilot studies with the device on a small cohort of the target patient population before the device can be sold to a broader population. Interviewee 1 shared their opinion on the importance of doing a pilot study somewhere well-known. They stated, "You know if it is a pilot someplace we have never heard of, then that is probably not going to hold much weight." They expressed that pilot studies can help prove the advantages and ROI of the device but that the studies must be done somewhere other practices and hospitals recognize and trust.

When discussing doing pilot studies with interviewee 11, they stated, “You know, some hospitals they don't like to be the alpha or beta site because there's a lot of work involved because you had to work out the kinks beforehand, and most people look for something that's already sort of ready, made off the shelf, ready to use type thing. So, you just have to find where the right fit is.” This supports how crucial planning a pilot study is and the difficulties DeDx may face when finding a site for the pilot studies.

DeDx is constantly looking for medical professionals and facilities interested in running a pilot study with the device once it is FDA-approved. Interviewees 3, 9, and 10 showed interest in running a pilot study with the device during the interviews. All talked through the processes of running a pilot study at their practice and emphasized the fact that funding is needed to do these studies and that they will have to be approved by their International Review Board (IRB).

4.7 Reliability and Accuracy

A topic important to every interviewee was the reliability and accuracy of the DeDx device. Providing accurate and reliable results will determine the device's acceptance in the medical community. Interviewee 6 backed this idea by stating, "That is the big thing, and that is critical because the result is not worth anything if the result is not accurate." In addition, Interviewee 5 stated that having some rigorous validation to determine how accurate this blood testing is will be absolutely necessary for healthcare systems to accept and start using this device.

Interviewee 9 expressed the need for reliable and accurate results by explaining that there are high risks associated with not getting their patient's true blood values, and if the chance of a false or inaccurate reading is high, then this is a high risk to the patient. They expressed this by stating, "So I am getting information that are, that do not reflect their true you know condition, then that could potentially lead to mismanagement and oftentimes, if the side effects are caught early, they can be managed, but if it is not caught early then they can potentially lead to more profound effect on the health." This point is crucial, especially when working with vulnerable populations where mistakes could cost a patient their life.

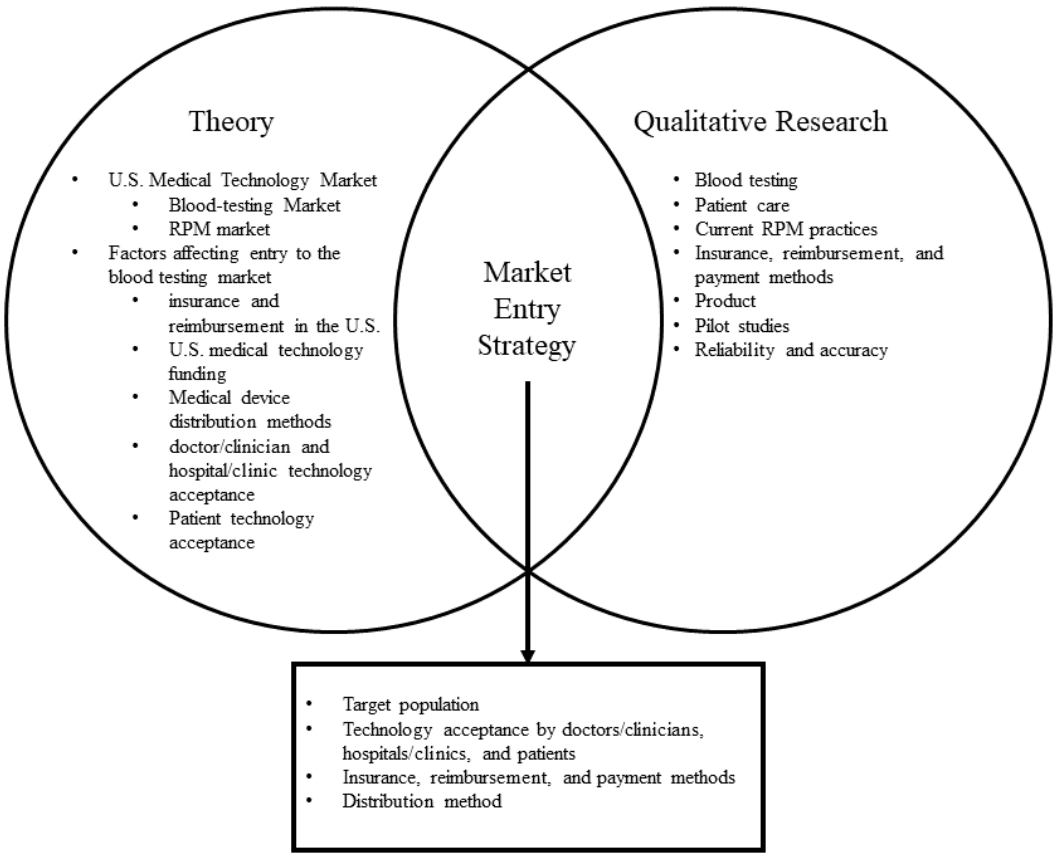
Interviewee 1 brought up a unique insight when they shared the need for reliability and accuracy. They stated how important it is to ensure this device works in all populations and with all races. They also shared some things that could affect the device's reliability and accuracy, such as platelet clumping and tired, exhausted, confused, and scared patients operating the device. These are all things DeDx needs to keep in mind when running reliability and accuracy tests.

5 Discussion and Conclusion

For this thesis, an abductive approach was used to develop a market entry strategy. This abductive approach uses aspects of the theory and aspects of the qualitative research to derive a new market access strategy. Based on the information collected from the theory research and qualitative research, the categories formed to explain the suggested market entry strategy in this discussion are as follows: target population, technology acceptance by doctors/clinicians, hospitals/clinics, and patients, insurance, reimbursement and payment methods, and distribution method. A diagram of this abductive approach is shown in Figure 3. Additionally, this section will discuss the limitations of this study and research, recommendations for continued research, and a conclusion summarizing the suggested market entry strategy.

Figure 3

Abductive Research Approach



Note: Figure 3 shows a vena diagram to show how aspects from the previously discussed relevant theory, and the information compiled from the qualitative research performed, come together to create a market entry strategy for DeDx.

5.1 Target Population

DeDx's target population is oncology patients receiving outpatient chemotherapy. Based on the theory and research in this thesis, DeDx should keep its target population as oncology patients receiving outpatient chemotherapy. There are many reasons to keep this as the target population for the DeDx device. In the U.S., in 2023, over 1.9 million new cancer cases are expected to be diagnosed (American Cancer Society, 2023). It was expressed by interviewees 4, 5, 9, and 10 that at least 60% of cancer patients receive chemotherapy, which would mean there would be nearly 1.14 million new cancer patients receiving chemotherapy in the year 2023 in the U.S., in addition to the patients diagnosed in earlier years and are still undergoing treatments.

Additionally, DeDx had many expert conversations with oncologists and patients before the beginning of this thesis, which expressed that outpatient chemotherapy patients receive frequent blood tests to monitor their blood counts for safety, and the interviews completed in this thesis research further confirmed this. According to the expert conversations completed before the research period and interviews completed during the thesis, oncology patients receiving outpatient chemotherapy get blood work done, and more specifically CBCs, before receiving each treatment. This can range from multiple times a week to just once every 3-6 weeks depending on the type and intensity of the chemotherapy regimen. The research showed that some oncologists could see a benefit in more frequent testing of CBCs with the DeDx device, while others stated they would not increase the number of tests their patients receive. Even if the oncologists do not increase the number of tests their patients do if they use the DeDx device, oncology patients receiving outpatient chemotherapy complete blood tests regularly and would be using the device regularly.

In addition, the theory and research both showed disparities in transportation for oncology patients. Though most state Medicaid programs cover NEMT, which would cover a cancer patient's transportation to an appointment for a blood draw and testing (National Academies of Sciences, Engineering, and Medicine, 2018), not all insurance plans cover these transportation costs (expert conversations by Fyr Hub with Insurance Company Former Global V.P. in the U.S. on April 22nd, 2022, and with Associate Director of a U.S. Insurance company on April 22nd, 2022). In the

research, three out of the five oncologists interviewed expressed that transportation can be an issue for many patients due to factors such as affordability, distance, and the inability to drive. Therefore, for these patients to have access to an affordable at-home blood testing device, the number of appointments they need transportation for could be decreased. Not only could the appointments be decreased, but by remotely monitoring the side effects of patients, doctors can have a more detailed overview of what the patient is experiencing (Macguire et al., 2020).

A further benefit of the DeDx device for not only this target population but also for the doctors, hospitals, and clinics treating this population is a decrease in hospitalizations and the ability to act swiftly to abnormal blood counts. Interviewee 10 stated that most of the time, what they are checking for with CBCs is if the patients' neutrophils are low and potentially neutropenic. They shared that for this population, knowing their blood count can be crucial because if they have a low neutrophil count in combination with a fever, they are likely neutropenic and need to go to the emergency room. According to a study by Tai, Guy, Dunbar, & Richardson (2017, p. e556), in 2012 the total cost in the United States of cancer-related neutropenia hospitalizations was $2.7 billion, $2.3 billion of that amount being for adults. On average, the length of stay in the hospital for these adults was 9.6 days, with an average cost of stay of $24,770 per stay (Tai et al., 2017, p. e552). Early detection of low blood count with the DeDx device could decrease the length of hospital stay for cancer patients by allowing earlier detection of neutropenia, decreasing their total costs related to cancer.

Regarding using the DeDx device in other medical specialties, this research supported the idea that this device may not be as beneficial for general medical practices as it would be for oncology. Interviewee 1 stated that they do not believe the target group would be general practice, and Interviewee 2, a general practitioner, shared that they do not believe they would have more than ten general practice patients using this device at a time out of their 10,000 total patients, but could see potentially more patients using it if it also had a CMP testing capability. In addition, both interviewees 2 and 7 stated that in general practice, patients usually only receive a CBC once a year, and there would not be a need for more frequent testing, further

confirming that the DeDx device would not be as beneficial for a general practice compared to other medical specialties.

Therefore, for the U.S. market entry, the focus of the DeDx device should stay on oncology patients receiving outpatient chemotherapy. In the future, DeDx could consider expanding to other medical specialties identified in this research, such as patients with chronic diseases, pre- and post-operation surgery patients, patients with hematologic diseases and malignancies, anemic patients, and patients with GI bleeds.

5.2 Doctor/Clinician, Hospital/Clinic, and Patient Acceptance

The technology acceptance amongst everyone in the medical community, from doctors/clinicians, hospitals/clinics, and patients, will be crucial in the market entry of DeDx. Without acceptance from each group of market players, the device may not survive on the market. A huge point emphasized in this research is the reliability and accuracy of this device. Interviewee 9 explained that it could be a risk to the patient and lead to mismanagement if the device is not reliable and accurate. In addition, Interviewee 1 explained that any false readings from the DeDx device could lead to a patient's life or death and lead to large malpractice lawsuits. Though DeDx will have to prove the reliability and accuracy of the device through thorough testing to receive FDA approval, DeDx must be sure that these tests meet the standards of the oncologists that will be having their patients use this device. This includes testing against standard equipment used at labs in the U.S. As a next step, DeDx should investigate what lab equipment is most common in the U.S. and what equipment oncologists and doctors would like to see compared with the DeDx device.

Another way DeDx can prove the accuracy and reliability of their device, as well as other benefits, cost reductions, and proving ROI, is through pilot studies. Interviewee 11, a Hospital President, stated that hospitals or facilities often do not want to be a product's alpha or beta sites as it takes time, money, and resources. They also shared that once pilot studies are completed, other facilities will be more willing to adopt the device. Interviewee 1 shared that pilot studies must also come from a well-established facility rather than a small unknown one. Through these interviews, three interviewees from well-established and well-known oncology facilities expressed interest in running pilot studies with the DeDx device. Keeping the connection and

growing a professional relationship with these three oncologists from the research is essential for DeDx because running pilots with these oncologists, their facilities, and their colleagues can help the DeDx device gain traction during the early roll-out phase. During these pilot studies, in addition to reliability and accuracy, DeDx can further investigate and prove the clinical benefits of the device. This will also aid in setting up reimbursement schemes with insurance companies. DeDx will have to perform a cost-benefit analysis and see what the device saves patients, practices, and insurance companies. This can include studies to prove reduced hospital stays, decreased neutropenia in patients, decreased travel time and decreased travel costs, etc. They can also investigate how the device can improve the quality of life for patients by, for example, giving surveys to patients using the device and patients not using the device at each treatment during the study period to determine a difference in their quality of life.

An interesting point that Interviewee 1 made is that DeDx needs to ensure tests are done with all types of populations. They stated that tests must be done with all races and people of all literacy levels. This interviewee told an interesting story about how pulse oximeters give different results for patients with darker skin tones. They shared that due to these different results, they saw some patients receiving care later than they should have due to the overestimation of blood oxygen levels by the pulse oximeter. After the interview, I confirmed this with a study by Shi et al. (2022), who stated, "On average, pulse oximetry probably overestimates blood oxygen saturation by approximately 1%, but overestimation may be as low as .29% or as high as 2%." Interviewee 1s story and the additional research read after the interview makes it clear that any level of inconsistency in results between races and different patient populations can waiver medical provider's trust in a device and makes it clear that DeDx needs to consider this when doing initial patient testing for FDA approval, and when doing pilot studies for market entry. The testing results must represent diverse populations, as the U.S. is highly diverse. The device cannot be exclusive, or as Interviewee 1 stated, certain facilities will be reluctant to use devices that cannot be made available to all their patients.

Though in this study period, patients were not interviewed, the doctors interviewed expressed the belief that their patients could draw their own blood at home,

especially if it were just a finger stick, and instructions were made clear to patients. Additionally, in conversations with patients before the study period, they expressed their ability to draw their own blood and their desire to use such a device.

Another critical aspect of DeDx's market entry strategy concerning doctor/clinician and hospital/clinic acceptance is device integration with different EMR systems. Many clinical organizations express that integration with their EMR is preferable (Kelley et al., 2020). In an expert conversation with Fyr Hub on April 19th, 2022, a GI oncologist also said it would be preferable to have results integrated into their EMR. The research in this thesis supported these statements. Not only did oncologists interviewed express the need for integration into their EMR, but so did general practitioners, clinics, hospital administrators, and managers. Six interviewees stated that their health system uses the EMR platform EPIC. As of 2019, Epic was the largest EMR system in U.S. acute care multi-specialty hospitals with a 29% market share, while Cerner followed behind at 26% market share (Tate & Warburton, 2020).

As a second option, DeDx considered delivering the results of the device via email, which was further investigated in this study. Many interviewees stated that receiving results via Email would not be sufficient, puts pressure on the doctor to check for results under time constraints or on days off, and faces cyber security issues. DeDx must create an integration plan with large EMR systems like Epic. DeDx should start communicating with these EMR systems as soon as possible and build a plan to make this integration happen. This step must be completed before pilot studies will begin to prove the device's highest benefits and ease of use. Out of the interviewees from the research interested in performing pilot studies with the DeDx device, two use the EMR system Epic, and the other uses the EMR system Cerner; therefore, the focus of DeDx should be to start an integration plan and begin contact with Epic.

One thing that could affect device acceptance that many oncologists mentioned in expert conversations with DeDx before the study period, and many interviewees mentioned in interviews during this thesis study, is that sometimes a CBC will not be enough to determine if the treatment can be received. Many oncologists expressed the need for a CMP to monitor the patient's kidney and liver functions and that they

would be more apt to have their patients use the device if it could perform both a CBC and CMP. DeDx has considered this idea and is evaluating the options to add this to their device in the future. Although some doctors expressed that they would also want to see a CMP, they still saw benefits in the use of an at-home CBC device to allow for further monitoring of their patients, checking for neutropenia, getting real-time results, cutting down transportation time for patients, and easing the workflow of labs by decreasing the number of patients that must come in for lab draws. Adding a CMP is something DeDx should continue to investigate adding to their device in the future, but it should not be the focus of their market entry strategy. The focus should be on building a reliable and accurate CBC device and gaining trust and acceptance within the medical community.

5.3 Insurance, Reimbursement, and Payment Methods

After evaluating the theory and the qualitative data, I have identified the two reimbursement and payment strategies that I believe make the most sense for DeDx during their market entry in the U.S.:

1. a RPM reimbursement scheme through an established RPM company
2. and by selling to clinics for them to distribute to their patients as needed.

Many interviewees expressed the desire for the device to be affordable for their patients. They emphasized that there would need to be a reimbursement plan for the patient and the doctors viewing and interpreting the device results. Additionally, if the clinics are purchasing the device, then ROI must be proven for the clinics to purchase the device.

As previously stated, the U.S. insurance system is made up of many players, from state programs to federal programs, to private insurance companies. Coverage by each player differs for the main elements related to DeDx: blood testing, remote patient monitoring, medical devices, and patient transportation. This makes each patient's insurance situation unique, which the interviews support. The research showed that each system, oncology or not, has a large range of how their patients are insured. However, focusing on the target population, in the research three oncologists in large inner cities shared that they would estimate their patients to be 50/50

between commercial insurance and Medicare or Medicaid (Interview 4; Interview 5; Interview 9). This is an important point for the DeDx market entry strategy as it is crucial to understand how their target population is insured.

Therefore, DeDx needs to evaluate and consider all the different reimbursement and payment schemes for the market entry strategy that would make the most sense with the target population of oncology patients receiving outpatient chemotherapy. According to the American Cancer Society (2023), "88% of people diagnosed with cancer in the U.S. are 50 years of age or older and 57% are 65 or older." Medicare can cover all people aged 65 or older. According to the National Health Statistics Report by Cha and Cohen (2022, p. 6), 39.8% of all adults in the U.S. aged 65 or older were covered by private insurance, 31.8% had Medicare advantage, 12.1% had traditional Medicare, 8.7% had a different type of coverage, 6.8% were dually covered by Medicare and Medicaid, while less than 1% were uninsured. Taking these statistics into consideration, in addition to the fact that three oncologists interviewed shared that Medicare or Medicaid covers at least 50% of their patients and the fact that most insurance companies follow the suit of Medicare, I recommend DeDx starts their market entry with an insurance coverage plan involving Medicare.

Medicare uses CPT codes developed and maintained by the AMA to have a uniform language for medical services and procedures for billing for doctors and health care professionals. Additionally, they use HCPCS Level II codes maintained by CMS to have a uniform language for DMEPOS billing. Medicare always uses these code systems, and Medicaid and private insurance companies usually follow suit. Interviewee 3 supported this statement by stating, "We're predominantly using the CPT codes which Medicare gives us and they update their fee schedule every year. And then the private insurance group, they follow suit because you know, typically whatever Medicare does, they are the leader of the pack, then everybody else follows." The Interviewee also shared that they bill across the board, and it does not matter if it is commercial insurance or Medicare; the different insurance companies will just pay different rates. This is an important fact to confirm, as working with every insurance company in the U.S. may be difficult. However, if DeDx can get the federal Medicare program on board with the product, other insurance companies will likely follow. Additionally, the theory proved that if DeDx wants patients to pay for

the device and wants the device to be reimbursable with insurance companies, they must apply for and receive a HCPCS code for their device after FDA approval and after at least three months of sales in the U.S., which will take time. Therefore, applying for an HCPCS code may not be the most appropriate option for initial market entry for DeDx.

Considering this information and feedback, the reimbursement plan that would make the most sense for DeDx for market entry is an RPM reimbursement scheme by partnering with an already existing RPM company. Medicare always covers RPM, while Medicaid and private insurance companies sometimes do. By partnering with an RPM company, DeDx gives those RPM companies an additional physiological reading that other RPM companies cannot give: CBC with white blood cell differential. This can appeal to RPM companies because it gives them another unique selling point. Additionally, by partnering with an RPM company, DeDx will not have to worry about setting up a billing system, creating additional products so patients can reach 16 physiological readings, designing a system for cleaning and collecting devices, etc. RPM companies already have these things established and would only need to add the DeDx device to their packages.

As mentioned in previous sections, pilot studies are needed to get insurance companies on board with covering a device by showing cost-benefits and cost-savings analysis. By going the RPM route with an established RPM company, healthcare providers will be reimbursed for using the device in a RPM program, and the RPM companies will cover the costs of the device. The RPM companies would buy or license the device from DeDx, allowing DeDx to bring in revenue. Many interviewees indicated they were doing no form of RPM for their patients, but they could see their patients and clinics benefiting from it. These RPM companies would then strongly appeal to oncology clinics, as the interviewees expressed that a blood count in combination with other vitals such as temperature would benefit oncology patients.

The second strategy for sales and payments in the market entry I recommend for DeDx is selling the device directly to clinics or hospitals for them to distribute as needed. This is a good strategy for DeDx's market entry for many reasons. First,

some interviewees explained that their clinics or hospital systems run their remote patient monitoring independently. This means if they want to add an RPM device to their system, they must purchase the devices and then add them to their system on their own. This would work for DeDx as they could sell the health systems the devices and cartridges, and then the health system can add the device to their system, and then DeDx again will not have to worry about distributing directly to patients, cleaning and collecting devices, etc. DeDx will only have to ensure compatibility with the health systems EMR before being able to sell to them, provide customer service for any technical issues, and sell cartridges to the health system as needed.

A good place for DeDx to start with this strategy, is by continuing contact and building a professional relationship with Interviewee 3. Interviewee 3 works for a hospital system spread throughout the state of Virginia and runs an RPM program through this system. They are partnered with a RPM platform company (software focused) also located in Virginia. Both the RPM company and the hospital system have a team that works with Epic to connect the devices to their system. Not only does the RPM company provide a software platform for the RPM devices, but they also take care of distributing the devices to patients, collecting them, and cleaning them. Interviewee 3 shared that adding a device is not difficult, but a pilot with their hospital system would be required first, which just takes time and money. Therefore, if DeDx maintains this connection, they could perform a pilot study with Interviewee 3's hospital system and their oncology patients. Assuming all goes well with the pilot study, DeDx could sell their device to Interviewee 3's hospital system who will then connect the device to their RPM system. This would allow DeDx to gain experience working with a hospital system and would be a good step for their device to be added to an RPM system. This RPM company that Interviewee 3 works with also works with healthcare systems in Florida, Indiana, Illinois, Nebraska, Minnesota, Iowa, and more. Therefore, if the DeDx device is used by Interviewee 3's hospital system in the state of Virginia, the RPM company they use could also recommend the device to the other hospitals and clinics that they provide RPM services for as they would have experience working with the device. DeDx could also approach these other healthcare systems the RPM company works with to sell them the device by using the pilot study with Interviewee 3 as support and by explaining that their RPM

company works with this device in other health systems and is capable of adding the DeDx device to RPM programs.

Additionally, the theory and the research also showed that not all clinics and hospitals use RPM, and not all are interested in setting up RPM programs. However, they also expressed that for some patients, it would be beneficial for them to do their blood work from home, to leave the hospital for the weekend and monitor their blood counts, or to allow more frequent blood count monitoring for patients. By selling directly to clinics, especially smaller oncology clinics, the clinic can distribute devices to patients as they see fit by either providing them free of cost or leasing them out to patients. Again, in this case, DeDx would not have to worry about distributing directly to patients, cleaning and collecting devices, etc.

5.4 Distribution Method

My suggested distribution method for DeDx in their market entry goes together with the reimbursement and payment methods which were explained thoroughly in the previous section. First, with the reimbursement method of partnering with established RPM companies, DeDx can either sell or license their product to RPM companies. As mentioned, this method would give RPM companies an advantage as it is not a device every company would have, and it would give them access to the oncology field as we know a device such as this one is in demand in the oncology field from the research. Additionally, this allows RPM companies to bundle the DeDx device with other devices that they, or their clients, see fit. The previous section also mentioned the second distribution method: selling the device directly to clinics and hospitals. This would allow clinics to distribute to patients as they see fit or allows them to add the device to their already existing RPM program. Both methods allow DeDx to make sales on the devices and cartridges while not having to create more products for initial market entry to create their own RPM platform/program, distribute directly to patients, or clean and collect devices after patient use.

Later, once DeDx has successfully entered the market, they could consider other distribution methods. For example, after initial sales and studies for clinical benefit, cost-benefit, and cost-savings, DeDx could consider applying for an HCPCS code

and negotiating with insurance companies to get the device covered with an HCPCS code. This would allow doctors to prescribe their patients the device, and their patients could pick it up from a medical device supplier. The supplier could then bill the patient's insurance, and the patient would be reimbursed for the cost of the device (depending on the price negotiated with that patient's insurance company). This distribution method would not make sense for initial entry as it requires a minimum of three months of sales, and DeDx first needs to gain traction in the oncology field through pilot studies and initial sales with clinics to gain support from oncologists.

5.5 Limitations and Suggestions for Further Research

Though the information gained through this research confirmed some ideas DeDx had, created new ones, and eliminated others, this study still has many limitations.

One limitation of the research portion of this study was time constraints. There were approximately two months to reach out to potential interviewees and complete the interviews. Many doctors and administrators have busy schedules, so some could not plan a meeting for several weeks or months. This led to some potential interviewees declining an interview due to the lack of time in their schedule and some not having time to schedule an interview until after the study period.

In addition, another limitation is that several oncologists were found through universities, as their emails as professors or clinical staff can be found on university websites. Therefore, it may be beneficial to talk to oncologists not part of university systems but also oncologists employed at smaller clinics or clinics/hospitals that are not in large cities, as most of the universities the interviewees were from are in large cities.

A limitation of the interview group is that six interviewees were from the state of Michigan, with two being from the same hospital system but having different administrative roles. Additionally, one more was from Illinois and another from Ohio, meaning that eight out of the eleven interviewees were from the mid-west region of the U.S. With that being said, the data received in this study potentially gives an overview of what a market entry strategy may look like in the mid-west region of the U.S., not the entirety of the country. With the U.S. having 50 states, it

would be beneficial to gain information from all states to get a better idea of the overall view of the device throughout the country. Therefore, I would recommend that DeDx continues to have conversations with oncology clinics throughout the U.S. to confirm the recommendations brought about in this thesis can apply to the entire U.S.

Though the interviewee's responses all pointed in the same general direction, another limitation of the study is that none of the administrators or managers worked directly in oncology. I believe it would have been useful to have the opinion of oncology clinic managers as they are the ones, in addition to the oncologists, working with the target population of oncology patients receiving outpatient chemotherapy. I recommend that DeDx reach out to oncology clinics or use their connections with oncologists in the U.S. to talk to oncology clinic managers and administrators, as they may also play a significant role in whether this device will be accepted at their clinic or hospital.

One thing that the qualitative research did not help to gain a better understanding of is how much money DeDx will need for market entry. Many interviewees mentioned that, for example, pilot studies cost time and money, but there was no range of how much money these studies may cost. DeDx is in contact with venture capitalists and other investors and applying for grants; however, further research should be done to understand how much money pilot studies will cost. This research could include reaching back out to interviewees 3, 9, and 10 to discuss the processes in more detail and break down the costs of a pilot study with their institutions.

Lastly, I recommend that more research be done on the existing RPM companies in the U.S. Since my recommendation is to distribute devices to established RPM companies, research should be done to identify further companies that may be interested in the product, as well as focusing research on RPM companies that already work with oncology populations. Researching RPM companies that already work with oncology populations could be extremely useful as DeDx could then make connections with these companies and talk to staff at the clinics and hospitals they work with to show a desire for the product by the oncology population.

5.6 Conclusion

There are many factors to consider when creating a market access strategy for a medical or pharmaceutical product, and an at-home blood testing device is no exception. This thesis brought together theories on the blood testing market, RPM market, insurance and reimbursement, funding, medical device distribution methods, doctor/clinician and hospital/clinic acceptance, and patient acceptance, with qualitative data from interviews on blood testing, patient care, current RPM practices, insurance, reimbursement, and payment methods, product information, pilot studies, and reliability and accuracy to create a market entry strategy for DeDx's innovative at-home blood testing device.

So, in summary, what does a feasible market entry strategy for an innovative at-home blood testing device in the U.S. look like? The theory and research confirmed that the target population of oncology patients receiving outpatient chemotherapy should be kept for the market entry. In the future, DeDx may be able to expand to other patient groups, such as those with hematology disorders, pre- and post-operation patients, or patients with GI bleeds. The next part of the market strategy is to continue forming professional relationships with those in the medical community and run pilot studies to ensure device acceptance amongst the medical community. These pilot studies will help prove the device's reliability and accuracy, clinical benefits, and ROI on the devices. Through this research, several potential partners were identified for pilot studies. These interviewees should be kept in contact with to build a professional relationship and partnership for the pilot studies after FDA approval. Next in the market entry strategy is identifying a reimbursement and payment scheme for the device, which also goes together with the last part of the market entry strategy, the distribution methods. The theory and research have led to two feasible options: reimbursement through RPM CPT code pathways by distribution through established RPM companies and selling the device directly to clinics or hospitals to distribute on their own terms. Established RPM companies would eliminate the need for DeDx to do any RPM billing work, distributing, or collecting devices from patients.

Additionally, RPM companies already have programs set up and could add the DeDx device to their offerings, a device that not all companies can offer. Selling directly to

clinics and hospitals also eliminates the need for DeDx to distribute directly to customers and collecting or cleaning devices. This also gives the clinics and hospitals flexibility in the distribution of their devices by allowing them to add the device to their own RPM programs or by giving or renting the device to patients directly as needed.

This recommendation of a market entry strategy is just the first step into the future of DeDx. Though the theory and research support the recommendation, there are aspects of the strategy that should be further researched as stated in the limitations and suggestions for further research. DeDx has a strong product many medical professionals and patients have shown interest in. Entering the market in the U.S. will take time and requires building strong relationships with stakeholders such as patients and doctors. However, with a strong and researched market entry strategy, DeDx could have much success in the future in the U.S. market.

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Appendix A

Script for All Interviews

Thank you so much for agreeing to meet. Again, my name is Kathryn Wagner. I am a master's student at Munich Business School getting my masters in innovation and entrepreneurship. The interview today is part of the research for my master's thesis, which is a case study on the company DeDx, and creating a market entry strategy for the United States. DeDx is creating an at-home blood testing device to support remote patient monitoring. The test is taken at home with just a drop of blood, placed in a microfluidic cartridge and analyzed by the machine, and the results are sent directly to the clinicians. We have completed many interviews with patients and doctors, but I am continuing these interviews to gather information to evaluate the best way to enter the US market.

I want to reiterate the right to confidentiality and anonymity. Nothing said by you will be attributed to you without your permission. You have the right not to answer questions and we can stop the interview at any time if you wish. Again, the information gathered today is qualitative data for my master's thesis. The data will be used to further evaluate and plan a market entry strategy for the company DeDx.

If you wish, I can share a summary of research findings with you in May.
Lastly before we get started, do I have your permission to record the interview electronically through the Microsoft Teams function? If no recording, can I use the transcript function to generate a transcript of our interview as we speak? (If permission, begin recording or transcript)

If you are ready, we can start with the interview now. The interview will take approximately 20-30 minutes. I will be asking you questions regarding your medical background, patients, technicalities of the DeDx device, and clinical implementation.

Name:
Gender:
Age:
Position:

Appendix B

Interview Guide Questions

Doctor (Oncology and General Practitioner) Guide Questions

Questions – Oncologists only

Which forms of cancer do you treat mainly?

How many of your patients receive chemotherapy?

Which challenges do you face monitoring and applying chemotherapy?

Elaborate on the care pathway for chemo patients, most pertinently regarding monitoring. What is the frequency of visits?

What parameters are necessary for an effective remote monitoring system? To what extent is tracking CBC alone enough? (Please list other necessary tests if more than CBC)

Does your clinic/practice use any RPM programs?

If not…

for what reason?

could you see any benefits, and cost or resource savings by implementing an RPM program? Or any downfalls?

If yes…

what does the care pathway look like? For RPM, what kinds of products/devices do you use for monitoring?

does the clinic/practice run it or is an outside RPM company used? If a company, which?

are there any benefits and cost or resource savings by having an RPM program? Any downfalls?

What value do you derive from person-to-person contact during visits? What impact would remote monitoring have on this aspect of the visit?

Questions – General Practitioners only

Elaborate on the care pathway for your patients, most pertinently regarding monitoring. What is the frequency of visits for patients?

Does your clinic/practice use any RPM programs?

If not…

for what reason?

could you see any benefits, and cost or resource savings by implementing an RPM program? Or any downfalls?

If yes…

What does the care pathway look like? For RPM, what kinds of products/devices do you use for monitoring?

does the clinic/practice run it or is an outside RPM company used? If a company, which?

are there any benefits and cost or resource savings by having an RPM program? Any downfalls?

To what extent could remote monitoring of patients' blood counts be valuable? To what extent would CBC alone be enough for an evaluation? (please list other necessary tests if more than CBC)

What value do you derive from person-to-person contact during visits? What impact would remote monitoring have on this aspect of the visit?

Technical – Oncologists and General Practitioners

What are the risks associated with patient-operated blood retrieval and remote monitoring? To what extent do you believe compliance would be adequate? (Maybe

in a follow-up question we can point towards capillary blood tests as in diabetes-blood-glucose-monitoring, as we won't need patients to find their vein.)

What is the current frequency of testing of your patients? Would more frequent testing be valuable? If so, why and what is the reason for not doing more frequent tests?

What other elements would be crucial to aid accuracy and reliability of the patient-operated test results? What safety parameters would be crucial?

What communication interface would be required? What elements will be crucial regarding the communication loop?

What concerns would you have regarding the proposed technology?

Are you aware of any current solutions which support remote monitoring of blood count?

Clinic/Implementation – Oncologists and General Practitioners

How could you imagine your clinic implementing such a device?

How could a device such as this one benefit your practice? Could this device save your practice money and resources?

Would you prescribe a device such as this one to a patient?

Could/would your clinic buy and distribute these devices? (Ex. Through patient renting, or distributing devices and patients just pay for cartridges, or clinic covering full costs)

(if they do not have an RPM program) - Would you be open to setting up and using an RPM system that has a blood testing device? (Given the fact that there is a set reimbursement pathway with CPT codes)

If not, for what reason?

Clinic/Hospital Administrators or Managers Guide Questions

RPM

Do you currently have any RPM programs running at your clinic/hospital?

If so…

for what patient groups?

Do you run the RPM program or are you partnered with an RPM company? If a company, which?

What was the incentive for starting the use of an RPM program? Does your RPM program save the clinic or hospital money or resources? (e.g., less staff needed)

Are there any negative effects of these RPM programs on the hospital or clinic?

What kinds of products does the RPM program consist of? (e.g., blood pressure cuff, thermometer, etc.)

As a clinic/hospital manager, could you request the addition of an at-home CBC to be part of your RPM program?

If not…

For what reasons do you not have any RPM programs?

Do you think there would be any benefits and cost or resource savings in running RPM programs at your hospital or clinic? Any downfalls?

would you be open to setting up an RPM program – with a blood testing device - at your clinic/hospital? (Given the fact that there is a set reimbursement pathway with CPT codes)

Blood testing

What is your current solution to blood testing right now?

How would an at-home blood testing device change the workflow of your hospital or clinic?

Which patient groups do you feel an at-home blood testing device could benefit most?

Do you have partnerships or contracts with labs for blood testing or do you run your labs in house?

Would there be a way to collaborate with your labs?

Partnerships

What would be the easiest way of integrating our solution to your clinic/hospital? How could this be handled best? (e.g., being part of an RPM system, selling this device to the clinic for them to distribute to certain patients, etc.)

Could you see your clinic/hospital benefiting from at home blood testing? If so, in what ways?

Could you see this device saving your clinic/hospital money or resources? How?