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Adoption and Diffusion of At-Home Medical Tests

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Abstract – The purpose of this study is to understand the at-home medical test market, including the medical and regulatory requirements when creating and marketing new at-home medical tests as well as the market factors that influence their adoption by consumers. In response to the COVID-19 pandemic, new at-home tests were rapidly approved by the FDA, bringing at-home testing to the forefront. The history of at-home health testing is reviewed along with the medical requirements for creating these tests, and how the pandemic has affected their adoption and use. Tables are also included to demonstrate currently available at-home tests and potential future tests. Companies interested in bringing at-home medical tests to the market must decide if they will utilize a preexisting laboratory test or develop a new test and if the tests will be physician-ordered or sold directly to the consumer in a retail setting. Our investigation focuses on the effect COVID-19 has had on the at-home testing market by applying traditional marketing concepts, the Rogers (2003) adoption and diffusion of innovations' framework, and critical success factors.

Key Words – At-home medical tests, New product adoption, Diffusion of innovations

Relevance to Marketing Educators, Researchers, and Practitioners - This is a review of the current and potential at-home testing market with an emphasis on adoption and diffusion of innovations. The in-depth review shows opportunities for the at-home test market. The review will be helpful to developers of at-home tests to better understand the nuances of the market. The application of established marketing principles to the at-home testing environment during the COVID-19 pandemic will be useful to marketing practitioners working in the healthcare sector.

Introduction

Less than four months after the start of the COVID-19 pandemic in the United States, Laboratory Corporation of American (LabCorp) received FDA Emergency Use Authorization (EUA) for an at-home collection kit for COVID-19 testing (Howard, 2020). Less than a month after the first approval, Rutgers University Lab received an EUA approval for the first at-home saliva collection kit (Rutgers News, 2020) and start-up firm Everlywell received approval for the first stand-alone at-home COVID-19 tests (Abbruzzese and Miller, 2020). For medical test developers looking to enter the at-home testing market, COVID-19 has provided an opportunity for expansion, as the public becomes more familiar and comfortable with at-home medical testing. The COVID-19 pandemic has also driven consumer demand for testing alternatives that avoid the doctor's office or laboratory settings.

Most at-home tests are considered medical devices by the FDA. However, some at-home tests are ordered by a physician and, therefore, are not regulated by the FDA. Additionally, the FDA does not regulate general wellness tests, such as food sensitivity tests. Other tests, such as

cholesterol tests and pregnancy tests, that have predicate devices and are low to medium risk can utilize the 510(k) pathway to undergo approval. If a low to medium risk device does not have a predicate device, then the De Novo pathways can be used to avoid the Pre-Market Approval (PMA) process. Home use or direct to consumer tests (DTC) which are classified as high risk must undergo the PMA process. Examples include the OraQuick HIV test and 23andMe's genetic test. The process for approval for a new test can take three to five years (Van Norman, 2016)

At-home tests provide consumers with the convenience of completing the testing at home, on their own time, and oftentimes at a lower cost. Additionally, at-home testing can improve patient engagement, which is critical in chronic disease management. However, at-home tests can provide either false positive or false negatives creating anxiety or a sense of comfort in patients for which the results were incorrect. Additionally, at-home tests do not substitute for a physician and test results should always be followed by a consultation with a healthcare provider (Grenache et al., 2017).

The purpose of this study is to evaluate the market for home health tests and new product development processes that lead to the commercialization and availability of such products. The purpose of the study will be done by (1) understanding the history and development process for at-home tests; (2) describing the diseases and diffusion of at-home tests and (3) applying critical success factors to consider in appealing to consumer adopters.

History and Current State of At-Home Health Tests

Prior to the Medical Device Amendment being passed in 1976, several at-home medical tests were available. The availability of the tests led to a discussion about how, and even if, at-home tests should be regulated by the FDA. Before 1976, the FDA could only regulate medical devices after the devices entered the market, meaning no pre-market testing was required. However, the FDA could require pre-market testing and other requirements for products classified as drugs. The debate about the distinction between drug versus medical devices went all the way to the U.S. Supreme Court in 1969 in the case *United States v. Bacto-Unidisk* (Bacto, 2017). Ultimately, the court ruled that the product in question was a drug, not a medical device, giving the FDA the ability to regulate the product prior to market entry. However, the ruling shined a light on the bigger issue of the different pre-market processes and regulations for drugs versus medical devices.

To answer the concerns voiced, the 1976 Medical Device Amendment was passed. "The 1976 amendments defined devices similarly to drugs but noted that drugs cause a chemical reaction in the body, whereas devices do not. They called for all devices to be divided into classes, with varying amounts of control required in each one" (Rados, 2006). Soon after, at-home glucose monitoring devices, fecal occult tests, and ovulation tests were available. In the late 1990s, several new products entered the market. New tests included HIV tests with results available in a week, other urine-based tests, and HbgA1c tests.

Current at-home medical tests are split into two categories: 1) test kits and 2) collection kits (Terrie, 2009). Test kits (**Table 1**) are tests that can be collected, performed, and read at home by the consumer. To date, at-home testing options now include traditional tests, such as pregnancy tests but also a large variety of new tests including genetic testing, cancer screening, and general wellness tests. Collection kits (**Table 2**) are where the specimen is collected at home and sent to a lab for review before results are sent to the consumer.

Table 1: At-Home Test Kits Available at Common Retailers

Test	Specimen	Test Format	Results Indicator	Availability of Results
AZO Urinary Tract Infection Test	Urine Sample	Individually-wrapped test strip	Color coded system used to show 3 outcomes: negative, trace, or positive	Results available in 2 minutes
Oraquick In-Home HIV Tests	Cotton swab for in-mouth saliva collection	One-use cotton swab.	Binomial test results: POSITIVE or NEGATIVE	Results available in 20 minutes
Pinnacle Biolabs Fecal Immunochemical Test (Colorectal Cancer)	Fecal Sample extracted from toilet tissue	Collect specimen using wand and insert wand into analysis tube	Binomial test results: POSITIVE or NEGATIVE	Results available in 5 minutes
First Check Home Cholesterol Test	Blood sample drawn from finger stick lancet (device provided)	Place sample on provided test well	Test evaluates HDL, LDL, and total cholesterol	Results available in 5 minutes
Test for Alcohol in Breast Milk	Breast Milk	Individually wrapped test strips	Binomial test: colored strip on test strip for positive, test strip stays white for negative	Results available in 2 minutes
Ovulation Predictor Test Kit (advanced-estrogen & LH)	Urine	Individually wrapped test sticks	No face (no LH surge), smiley face (LH surge), big smiley face (peak LH)	Results available in 3 minutes

Ovulation Predictor Test Kit (LH only)	Urine	Individually wrapped test sticks	Binomial test: 2 stripe indicators, both blue if positive, one blue if negative	Results available in 3 minutes
A1C	Finger prick blood (lancets provided)	Lancet and small handheld machine	Digital numeric reading	Results available in 5 minutes
SpermCheck Male Fertility Test	Sperm sample	Solution to mix with sperm sample and drops are put on a testing device	Binomial test: Positive indicating normal sperm count (two lines), negative indicating low sperm count (one line)	Results available in 10 minutes
Menopause Test (FSH)	Urine	Individually wrapped test strips	Binomial test: 1 line (negative) not menopause, 2 lines positive (menopause)	Results available in 5 minutes
Pregnancy Test	Urine	Individually wrapped test strips	Binomial test: 1 line (negative) not pregnant, 2 lines (positive) pregnant	Results available in 3 minutes
Pregnancy Test (digital)	Urine	Individually wrapped test strips	Binomial test: pregnant, not pregnant	Results available in 3 minutes
Vaginal Secretion Test	Vaginal secretions	pH test strips	Binomial test: Blue/green color is abnormal vaginal pH; yellow color is normal vaginal pH	Results available in 5 minutes

Source: Original

Table 2: At-Home Collection Kits available at Common Retailers

Test	Specimen	Test Format	Results Indicator	Availability of Results
Identigene DNA Paternity Tests	Cotton swab for in-mouth saliva collection	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available 2 days after their receipt at the laboratory
Progene Testosterone Test	Spit sample inserted into collection tube.	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5-7 days
everlywell® Home Diabetes Test	Blood sample drawn from finger stick lancet (device provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5-7 days
everlywell® Food Sensitivity Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Vitamin D and inflammation test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Sleep and Stress Test	Urine (strips) and blood (finger prick)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days

everlywell® Indoor and Outdoor Allergy Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Metabolism Test	Finger prick blood (lancet provided) and tube of saliva	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Folic Acid Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Testosterone Test	Salvia (tube provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
everlywell® Thyroid Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 3 days
LetsGetChecked® PSA	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Hepatitis B & C	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days

LetsGetChecked® Herpes	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Chlamydia and Gonorrhea STD Test	Urine sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Complete 5 or 10 panel STD	Finger prick blood (lancet provided) and urine sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Cortisol	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days
LetsGetChecked® Thyroid	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Colon Cancer	Stool sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Cholesterol	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days

LetsGetChecked® CRP Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days
LetsGetChecked® Ovarian Reserve	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days
LetsGetChecked® Vitamin B12 Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Female Hormone Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days
LetsGetChecked® Vitamin D Test	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Lyme Disease	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
LetsGetChecked® Progesterone	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days

American Diabetes Association Cholesterol Panel	Finger prick blood (lancet provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 5 days
myLab Chlamydia and Gonorrhea for Men and Women	Urine sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
myLab 8 Panel STD Test for Men	Urine and blood sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
myLab 8 Panel STD Test for Women	Vaginal swab and blood sample	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 2-5 days
23 and Me® Ancestor and Health Genetics	Saliva (tube provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 6-8 weeks
Ancestry Health Genetics	Saliva (tube provided)	Specimen must be mailed to a lab for processing.	Processing lab provides detailed information to the consumer.	Results available in 6-8 weeks

Source: Original.

Diffusion of At-Home Medical Tests

COVID-19 has created an opportunity for firms looking to enter the at-home testing market. Generally, diffusion is a natural social phenomenon that occurs with three fairly distinct processes: presentation of a new idea to the market, acceptance by the market, and integration of the accepted idea into the existing market. Specifically, diffusion is the process through which an innovation is communicated through certain channels over time among the members of a social system (Rogers, 2003).

Diffusion of Innovation (DOI) Theory, developed by Rogers in 1962, is one of the most well know and established theories in social science. Rogers fifth and final edition of his ground-breaking research was published in 2003. Rogers (Rogers, 2003) described five categories of adopters in two main groups: earlier adopters and later adopters. Earlier adopters consist of innovators, early adopters, and early majority, while late majority and laggards comprise later adopters. Rogers identifies the differences between these two groups in terms of socioeconomic status, personality variables, and communication behaviors. Previously, research done on early adopters in the direct-to-consumer testing space found consumers were looking to learn more about health-related issues and satisfy their curiosity (Gollost et al., 2012)

COVID-19 has changed this, as not only early adopters, but also early and late majority adopters are now seeing the benefits of at-home testing. The additional attention on at-home testing allows firms to bring innovations to the market with less resistance to diffusion, based on how COVID-19 has affected the different aspects of the Diffusion Theory.

Elements of Diffusion

Components of diffusion include adopters, innovation, communication channels, time, and social systems. There can be no diffusion without adopters or members of a consuming population. In addition, there are four main interacting elements of diffusion (Rogers, 2003): 1) an innovation, 2) communicated through certain channels, 3) over time and 4) among members of a social system. Innovation is an idea, practice or object that is perceived as new by an individual or group. Communication is the process by which participants create and share information to one another in order to reach a mutual understanding. Time involved in the innovation-decision process includes the time taken to adopt an innovation by the adopter and the adoption rate across the social system. Social systems are a set of interrelated social units, such as individuals or groups that are engaged in problem solving to achieve a common goal. Particularly, it determines the boundary for a diffusion process; it can be affected by norms, and the degree to which individuals can influence one another.

The main component of diffusion has been affected by the COVID-19 pandemic. The presence of adopters, the minimal unit of analysis, for instance, has been shifted from the individual to a provider's patient populations, and even entire health systems. For COVID-19 testing it may not be about what test the consumer wants, but what test is offered near them. If no test is offered nearby, using an at-home test may be the best option for the consumer, even if it is not the type of tests the consumer would choose.

The element of innovation has been affected by the COVID-19 pandemic as most firms in or entering the at-home testing market have recently focused their developmental resources on developing a COVID-19 test. Previous at-home tests have almost always relied on a pre-existing laboratory test. The innovation in these tests is the ability to administer the tests through a finger

prick instead of a lab draw, not necessarily the tests itself. This leaves firms now looking to enter the market opportunity to bring forth innovation in terms of test type, in addition to the delivery innovations.

During the pandemic communication channels also increased exponentially, resulting in information shared rapidly between organizations. The White House requested health systems share the daily updates from their in-house labs with federal agencies (Miliard, 2020). The unprecedented information sharing expedited many of the testing capabilities. Additionally, the public-private partnership between laboratory companies and the federal government helped LabCorp achieve the first at-home collection kit (Etherington, 2020).

The rapid move to approve at-home COVID-19 tests is a shift from traditional diffusion theory in healthcare, where innovations are slow to diffuse (Berwick, 2003). Before COVID-19 this was the case with at-home medical tests. For instance, the first HIV test was available in 1985, however, it wasn't until 1996 the first at-home collection kit was available and 2012 the first at-home testing kit was an option (HIV.gov, 2020). In contrast, the first known cases of COVID-19 in the United States started in late January or early February. The first available at-home test for COVID-19 was by late April 2020 followed by approval for two more at-home tests by mid-May 2020, emphasizing the rapid rate of adoption for COVID-19 at-home tests. While differences in the conditions account for some of the differences in length of time, the rapid diffusion process can largely be attributed to the pandemic and the need for rapid, widely available testing.

Finally, social systems play a large role in diffusion. COVID-19 coverage consumed mass media. A national task force was created, press conferences were held telling the American people of new updates, and government mandates went out encouraging people to stay home. Sanson-Fisher (2004) writes that "the [healthcare] system is often bureaucratic, with social norms hinder rapid change". However, the COVID-19 pandemic removed many of the traditional barriers associated with the bureaucracy of healthcare systems and FDA approval. In addition to barrier removal to make at-home tests more accessible, key opinion leaders such as the FDA, media outlets, and providers all treated FDA approved tests as an acceptable testing option.

Each of the diffusion of innovation elements have been influenced by COVID-19, leading towards an increase in COVID-19 at-home tests. The increase of COVID-19 tests have exposed more people to at-home testing options and have made at-home medical tests a legitimate alternative option in testing, ultimately making at-home testing more commonplace.

Stages of the Decision Innovation Process

The stages of decision making in the diffusion process have also been accelerated. In the diffusion of innovations theory (Rogers, 2003), the innovation-decision process involves five stages: (1) knowledge, (2) persuasion, (3) decision, (4) implementation, and (5) confirmation. The sequence typically flows in a time-ordered manner. Knowledge, the first stage involves awareness and learning about the innovation. Persuasion, the second stage, refers to the forming of favorable attitudes and beliefs regarding the innovation, in reaction to knowledge gained in the previous stage. Decision, the third stage, indicates the development of behavioral intentions to implement the innovation. Implementation, the fourth stage, demonstrates overt behavior. Confirmation, the fifth and final stage includes the seeking of reinforcement of the decision that has been made and recognition of the benefits of the innovation.

Many people are already aware of at-home testing and may have even used some forms of at-home testing. Before COVID-19, at-home tests were more commonly utilized as a first-line

option, with follow-up with a provider as the next step. For instance, after a positive pregnancy test, most women follow-up with their provider. Urinary Tract Infection (UTI) tests are similar, a patient needs confirmation from a provider. For consumers undergoing genetic testing, one of the motivations for early adopters was to learn more about their health. Most of these early adopters shared their information with their healthcare provider (Gollust et al., 2012). The COVID-19 pandemic has shifted the way people use at-home tests. The change has been away from testing and consulting with a known, personal healthcare provider towards testing and receiving treatment, if needed, from a provider associated with a testing company.

While knowledge about at-home testing had increased, many consumers were looking for an alternative way to receive COVID-19 testing, having been told to stay home to avoid overwhelming the healthcare system. The consumers searching for an alternative fall into the persuasion stage of the diffusion innovation process. In the persuasion stage, consumers actively seek out information on the innovation. For consumers interested in the at-home COVID-19 test there is ample opportunity to find information, from periodical articles, press conferences, and government announcements, such as the FDA approval for several tests. The plethora of available information accelerates the process of persuasion by giving the consumer ample information.

Consumer decision making was also affected by the pandemic. Previously, consumers might complete an at-home test, even if a comparable in-laboratory test was available, for various reasons, such as ease of completion or not having a primary care provider. However, during the COVID-19 pandemic, this level of decision making was removed. For some consumers, the only way to access a COVID-19 test was through at-home testing options.

The stated effects of the COVID-19 pandemic on the knowledge, persuasion, and decision-making stages lead to more consumers entering both the implementation and confirmation/ continuation stages. While empirical studies often are still catching up to the COVID-19 pandemic and there is little to no peer-reviewed evidence on the effects of the pandemic on consumer behavior, to date, companies expect consumer utilization of at-home testing will increase due to acceptance of at-home tests during COVID-19 pandemic (Ducharme, 2019). The benefits of at-home tests include completing the test at home when the time is convenient for the consumer, and the tests being minimally invasive. These advantages may ultimately lead to more consumers utilizing at-home tests.

Adopter Categories

Adopter categories include innovators, early adopters, early majority, late majority, and laggards (Rogers, 2003). Within the five established adopter categories, the majority of the general population tends to fall in the middle categories. It is important to understand the characteristics of the target population. When communicating the introduction of an innovation, there are a variety of strategies used to appeal to the different adopter categories.

Innovators are individuals who want to be the first to try or buy the innovation. They are venturesome and risk takers Very little, if anything, needs to be done to appeal to this population. They tend to simply buy for the sake of newness.

Early Adopters are considered the opinion leaders. They enjoy leadership roles, while embracing change opportunities. They willingly accept the need to change and are very comfortable adopting new ideas. Strategies to appeal to this segment include how-to manuals and information sheets on implementation. They are confident and do not need information to convince them to change.

Early Majority adopters are individuals who adopt new ideas before the average person. They typically need to see evidence that the innovation works before they are willing to adopt it. Strategies to appeal to this population include success stories and evidence of the innovation's effectiveness.

Late Majority are individuals who are skeptical of change and will only adopt an innovation after it has been tried by the majority. Strategies to appeal to this group include information on how many other people have tried the innovation and have adopted it successfully.

Laggards are traditional and very conservative. They tend to be skeptical of change and are the hardest group to persuade. Strategies to appeal to this population include statistics, fear appeals, and pressure from people in the other adopter groups.

For at-home testing, the biggest effect seen from COVID-19 has been in the early and late majority groups. Early majority consumers are those who want to try innovations that meet their needs over those that are interesting (Berwick, 2003). Late majority consumers are those that want to use innovation when it is standard or meets guidelines (Berwick, 2003). Prior to COVID-19, innovators and early adopters were already enjoying the benefits of at-home testing. The majority underwent at-home testing to learn more about their health. However, with the pandemic straining the healthcare system both early and late majority adopters were pushed into at-home medical testing. Consumers who did not want to leave their house but wanted to be tested found an opportunity in at-home tests. Consumers who were not sure about the validity of at-home tests suddenly found the federal government approving at-home tests as an acceptable alternative to in-person tests. These consumers may not have become adopters of at-home tests as quickly, if the pandemic did not necessitate the need for alternative testing avenues. With both early and late majority consumers finding themselves adopting at-home COVID-19 tests the time frame to achieve diffusion has shortened. The rapid diffusion of COVID-19 testing that has primed the population to begin using other at-home medical tests in a greater capacity. Firms looking to enter the at-home testing market have an opportunity to bring innovation to the market with less effort required to reach consumers who previously had not adopted at-home tests.

Critical Success Factors for At-Home Testing

Firms looking to enter the at-home testing market have a unique opportunity because at-home testing, by nature, is suited to many of the critical success factors. According to Rogers (2003), there are five main factors that influence adoption of an innovation, and each of these factors is at play to a different extent in the five adopter categories. Relative advantage is the degree to which an innovation supersedes the idea before it. Compatibility is the degree to which an innovation is perceived as being consistent with existing values, past experiences, and consumer needs. Observability is the degree to which the results of an innovation are visible to others. Complexity is the degree to which an innovation is perceived as difficult to understand and use. Trialability is the degree to which an innovation may be experimented with on a limited basis. These elements demonstrate that evaluation of an innovation will yield different results depending on the individual doing the evaluation.

Relative Advantage

Relative advantage is the first critical factor of success. Some of the relative advantages of at-home testing are obvious. For instance, consumers can complete the test in their home. This eliminates the need for consumers to drive to a lab or even take the test during business hours. Additionally, test kits give the result within minutes of taking the test. While collection kits do not give the results right away, when the results do come in patients can review their results on a website or app. Many of the result portals also offer additional information about the lab results to help the consumer interpret their results. Other advantages may not be as obvious. For instance, with OraQuick's HIV test there is a 24-hour hotline for consumers to call (Ibitoye et al., 2014). Ancestry Health has genetic counselors call patients for whom a mutation has been identified. Everlywell has physicians reach out to patients with a positive STD test to offer treatment and answer questions (Boyd, 2020).

Compatibility

"Compatibility is a measure of the degree to which an innovation is perceived as being compatible with existing values, past experiences, and the needs of potential adopters" (Betts and Korenda, 2018). COVID-19 has pushed at-home tests to be more compatible with both consumers and providers. The perception of consumers who in the past may not have been comfortable with at-home tests or worried about the legitimacy of at-home tests has been shifted. With COVID-19 consumers have been encouraged to stay in, making at-home testing an option, especially for those self-quarantining, living in testing shortage areas, or needing non-COVID related treatment Ducharme (2019). Visible FDA approvals for several at-home COVID-19 tests have also shifted norms, again placing at-home tests on an equal level with traditional lab tests. The COVID-19 pandemic has shifted cultural patterns, making at-home testing more compatible with the new normal that is the result of the pandemic.

Observability

Observability is how visible the innovation is to others. Prior to COVID-19 at-home testing was gaining visibility and becoming more popular among consumers. Deloitte's research found that over fifty percent of consumers were comfortable using an at-home test to diagnose before going to see a physician. Over forty percent were comfortable using testing for genetics, using at-home blood tests, and mailing off stool samples (Betts and Korenda, 2018). Additionally, companies entering the market such as Everlywell and 23andMe have made a concerted effort to expand retail partnerships and marketing. These efforts have enhanced the visibility of the companies' products, but also at-home tests in general, specifically at-home collection-kits. COVID-19 has further expanded this visibility through FDA approvals for at-home COVID-19 tests, addressing the common concern about at-home testing's scientific validity. Going forward, other at-home test makers may benefit from the initial marketing effort of current companies, along with the gained exposure from COVID-19 to patients who may not have been familiar with or used at-home tests.

Complexity

At-home tests are uniquely suited to address the issue of complexity or how difficult it is to use and understand an innovation. At-home tests are made to be simple for the consumer to interpret. The process of obtaining a test is streamlined, reducing complexity. Most at-home kits are either available at retailers or can be shipped to the consumer and then returned to the company. At-home testing kits, such as pregnancy tests or fertility tests, tend to have binary results, one line or two; a smiley face or frowny face. This makes the tests easily understandable for the consumer.

At-home tests also tend to be less complex to complete than a traditional laboratory-based test. For instance, at-home collection kits utilize salvia samples or blood samples from a finger prick. Most laboratory tests use a venous blood draw, which is less consumer-friendly than other testing mechanisms, such as a finger prick which is preferred by patients (McMullen et al., 2015).

At-home tests may offer information to help patients understand their results, such as consultations with providers or informational videos. For DTC at-home tests like 23andMe tests, part of the PMA process is ensuring the test results are understandable by the general consumer. "The FDA also looks at whether the test offers accurate descriptive information that can be easily understood by a consumer without the involvement of a healthcare provider. This is done by reviewing the language used to instruct users on collecting the sample and interpreting the test result report" (FDA.gov, 2019). This is in addition to test accuracy, validity, and claims, demonstrating how imperative it is that at-home testing companies make tests that are consumer-friendly. Each step of completing an at-home test is based on eliminating complexity, from obtaining the tests to completing the test and understanding the results.

Trialability

There are several aspects of at-home tests that make them conducive to trialability. The first is the price point, at-home tests fall anywhere from under $10 for UTI tests to $200 for a genetic test. These tests are at a similar or lower price point compared to traditional laboratory-based tests. Additionally, the tests are easily accessible, either at a retail store or sent straight to the consumer's home, again making the tests easy to try. Finally, the tests are for one-time use, so the consumer is not committed if they do not like the test. At-home testing company Everlywell has capitalized on the concept of trialability. Everlywell has partnered with Humana to offer FIT colorectal screening tests or HbA1c tests through the Everlywell at-home tests for Humana enrollees (Cohen, 2019). This is a benefit for both parties as Humana has their enrollees' complete standard screenings and these same consumers can try an Everlywell test at no additional cost to themselves.

Conclusion

COVID-19 has shifted many aspects of the healthcare landscape from telehealth to drug supply chains to medical testing options. One area that may see a large shift in consumer preference is medical testing, specifically, the at-home medical testing market. COVID-19 has greatly enhanced the visibility as consumers look for ways to avoid waiting in doctors' offices, while still receiving treatment. Additionally, FDA approval of several new at-home tests have brought credibility to at-home medical testing makers.

Since the inception of the 1976 Medical Device Amendment the FDA has regulated medical devices in the United States. Firms looking to enter the at-home medical testing market have had to balance bringing new innovations forward, while following stringent FDA requirements. Early at-home tests where simple pregnancy tests or glucose tests using urine. However, in the late 20th century and early 19th century at-home testing has grown to include infectious diseases, like HIV, general wellness tests, such as food sensitivity tests, and even genetic testing.

The large amount of growth in this sector has exposed many consumers to the plethora of options available for at-home medical testing. Firms looking to take advantage of the shift towards at-home testing, that has been accelerated by COVID-19, should understand the nuances of the at-home medical market. Going forward, firms looking to enter the at-home testing market must decide if they would like to create new tests or utilize pre-existing tests. The firm will then need to determine the best way to get the test to the consumer, by FDA approval, provider order, or otherwise. Finally, the firm will need to be able to recognize the pitfalls that are encountered in bringing a new medical device to the market, such as associated cost and regulatory approval. A firm that appreciates these nuances, detailed in this paper, will be able to capitalize on the new expanse of consumers that have had exposure to at-home testing, in part due to the COVID-19 pandemic.

References

Abbruzzese J, & Miller, S. (2020). Coronavirus Testing at Home: What you Need to Know. NBC News, April 19, 2020. Retrieved from https://www.nbcnews.com/health/health-news/what-you-need-know-about-coronavirus-testing-kits-n1181141

Berwick, D. (2003). Disseminating Innovations in Health Care. *JAMA*, 289(15), 1969-1975. Retrieved from: https://doi.org/10.1001/jama.289.15.1969

Betts D, & Korenda L. (2018). Inside the Patient Journey: Three Key Touch Points for Consumer Engagement Strategies. Deloitte.com, September 25, 2018. Retrieved from https://www2.deloitte.com/us/en/insights/industry/health-care/patient-engagement-health-care-consumer-survey.html?id=us:2el:3dc:4di4632:5awa:6di:&pkid=1005423

Boyd, C. (2020). STDs in Women: A Comprehensive Guide. Everlywell.com. Retrieved March 27, 2020, from https://www.everlywell.com/blog/std-test-female/stds-in-women/

Cohen, A. (2019). At-Home Health Tests Get the Direct-to-Consumer Treatment. Bloomberg.com, July 23, 2019. Retrieved from https://www.bloomberg.com/news/articles/2019-07-23/at-home-health-tests-get-the-direct-to-consumer-treatment

Direct-to-Consumer Tests (2019). FDA.gov. Retrieved from https://www.fda.gov/medical-devices/vitro-diagnostics/direct-consumer-tests

Ducharme, J. (2019). Your Doctor's Appointments Have Been Canceled. Are at-Home Tests a Good Solution?. Time.com, March 31, 2019. Retrieved from: https://time.com/5809606/covid-19-at-home-testing/

Etherington, D. (2020). LabCorp's at-Home COVID-19 Test Kit is the First to be Authorized by the FDA. Techcrunch.com, April 21, 2020. Retrieved from https://techcrunch.com/2020/04/21/labcorps-at-home-covid-19-test-kit-is-the-first-to-be-authorized-by-the-fda/

Gollust, S., Gordon, E., Zayac, C., Griffin, G., Christman, M., Pyeritz, R., Wawak, L., & Bernhardt, B. (2012). Motivations and Perceptions of Early Adopters of Personalized Genomics: Perspectives from Research Participants. *Public Health Genomics*, 15,22-30. https://doi.org/10.1159/000327296

Grenache, D., Joyner, M., Holmes, D., & Seccombe, R. (2017). Direct-to-Consumer Testing. *Clinical Chemistry*, 63(3), 635–641.

HIV.gov (2020). A Timeline of HIV and AIDS. *HIV.gov.* Retrieved April 21, 2020, from https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline

Howard, J. (2020). New COVID-19 Test Allows Patients to Collect Samples at Home, Send to Lab for Results. CNN.com, April 21, 2020. Retrieved from: https://www.cnn.com/2020/04/21/health/home-covid-19-test-approved/

Ibitoye, M., Frasca, T., Giguere, R., & Carballo-Diéguez, A. (2014). Home Testing Past, Present and Future: Lessons Learned and Implications for HIV Home Tests. *AIDS and Behavior*, 18, 933-949. Retrieved from https://doi.org/10.1007/s10461-013-0668-9

McMullen, H., Griffiths, C., Leber, W., & Greenhalgh, T. (2015). Explaining High and Low Performers in Complex Intervention Trials: A New Model Based on Diffusion of Innovations Theory. *Trials*, 16, 242-257. Retrieved from https://doi.org/10.1186/s13063-015-0755-5

Miliard, M., (2020). White House Asks All Hospitals to Report Data on COVID-19 Testing. *Healthcare IT News*, March 30, 2020. Retrieved from: https://www.healthcareitnews.com/news/white-house-asks-all-hospitals-report-data-covid-19-testing

Rutgers News (2020). New Rutgers Saliva Test for Coronavirus gets FDA Approval. *Rutgers News*, April 13, 2020. Retrieved from https://support.rutgers.edu/news-stories/new-rutgers-saliva-test-for-coronavirus-gets-fda-approval/

Rados, C. (2006). Medical Device and Radiological Health Regulations Come of Age. *FDA Consumer Magazine*, January–February, 58–65. Retrieved from https://www.fda.gov/files/about%20fda/published/Medical-Device-and-Radiological-Health-Regulations-Come-of-Age.pdf

Rogers, E. (2003). *Diffusion of Innovations*. Free Press, New York.

Sanson-Fisher, R. (2004). Diffusion of Innovation Theory for Clinical Change. *Medical Journal of Australia*, 180, S55-S56.

Terrie, Y. (2009). At-Home Diagnostic Kits: A Growing Trend. *Pharmacy Times*, March 1, 2009. Retrieved from https://www.pharmacytimes.com/view/2009-03-10050

Van Norman, G. (2016). Drugs, Devices, and the FDA: Part 2: An Overview of Approval Processes: FDA Approval of Medical Devices. *JACC: Basic to Translational Science*, 1(4), 277-287. Retrieved from https://doi.org/10.1016/j.jacbts.2016.03.009

United States v. Bacto-Unidisk (1969). 394 US 784.

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