Expanding the AI-assisted Diagnosis Market in Hospital Pathology Labs: Challenges and Opportunities

An Interactive Qualifying Project Proposal

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By:

Gabrielle Healey

Matthew Hlushko

Benjamin Nguyen

Maria Wojciechowski

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Report submitted to:

Phoebe Liang

aetherAI

Professors Grant Burrier and Melissa Butler

Abstract

Pathology studies disease through the examination of organs, tissues, and bodily fluids. Current pathology practice in the US predominantly involves the use of glass slides and microscopes. Some avoid digitalization, while others use digital pathology in varying capacities. aetherAI, a Taiwanese medical imaging AI company, tasked the team with identifying the barriers and opportunities for digital pathology in the US. The team interviewed to characterize pathology and understand pathologists' sentiment towards digital pathology. Interviewees reported the largest barriers in the US as costs, technology issues, security concerns, and regulations. Opportunities presented in the VA system and grants from organizations like the National Institute of Health developed recommendations for US digital pathology implementation.

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0.0 Executive Summary

0.1 Motivation

Pathology is a practice that has not seen significant changes in decades. With widespread modern computers and the continuous improvement of artificial intelligence, a digital system has the potential to greatly assist pathologists and improve healthcare. For years, pathologists have diagnosed patients by examining tissue in glass slides under a microscope, but hospitals are looking to modernize. Digital pathology refers to the digitalization of glass patient sample slides for analysis, education, consultation, storage, and annotation (Bury & Griffin 2019). Digitalization of pathology labs through digital pathology technology is critical in the transition from manual diagnosis with a microscope to AI diagnosis, as the AI program needs a digital image of the glass slide in order to perform pathological analysis. To date, digital pathology systems outfitted with AI have successfully screened for cancer, performed cell counts for patient samples, organized and digitized pathology lab records for faster results, and are working on other relevant and advanced applications.

aetherAI is a Taiwanese medical imaging AI company interested in digitalizing pathology labs through their digital pathology and AI technology. After finding success in Taiwan, they tasked the team with identifying the barriers and opportunities for implementing digital pathology in the US. aetherAI's goal is to expand into the US and help pathology labs integrate digital pathology and, eventually, AI into their workflow. However, despite the benefits of digital pathology and AI, there are significant causes for resistance from the pathology field in the US, such as costs, lack of digital training and education, and workflow disruption. Using archival research, interviews, and surveys, our IQP team investigated the state of pathology labs in the US and ways in which adoption of digital pathology might find the path of least resistance. Through our archival research, surveys, and interviews, we identified pathologists' opinions towards digital pathology, evaluated the progress in digital advancement in the US pathology field, and produced a report that lists recommendations for digital pathology to succeed in the United States.

0.2 Approach

Our team interviewed pathologists, lab managers, professors, and AI developers to build a full perspective on the use of digital pathology systems and AI in hospitals. Through outreach and networking with personal and industry connections, our team contacted twenty-seven individuals. Of those we contacted, we interviewed fourteen individuals from: the University of Rochester Strong Memorial Hospital, Worcester Polytechnic Institute, West Virginia University, University of Alabama, Rochester Institute of Technology, and the Massachusetts Veterans Affairs (VA) health systems. Additionally, we interviewed personnel that had already implemented aetherAI in Taiwan. The team conducted approximately half-hour long interviews from mid-March to mid-April via Zoom

during times that were convenient for the interviewee and our team.

Our team asked hospital pathologists, lab directors, and lab managers in research hospitals to describe their workflows, the room for growth in their routines, common barriers to implementing digital pathology, and how to best approach barriers in the future. Interviews with professors focused on the logistics and economics of implementing digital pathology. We sought an in-depth understanding of the logistical considerations of implementing a digital pathology system, such as insurance, liability, and administration, which may be out of the scope of a pathologist's work and expertise. AI developers were able to give us further perspective on the technical considerations of implementing AI and digital pathology, such as data storage.

Archival research was an ongoing process throughout our project to compare our findings with multiple sources and understand the complexities of pathology practice based on interviewee responses. Our team emphasized research surrounding the opinions of pathologists, hospital executives, and physicians about their experiences with digital pathology software, but we also researched the structure of healthcare in the United States and Taiwan. The literature gave us insight into the process, reasoning, and advantages behind adopting digital pathology. Using JSTOR, ScienceDirect, and PubMed, we accessed reviews of pathology as a field, examples of digital pathology and AI, peer-reviewed papers on the digitalization of pathology, and articles on pathology departments updating their technologies to provide a more comprehensive understanding of pathology labs. In our search on ScienceDirect, we used terms such as "Digital Pathology," "Whole Slide Imaging," "AI in Pathology," "Barriers Digital Pathology," and "AI Resistance in Medicine." PubMed was more helpful for medical research in digital pathology. JSTOR was useful for more social science research as we found more research pertaining to the healthcare systems.

Our team also developed and distributed surveys to allow our team to gather a wide range of responses on digital pathology from different sources. The targeted population for surveys included pathologists, lab managers, and hospital executives at research hospitals who were unable to conduct an interview or who were not as directly connected to us. The survey included a mix of twelve opened-ended and multiple-choice questions regarding implementation barriers to new innovative technology as well as general questions about the state of hospital labs. Although the survey was open for six weeks, from March 16th to April 20th, we only received seven responses and all but two were incomplete so we were unable to use the data for analysis.

0.3 Results

Our team found that challenges in adopting and implementing digital pathology often stemmed from the cost of the system. Out of the eleven pathologists interviewed, six discussed the steep costs of digital pathology, referencing the several interworking, expensive parts such as the

scanning equipment, software, and hardware required to run a fully digital pathology workflow. An example of one integral part is the scanner, which is a considerable and necessary investment, costing between $100,000 to $400,000 for a high throughput whole slide scanner (Lujan 2021). One pathologist commented, "*It's very costly…we've laid the groundwork, but it is exceedingly expensive to get into digital pathology, and I suspect that's why a lot of groups are hesitant"* (Dr. Park, personal communication, 4/1/2022). However, in our interview with a pathologist who worked in Veterans Affairs hospitals, they noted that there are less financial restraints for government funded hospitals (Dr. Patterson, personal communication, 3/25/2022).

Despite the cost, the technology that is currently in use in hospital pathology labs, including the computers, monitors, scanners, software, and lab equipment, is often lacking. More than 70% of pathologists' interviewed reported an issue with slow scanners, outdated computers unable to run advanced software, not enough space on hard drives, or a combination of all three. Lower throughput scanners were particularly discouraging to pathologists, as the low number of slides being scanned at once makes for a slow, tedious process that halts lab productivity. As one pathologist stated, "*That means that at the beginning of the day, before any pathologist has a chance to look at them, you're going to be scanning, digitizing all these slides. It's gotta go pretty fast, because pathologists wanna get started"* (Dr. Reynolds, personal communication, 3/16/2022).

Once slides have been scanned, pathologists require the digital images to have excellent resolution, near-instant loading times, an easy viewer, simple interface, and the ability to see the depth of the slide to compare to microscope manual analysis. These attributes are often missing in digital pathology programs, causing an unease and unfamiliarity with them. The systems are not intuitive or easy to use, making pathologists take longer to analyze slides and feel more uncomfortable making diagnoses.

Level of comfort with the new system also affects the use of digital pathology programs. Jahn (2020) cites a specific study of digital pathology implementation that reported 48% of pathologists being uncomfortable making a diagnosis without the availability of glass slides to use just in case. The lack of training in digital pathology can be traced back to pathological medical education. In Elmore (2020)'s study of pathology trainees and digital pathology, they found the majority of trainees receiving less than 10 hours of total exposure to digital pathology in medical school with some receiving none. Interestingly, Elmore (2020) found that before 2017, only 54% of trainees had received WSI training compared to 75% of trainees after 2017.

On top of the resistance due to costs, insufficient technology, and lack of comfort, path dependence was a strong barrier mentioned throughout our research. Most pathologists have extensive training with physical slides and little with digital methods. They are dependent on the older methods and confident in their abilities with

physical slides to diagnose even the most complex cases, thus they are uncomfortable with the switch to digital. The transition is therefore seen as unnecessary and risky; their current methods work well and provide accurate diagnosis while digital pathology is unfamiliar and creates new, unfamiliar problems, such as software glitches and improper scans. *[Digital Pathology is] a new paradigm, that's a new way of thinking that these people have to adapt to if they want to use this new technology* (Dr. Cera, personal communication, 3/29/2022).

The transition to digital pathology also requires a secure location to store digital slides with sensitive patient information. These digital slides can contain personal data that can create huge legal problems in the event of a security breach, raising a valid concern from pathologists and patients alike when considering digitalization. Stakeholders like the VA that especially value privacy and cybersecurity would be the most stringent about collaborating company security when establishing a digital pathology program.

Finally, approval from the United States Food and Drug Administration (FDA) is necessary to establish a successful clinical technology, as described by interviewees and literature. Companies that make medical devices and software that will directly affect the health of people need FDA approval before they can sell and advertise their products. In our interview with Professor Finch, he stated, *People are not gonna support something like [digital pathology] unless there is US based healthcare organizations that have validated it, and that there's clinical data that comes out of the US, they just won't* (Professor Finch, personal communication, 4/6/2022).

FDA regulations are not the only hurdle to overcome for new medical technology approval. Every year, the College of American Pathologists (CAP) releases a new set of guidelines for pathology. The majority of hospitals and pathologists will not use a new device or software if it does not follow the CAP guidelines. Another set of regulations that companies must acknowledge

0.4 Conclusions

One of the largest sources of resistance to digital pathology is pathologists' unfamiliarity with the new digital workflow. To circumvent the unfamiliarity issue, aetherAI could focus more on services designed for research, telepathology, and education. Several of our interviewees are already using digital slides for consultations, hence, there are already pathologists familiar with digital pathology systems. Once a lab has implemented research, telepathology, and education digital pathology, pathologists have the ability to familiarize themselves with the digital slides in an environment with less severe consequences, which would make it easier for labs to transition to fully digitalized clinical diagnosis in the future.

Due to the large size and lack of cohesiveness in the US healthcare system, it could be prudent to focus on a particular city, state or region within the United States. For example, although the metropolitan Boston, Massachusetts and Philadelphia, Pennsylvania areas are well-funded and conducting a significant number of research

projects (as seen in the NIH Funding Profile) they work independently of each other. Within these small regions, however, institutions generally have consistent needs and capabilities, making the implementation of digital pathology simpler. Therefore, focusing on gaining a foothold in one area at a time could ease the process of expansion. Experience in expanding in more local areas can then provide insight into growing into other areas, and gaining a reputation in a renowned area like Boston would greatly increase the credibility of the product and company

FDA approval carries significant weight in implementation and warrants attention in the implementation process. Without this, it is highly unlikely aetherAI's technology will be implemented by any hospital, no matter how credible an external approval or clinical trial is. Following this, aetherAI should reach out to large hospitals and institutions that are well funded. They can find these hospitals and institutions by analyzing the NIH website and filtering for digital pathology grants. These institutions will have the most funding and will be the ones that will be more open to adopting cutting edge technology and more willing to take the risk with new technologies.

Regarding overcoming pathologists' resistance and issues with digital pathology, there are two options. The first option, the more passive approach, is to target methods of digital pathology already accepted by pathologists in the United States, such as research, telepathology, and education. The second option, the more active approach, is to develop a cohesive plan to change pathologists' and administrators' sentiments regarding digital pathology by including direct and creative ways to incentivize change. Among other strategies, aetherAI would need to provide clear, quantified returns on investment to adopting digital pathology and AI, undergo US testing and validation (which might vary, depending on the institution), adapt to differing cybersecurity and insurance systems, provide training for customers, and promote user-friendly interfaces with high resolution and multi-plane images.

The research we have gathered over the course of our project was not without limitations. We were unable to report general trends within the pathology field beyond what we had learned from individual's experiences due to our low survey response. The individuals we did interview, however, were experts in their fields, thus their perspectives can be assumed to be representative of opinions in the northeastern US. Although we gained valuable insight from our interviewees, more administrators and executives would have been able to give more perspective on the inner workings of implementation, including licensure, budgeting, and negotiation, that pathologists may not be able to provide. Lastly, our study was focused largely on the east coast of the US, limiting the experiences we reported to one geographic area. A wider range of locations could provide insight into any geographic differences in the use of digital pathology research across the US.

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Authorship

Section	Author	Editor
Abstract	Ben	Matt, Gabrielle
Executive Summary	Matt/Gabrielle	Gabrielle
Introduction	Maria	All
Digital Pathology	Maria	All
Potential Stakeholders for Digital Pathology Programs	Gabrielle	All
Healthcare in Taiwan	Matt	All
Healthcare in the United States	Matt	All
Past Modernizations of Healthcare Technology in the United States	Ben	All
Current State of AI Technology	Maria	All
Methods	Matt	All
Online Interviews	Maria	All
Archival Research	Ben	All
Online Surveys	Matt	Matt
Data Collection	Ben	All
Data Analysis	Maria	All
Ethical Considerations	Matt	All
Findings Overview	Gabrielle	Gabrielle/Maria
Digital Pathology Implementation Challenges	Gabrielle	Gabrielle/Maria
Financial Barriers	Matt	Gabrielle
Technological Issues and Resistance	Ben	Gabrielle
Security Concerns	Matt	Matt
Regulations	Ben	All
Conclusion Overview	Matt	Matt/Maria/Gabrielle
Recommendations	Ben/Matt	Matt/Maria
Future research	Gabrielle	Gabrielle/Matt

Table of Contents

Abstract i

Acknowledgements ii

0.0 Executive Summary iii

0.1 Motivation iii

0.2 Approach iii

0.3 Results iv

0.4 Conclusions vi

Authorship ix

List of Figures xii

1.0 Introduction 1

2.0 Literature Review 3

2.1 Digital Pathology 3

2.2 Potential Stakeholders for Digital Pathology Programs 6

2.3 Comparing Healthcare in Taiwan and the United States 9

2.4 Past Modernizations of Healthcare Technology in the United States 13

2.5 Current State of AI Technology 15

3.0 Methods 17

3.1 Online Interviews with Pathologists, Hospital Executives, and Other Experts 17

3.2 Archival Research into Pathology Labs in Online Information Databases 19

3.3 Online Surveys Distributed to Experienced Pathologists and Hospital Administrators in Hospitals and Research Labs 20

3.4 Data Collection Method Requirements and Intentions 21

3.5 Data Analysis and Visualization 22

3.6 Ethical Considerations 23

4.0 Findings 25

4.1 Digital Pathology Implementation Challenges 26

4.2.1 Financial Barriers 27

4.2.2 Digital Pathology Technological Issues and Resistance 30

4.2.3 Security Concerns 35

4.2.4 Regulations and Guidelines 37

5.0 Recommendations and Conclusion 40

5.1 Focus on Research and Identify Well-funded Hospitals in the US 41

5.2 Focus on Telepathology and Education 42
5.3 FDA Approval and Systematic Implementation 42
5.4 Limitations and Future Research Opportunities 44
References 46
Appendix A: Interview Informed Consent 49
Appendix B: Survey questions 50
Appendix C: Interview Questions 53

List of Figures

Figure 4.1: Interviewee Professions 25
Figure 4.2: Interviewee Institutions 26
Figure 4.3: Common Barriers To Digital Pathology Implementation 27

1.0 Introduction

Artificial intelligence (AI) has the potential to revolutionize healthcare by improving workflows in hospital pathology laboratories and providing quicker, higher throughput, and more accurate diagnoses in healthcare through software and techniques like machine learning. For years, pathologists have diagnosed patients by examining tissue in glass slides under a microscope, but hospitals are looking to modernize. Digital pathology is the critical steppingstone from manual diagnosis with a microscope to AI diagnosis, as the AI program needs a digital image of the glass slide to perform pathological analysis. Through development and testing, digital pathology systems outfitted with AI have successfully screened for cancer, performed cell counts for patient samples, organized and digitized pathology lab records for faster results, and are working on other relevant and advanced applications.

aetherAI is a digital pathology and AI technology company founded in Taipei, Taiwan in 2015 seeking to improve the pathology field through image analysis and digitalization combined with AI. After experiencing successful implementation in Taiwanese and Japanese hospitals, aetherAI now sees potential in expanding its technology, specifically aetherSlide, to assist hospital pathology laboratories in the United States. aetherAI developed a program called aetherSlide that allows for a smoother workflow through quicker annotation and analysis of patient sample slides, image slide organization, and various add-in packages to identify particular aspects in images (Immunohistochemistry (IHC), cancer screening, and differential counting). From previous research and experience, aetherAI has realized that hospital pathology labs have decreased throughput and accuracy when not utilizing digital pathology. By, incorporating

digital pathology, hospitals will have the potential to be able to diagnose patients with higher throughput and accuracy.

aetherAI's goal is to expand into the US and help pathology labs integrate digital pathology and, eventually, AI into their workflow. However, despite the benefits of digital pathology and AI, there are significant causes for resistance from the pathology field in the US..The goal of this project was to identify the state of digital pathology in United States research hospitals and the barriers to integration in routine workflow. Using archival research, interviews, and surveys, our IQP team investigated the state of pathology labs in the US and ways in which adoption of digital pathology might find the least resistance. Through archival research, surveys, and interviews, we identified pathologists' opinions towards digital pathology, evaluated the progress in digital advancement in the US pathology field, and produced a report that lists recommendations for digital pathology to succeed in the United States.

2.0 Literature Review

Before conducting interviews and surveys, our team needed to develop a more comprehensive understanding of digital pathology, potential stakeholders, the differences between healthcare systems in the US and Taiwan, past cases of modernization of technology in the US, and the current state of AI programs. We researched how digital pathology works and how prevalent digital pathology is in the US to develop a strong background in the state of pathology and digitalization. aetherAI, is looking to grow in the US, we researched the intricacies of both Taiwanese healthcare and US healthcare and how the differences between them might affect the reception of Taiwanese programs in the US. We used instances of implementation of other types of digital technology in the US, like EMRs, as case studies for how modernization in hospitals takes place. Finally, we looked into current AI programs in healthcare to familiarize ourselves with programs developed through aetherAI and with programs developed elsewhere. All the information we gathered helped guide our interviews and make final conclusions on how hospitals and research institutions can integrate digital pathology, and eventually AI.

2.1 Digital Pathology

For decades pathologists have used a microscope to analyze tissue on glass slides; the manual, physical method is reliable and trusted to quickly diagnose patients due to pathologists' extensive training in the manual method. After education and training, most pathologists can look over a slide in just a couple seconds. Digital pathology refers to the digitalization of glass patient sample slides for analysis, education, consultation, storage, and annotation (Bury & Griffin 2019). The field relies on Whole Slide Imaging (WSI), a process that scans a glass slide with a slide scanner and displays it on a computer screen with the similar resolution as a

microscope. Companies like Huron and Inspirata provide scanners and software to scan and organize varying amounts and varied sizes of slides, depending on what the customer needs (Huron Digital Pathology, Inspirata, 2022). On the other hand, the SPOT Imaging program is an example of a live imaging and static imaging technique which relies on using the microscope to move around images on a digital screen (Hanna 2019, Pantanowitz 2019).

WSI differentiates from programs like SPOT by removing the need for a microscope in a lab completely with the slide scanner. As with any new technology, however, there are considerable costs to purchasing such a scanner (Jahn, 2020) so only 7% of lab directors, pathologists, medical directors, and lab managers said they scan all their glass slides and 23% scan none of their slides (Sage Growth Partners & Hanamatsu Corporation, 2021). Much of the resistance is due to general unwillingness to alter the current workflow and familiar technology (Jahn, 2020, Sage Growth Partners & Hanamatsu Corporation, 2021). Other sources of resistance can stem from limited storage space for large image files, as WSI commonly takes up large amounts of space, and loss of a personal connection between if wprkers use digital pathology remotely. Additionally, legal complexities frequently complicate virtual consultations through digital pathology (Jahn, 2020).

Despite the resistance, the benefits of digitizing sample slides through WSI include easy storage and accessibility through the cloud or hard drive archives and quicker transfer of digital slide files. Digitally sharing files allows pathologists at different labs to view the samples simultaneously to make quicker diagnoses, provide secondary opinions, and have more effective and detailed discussions about findings (Hanna, Pantanowitz 2019, Tierney 2020). The quick distribution encourages collaboration between pathology institutions through the creation of virtual slide banks (Bury & Griffin 2019). Greater collaboration between pathologists has the

potential to ease pathologists' pressures, allowing more pathologists the ability to work on samples at once, and therefore increase the quality of healthcare everywhere in the US, since pathologists will have access to more information and will receive more support from peers.

Easy distribution and viewing of digital slides benefit education as well as industry, giving students the opportunity to view the slides alongside experts. Digital pathology software allows effective slide organization to navigate sample archives, annotation to highlight sample morphologic and stain abnormalities, and integration for resources like links and questions to facilitate quality learning (Bury & Griffin 2019). In the last few years, digital resources have gained importance as the majority of education transitioned to online learning. Digital slides with intuitive programs for annotation give students the opportunity to train remotely, regardless of physical location, causing an increase in the number of trained pathologists; an ideal solution to the problem of understaffed hospitals in underdeveloped areas (Hassell, Afzal, 2021). However, virtual learning could decrease the amount of in-lab experience students have, causing them to lose certain expertise gained through on-site training. If more pathologists have the ability to diagnose patients from anywhere in the US, it could lead to competition between institutions or pathologists rather than collaboration (Jahn, 2020).

Digitized sample slides offer more durability than physical glass slides. Image files preserve slides at peak condition and therefore eliminate issues with glass slides, which can fade, degrade, and break easily (Bury & Griffin 2019). Sample slides that are stained with fluorescent dyes fade within hours or days depending on the type of dye and refrigeration, and thus would immensely benefit from digitalization to preserve the slide and allow pathologists to look back on the slides with perfect clarity.

Adopting digital pathology programs in pathology labs opens the possibility for automated and/or semi-automated image analysis techniques, including AI, that can locate patterns in the images, group pixels together to identify specific structures, measure lengths and areas of structures, and build prediction models for response to treatment and survival (Bury & Griffin 2019, Xing, Zhang 2021). The image analysis programs can increase the speed, accuracy, objectivity, and consistency of disease characterization and can increase the reproducibility of measurements used in pathological techniques (Xing, Zhang 2021). However, any AI or machine learning programs require digital slides, since the computer uses the image pixels for analysis (Xing, Zhang 2021). Digital pathology facilitates organization, preservation, and distribution of slides and the necessary first step toward using AI in pathology.

2.2 Potential Stakeholders for Digital Pathology Programs

After examining digital pathology as a technology, our team set out to understand the stakeholders in its implementation. The identified stakeholders included digital pathology companies, pathologists, and hospital administrators.

Digital pathology companies come into focus with data-sharing policies. Companies involved in digital research and AI research face a considerable amount of mistrust as commercial third parties involved in digital pathology projects (McKay 2022). Patient data is particularly sensitive, requiring more protection and caution from companies. Concern stems from mishandling and lack of transparency from companies when handling and using personal data in the past, which need companies need to address during implementation (Coulter 2021). Goirand et al., in their examination of AI ethics in healthcare, specifically note instances where businesses with personal data have failed to uphold customer privacy, such as leaking of personal data after being kept and used for Royal Free London NHS Foundation Trust and

Google DeepMind (2021). Given the past mishandling of personal data, fears about leaks of medical data are not unfounded, as companies working in healthcare can leak medical information just as they leaked other personal data, especially if the companies value the quick development of AI over the privacy of its users. Coulter (2021) lists suggestions in regards to companies developing and selling digital pathology programs, including "transparency about data uses and the inclusion of the views and opinions of the public in decisions". The suggestions come from pathologists to help ease the adoption process, as they will be the target users of digital pathology technology.

While there are several benefits for pathologists in adopting digital pathology including but not limited to; a new opportunity for easier consulting and collaboration work, flexible work conditions, availability of digital tools for measuring and counting, and accessible digital archives, there remain significant concerns (Pallua 2020). Concern arises from the use of a new system, which has the potential to create anxiety over longer digital processing times and time sensitive cases; lack of comfortability over unfamiliarity with a new system, and anger at mandated use of a different workflow (Evans, 2017; Jahn, 2020; Elmore, 2020).

Digital pathology, despite its promises of a more efficient system, faces frequent skepticism from pathologists about the speed with which they can make diagnoses on digital against glass slides. Pathologists report slower diagnosis times on digital platforms, needing more time to scroll around the image and locate areas of concern (Randall 2015, Hanna 2022). Without the promise of a better system, pathologists will not be as invested in a digital pathology program that operates slower than their current set up.

Beyond speed, general comfortability with the new system affects the use of digital pathology programs by pathologists. Jahn (2020) cites a specific study of digital pathology

implementation that reported 48% of pathologists being uncomfortable making a diagnosis without the availability of glass slides to use without being able to also rely on glass slides. The lack of training in digital pathology traces back to medical education in pathology.In Elmore's study (2020) of pathology trainees and digital pathology, they found that most trainees receive ten hours or less of total exposure to digital pathology throughout medical school, with some respondents receiving none. This study also found that only 54% of trainees received WSI training before 2017, but 75% of trainees received training in digital pathology after 2017

Pathologists' lack of familiarity connects to a lack of comfortability with digital pathology systems, a problem experienced by pathologists in Evans' paper (2017) detailing the implementation of digital pathology programs at their institution. An additional problem with digital pathology was possible anger of pathologists at starting a new workflow at the behest of hospital administrators, which can create tension between two warring perspectives, no matter how useful the technology (Evans, 2017).

Hospital leaders or administrators have a different set of worries from pathologists. Often having experience as a pathologist prior to becoming an administrator, they understand the workflow of pathologists, but now take on responsibilities such as financials, negotiations, and regulatory practices (Zarella, 2019).

Digital pathology systems contain several complicated and expensive parts. An example of one integral part is the scanner, which is a necessary investment, costing between $100,000 to $400,000 for a high throughput whole slide scanner (Lujan, 2021). The cost for the expensive and necessary parts for fully digital pathology systems is a complex and individual barrier for hospital administrators. The financial decisions hospitals make regarding digital pathology depend on a variety of factors, including, but not limited to, geographical location, leadership

organization, volume of slides assessed, the number of workstations to review digital slides, and the amount of time to retain the images in the hospital's archives (Hanna 2022, Lujan 2021). In addition, negotiations of the budget, from other departments or collaborators, fall on the shoulders of hospital administrators, a feat more difficult to achieve than it would seem, contrary to what Zarella (2019) suggests.

Hospital administration guides the direction and development of digital pathology programs and provide leadership, encouragement, and support throughout a successful implementation (Zarella 2019). Administrators must ensure effective organization in the digital pathology system among their staff, identifying critical staff to create documentation and provide training, and must be supportive throughout a likely multi-stage, lengthy transition process (Evans 2017, Zarella 2019). In the implementation process, administrators and hospital leadership are critical, but implementation requires their exhaustive and constant effort to ensure success, all while considering their hospital's regulation and implementation processes. This time consuming, intensive process is a major concern for hospital administrations, and a major barrier to digital pathology programs. Even with adoption of digital pathology technology, hospitals can end up with unused equipment and policies for digital pathology if leadership is unable to convince, train, and organize their staff to use it (Evans 2017).

2.3 Comparing Healthcare in Taiwan and the United States

While our sponsor is based in Taiwan, their desire to expand into the United States necessitates a review on the similarities and differences in healthcare systems in order to successfully implement their technology. The Taiwanese government subsidizes healthcare facilities, meaning effectively all hospitals rely on the government to pay employees, fund research and new technology, and cover expenses. Government funding is provided through the

National Health Insurance (NHI) run by the National Health Insurance Administration (NHIA), which falls under the Ministry of Health and Welfare. Through the NHI, every citizen of Taiwan is guaranteed full coverage of inpatient and outpatient care, prescription drugs, dental care, and more. All citizens, excluding low-income families, veterans, and military personnel receive an inexpensive copay of anywhere from 50-420 Taiwan Dollars or 1.65-13.86 United States Dollars for their visits (The Commonwealth Fund, n.d.). The low copay makes almost all doctor appointments and healthcare related issues affordable for devotes an increasing amount of money into the NHI each year. To keep costs manageable, the NHI limits medical school admissions to 1,300 per year, just enough to satisfy the needs of hospitals and offices throughout the country (The Commonwealth Fund, n.d.). The NHI ensures quality of care through incentives for medical professionals. The government grants bonuses to medical workers and facilities based on how many patients they process on a yearly basis. Since each citizen is free to choose whichever doctor or facility they'd like to visit, this incentivizes medical workers to provide the best care possible. (The Commonwealth Fund, n.d.)

Taiwan's centralized system makes it simple to introduce new technology to hospitals around the country. Since the government insures hospitals, they are seldom short of funding, allowing them to keep up with advancing technology. If one hospital can afford digital pathology, it is likely a feasible investment in most hospitals in the country. As for patients in the centralized system, each citizen in Taiwan carries an electronic card, which details basic medical information. PharmaCloud, which NHI manages, stores all citizen data offering a secure, comprehensive location for all medical needs, including electronic medical records and, relevant to our research, digital pathology information (The Commonwealth Fund, n.d.). The Taiwanese government takes data security quite seriously, all but ensuring the safety of sensitive medical

information. Taiwan's National Center for Cybersecurity Technology (NCCT) works to ensure the privacy and security of data in the country (*About NCCST - National Center for Cyber Security Technology*, n.d.).

On the other hand, the U.S. has a fragmented hospital system that increases risk for cyberattacks and a complex, multi-tiered insurance system that leads to high costs that can greatly hinder the development of digital pathology.

The United States' healthcare system is largely privatized, with the majority of citizens receiving health insurance through their employment.

Government run insurance only exists for a small percentage of citizens or to protect those who may struggle to obtain healthcare. US citizens with disabilities and citizens age 65 and over are eligible for Medicare, while Medicaid supports low-income citizens, and the Department of Veterans Affairs(VA) provides coverage for US military veterans. The rest of the population receives insurance either from their employers, private for-profit corporations, or are not insured at all. As of 2018, it was estimated that 92% of the United States citizens were covered by some form of insurance, while the remaining 8%, a staggering 27.5 million people, were uninsured (The Commonwealth Fund, n.d.).

The working parts of US healthcare create a fragmented system that is difficult to navigate. The fragmented system has resulted in a huge difference in access to and quality of care in the United States. Each hospital has a very different budget, with some hospitals having considerable budgets to spend on research and development, and others struggling to stay afloat. Standardization of implementation for new systems becomes difficult with such fragmentation, as each hospital can and must decide for themselves whether to move to a new system based on their preference and budget limitations.

Studies show that hospitals that conduct more research provide better care and overall result in a lower risk of fatal conditions (Massachusetts General Hospital, n.d.). Considering this, logically, a disparity in research funding would indicate a disparity in hospital quality. Massachusetts hospitals received a total of 3.3 billion USD in funding from the government for research purposes in 2021; while states such as Wyoming receiving a total of 12 million USD in 2021, and Florida receiving 795 million USD despite having a population more than 3 times as large as Massachusetts (*NIH Awards by Location and Organization - NIH Research Portfolio Online Reporting Tools (RePORT)*, 2021). The disproportional and inequal funding greatly impacts the decision-making process regarding implementation of digital pathology in hospitals across the United States, making the push for an expensive technology like digital pathology all the more difficult.

The US does, however, have one notable unified hospital system. The Veterans Health Administration is the largest integrated healthcare system in the US and falls under Veterans Affairs (VA) and is funded by the government. Therefore, there is a more unified decision-making process to determine where to allocate funds, which is then approved by Congress. The VA provides care at 1,243 health facilities throughout the US, making it a notable exception to an otherwise fractured hospital system (Office of Performance Management, n.d.). Because of its more consolidated structure, the VA unified hospital system can be an opportune entrance for digital pathology in the US.

Another major concern in United States hospitals is the risk of cyberattacks. Without a reliable way of storing sensitive data, hospital executives and workers may be reluctant to digitalize data. The 2020 HIMSS Cybersecurity Survey showed that 70% of U.S. hospitals surveyed had experienced a “significant security incident” within the past twelve months,

including phishing and ransomware attacks that resulted in data breaches (21%) and financial losses (20%) (West, n.d.). Hospitals and medical institutions cannot ignore these issues, especially when holding sensitive personal information, making some hospitals and patients reluctant to modernize to digital systems.

2.4 Past Modernizations of Healthcare Technology in the United States

Rather than speculating about the challenges of marketing a new product based on healthcare differences, it can be helpful to assess previous modernizations of healthcare in the United States. The past is arguably the most powerful tool when attempting to predict future trends. There are many parallels between the resistance to the transition from physical to digital pathology, and the transition from physical to electronic medical records (EMRs) in the United States. Because of the overwhelming utility and convenience of modern computers, both digital pathology and EMRs seem like the intuitive and necessary next step to modernizing healthcare.

While EMRs are standard in most hospitals today, the transition from physical records was long and difficult. Many different problems arose, most prominently the lack of a unified effort and a strong resistance to change. In a 2011 study, researchers found that one of the biggest barriers of entry for spreading modern technology, specifically EMRs, in healthcare is a unified effort (Kumar & Aldrich, 2010). Since a majority of hospitals in the United States are decentralized, they run independently of each other and there is no single authority dictating exact protocols. The lack of authority leads to change being slow and staggered. Slow and staggered change brings about more issues, such as poor communication of medical records between hospitals, and frustration towards the system.

Because the transition to EMRs was relatively recent, many stakeholders in the medical industry remember the huge effort it took and the central frustrations of the process. It is

important to consider the most aggravating points of the process, as promise and proof of problem mitigation may help convince stakeholders to begin the transition to digital pathology. In a 2014 study, researchers found through various interviews that the most frustrating aspects of the transition to EMRs were "departing from the organization's established routines" and the slow transition to uniformity and accessibility of medical records (Magsamen-Conrad & Checton, 2014). The fear in deviating from established routines is a known phenomenon called path dependence. Path dependence is the fear or the resistance to change in workflow or norms. The resistance due to path dependence can be understood as "the relative benefits of the current activity compared with other possible options increase over time...the costs of exit – of switching to some previously plausible alternative – rise" (Pierson, 2000). Even if the alternative is "plausible" or perhaps even more efficient and better performing than the typical route, society will refuse to deviate from the familiar, usual path. Digital pathology is still new, thus most pathologists are expected to resist and oppose changing their familiar way of organizing and analyzing sides.

The 2014 study by Magsamen-Conrad and Checton explores the biggest benefits to stakeholders after transitioning to EMRs. These benefits include efficiency, uniformity, and accessibility (Magsamen-Conrad & Checton, 2014). The biggest attraction of EMRs was the promised ease of access once the transition was complete. Rather than limited paper copies, all workers could store and access medical records from anywhere, making stakeholder's lives and professions more convenient and productive. These benefits of EMRs intuitively hold true for the transition from physical to digital pathology. Therefore, emphasizing these advantages can greatly assist in incentivizing further change and modernization of pathology.

2.5 Current State of AI Technology

As the ultimate promise of digital pathology, AI's success decides the fate of digital pathology. If AI lacks success in the medical field, the transition to digital pathology could be seen as unhelpful, inconvenient, or useless. In recent years, however, there have been successful trials of AI in healthcare, through research studies, actual medical diagnoses, and administrative tasks. aetherAI has contributed to several projects that investigate the use of AI in healthcare. One of these projects uses aetherAI's artificial intelligence to help diagnose intestinal T-cell lymphomas. AI programming "achieved a comparable result to that of the incorporation of immunophenotype and to that of the senior hematopathologist", leading to increased accuracy, efficiency, and consistency of diagnosing cancers in the future (Yu, 2021). In another study, using WSI and a similar machine learning program, aetherAI researchers were able to detect glomerular lesions with a multi-step identification model. With improvements in algorithms, inputs, and more training data, the program has potential clinical applications, which is promising for the actual application of digital pathology and AI in the medical field (Yang et al, 2021). Additionally, aetherAI collaborated with pathologists and researchers in Pennsylvania, Taipei, and South Africa to develop another AI program which successfully identified acid-fast bacilli and "proved to be more sensitive and accurate, took pathologists less time to screen cases, and was easier to use than either manual microscopy or viewing WSIs" (Pantanowitz, 2021). An algorithm developed in conjunction with aetherAI detected metastatic colorectal cancer with 98.5% accuracy on 1000 WSIs (Chuang, 2021). Although these projects will need much work before they can be routinely used in clinical practice, the results show that AI could be a promising tool in the field of pathology. Indeed, in September of 2021, the US Food and Drug Administration approved the commercialization of Paige Prostate, a program that identifies possibly cancerous areas on digital slides. The program, however, cannot work on its own; a

pathologist still needs to make the final diagnosis, but uses the program as a tool. With the help of Paige Prostate, detection of cancer in digital slides increased by 7.3% (McCarthy, 2021).

Understanding how digital pathology works, who might be interested in digital pathology, the key differences between US and Taiwanese healthcare systems, the process of modernization in the US, and the state of development of AI, we now have a basic understanding of the background of our project. We used this information on the current US pathology field, hospital finances, and the advantages and disadvantages of digital pathology and AI to conduct interviews and formulate survey questions.

3.0 Methods

The goal of our project was to identify the state of digital pathology in United States research hospitals and the opportunities and barriers to integrate digital pathology into routine workflow. Our objectives to achieve our goal were to identify pathologists' opinions towards digital pathology, evaluate the progress of digital advancement in the U.S. pathology field, and produce a report that lists recommendations for digital pathology to succeed in the U.S. Using online interviews, surveys, and archival research conducted from March to April 2022, our team investigated and analyzed the current state of digital pathology in the United States to identify barriers to digital pathology's full adoption. Our team created logical and ethical guidelines for our research, as well as a schedule, to preserve integrity and efficiency. Each method gave valuable insights, allowing us to ultimately form a report with recommendations on how to implement a digital pathology system in United States hospital pathology labs.

3.1 Online Interviews with Pathologists, Hospital Executives, and Other Experts

With respect to interviews, our team attempted to discover the current trends and gaps in hospital pathology labs and AI applications in healthcare. Through outreach and networking with personal and industry connections, our team contacted twenty-seven individuals. Of those we contacted, we interviewed fourteen individuals from: the University of Rochester Strong Memorial Hospital, Worcester Polytechnic Institute, West Virginia University, University of Alabama, Rochester Institute of Technology, and Massachusetts VA health systems. These contacts connected us with pathologists, professors, lab managers, AI researchers, and VA hospital workers for interviews to be held online. Additionally, we contacted personnel that already implemented aetherAI through connections from our sponsor. The team conducted 30-

minute interviews from mid-March to mid-April via Zoom during times that were convenient for the interviewee and our team.

We interviewed a wide audience of pathologists, lab managers, professors, and AI developers to build a full perspective on the use of digital pathology systems and AI in hospitals. Our team asked hospital pathologists, lab directors, and lab managers in research hospitals to describe their workflows, the room for growth in their routines, common barriers to implementing digital pathology, and how to best overcome challenges in the future. Interviews with professors focused on the logistics and economics of implementing digital pathology. We asked for in-depth understanding of the logistical considerations of implementing a digital pathology system, such as insurance, liability, and administration, which may be out of the scope of a pathologist's work and expertise. AI developers were able to give us perspective on the technical considerations of implementing digital pathology, such as cybersecurity and data storage.

According to Lune and Berg (2017), interviews can be beneficial in that people will often be open and connect with interviewers about their topics, but there is also the potential for interviewees to omit information or give an unreliable account. While interviews can provide personal and valuable insight that can explain some trends in the field, they are not as capable of showing the general opinions of a group due to their individual nature. Because we conducted the majority of these interviews while our team was at our project center in Hawaii, they needed to be virtual meetings, which also have advantages and disadvantages. While virtual interviews were much easier to schedule since no one needed to travel to the meeting, it is considerably more difficult to create a comfortable environment for interviewees through a computer screen, which could cause interviewees to be less forthcoming.

3.2 Archival Research into Pathology Labs in Online Information Databases

Archival research was an ongoing process throughout our project to compare our findings with multiple sources and compare our findings with multiple sources and understand the complexities of pathology practice based on interviewee responses. Our team focused our archival research on the marketing, implementation, operation, and future of pathology labs and on developing a better understanding of the U.S. healthcare system. We gained valuable information from interviews, but we sought to verify our findings with other research in similar hospitals and research labs that we were not able to directly contact. Our team emphasized research surrounding the opinions of pathologists, hospital executives, and physicians about their experiences with digital pathology software, in terms of diagnosis and implementation barriers especially, but we also researched the structure of healthcare in the United States and Taiwan. The literature gave us insight into the process, reasoning, and advantages behind adopting digital pathology.

Using JSTOR, ScienceDirect, and PubMed, we accessed reviews of pathology as a field, examples of digital pathology and AI, peer-reviewed papers on the digitalization of pathology, and articles on pathology departments updating their technologies to provide a more comprehensive understanding of pathology labs. ScienceDirect proved to be the most helpful in finding articles about the technical aspects of the technology and the challenges pathologists reported with the technology through studies of pathologists' opinions. In our search on ScienceDirect, we used terms such as "Digital Pathology," "Whole Slide Imaging," "AI in Pathology," "Barriers Digital Pathology," and "AI Resistance in Medicine." PubMed was more helpful for medical research in digital pathology, such as validation trials of using AI to identify abnormalities in pathological s while JSTOR was useful for more social science research related

to healthcare systems in-depth perspectives of hospital executives and AI businesses. can be limited by selection bias, essentially selecting sources for what we want to find and not what is representative of all sources on the topic. We actively tried to avoid bias through the use of multiple sources, critical assessment of the authors, publishers, journals, and websites used, coordination of information from the archival research with interview findings, and the exploration of several schools of thought.

3.3 Online Surveys Distributed to Experienced Pathologists and Hospital Administrators in Hospitals and Research Labs

Surveys allow our team to gather a wide range of responses on digital pathology from different sources. Through the surveys, we had hoped to understand general trends in pathology in regards to digital pathology. The targeted population for distribution of survey included pathologists, lab managers, and hospital executives at research hospitals who were unable to conduct an interview or who were not as directly connected to us, such as members of pathological societies. To reach our intended audience, we asked lab managers and pathologists we spoke to in interviews and pathological societies to forward the survey to anyone qualified to speak on digital pathology who might be interested in completing the survey. Surveys were sent out to contacts of interviewees and pathology organizations through email. Our survey was open for six weeks, from March 16th to April 20th, and asked for similar information as the interviews: insight into the pathology field and its various states of digitalization. This time frame allowed people plenty of time to answer the survey.We kept our survey short enough to be completed in less than ten minutes and minimized open-ended questions to encourage more responses.

The advantages of surveys are they are easy to develop and distribute, meaning there is little effort required in exchange for a large benefit, and they show general trends within the field you are investigating, given a large enough sample size. However, as we saw with our survey, surveys often do not receive the number of responses that researchers hope. Without a sufficient number of responses, surveys are not able to show the general trends and correlations between respondents. Our team received an extremely underwhelming total of 7 responses to our survey, many of which being incomplete or completed by someone we had already interviewed. Despite our team's efforts to distribute our survey through contact with pathology organizations such as the Digital Pathology Association and the American Society of Clinical Pathology and asking almost every pathologist we interviewed if they could pass along our survey to their colleagues, our survey data was not sizable enough to analyze.

The lack of a widespread survey is a large limitation of our study, as we are not able to obtain the wide-ranged, quantitative data we had hoped to collect. Without those quantitative large-scale results, our findings cannot be generalized to cover pathology on a broader scale in the United States. Instead, our findings are limited to in-depth, personalized results from a select number of institutions.

3.4 Data Collection Method Requirements and Intentions

The team conducted interviews on Zoom using a computer, camera, microphone, and Zoom's built-in recording software so that we could review interviews upon completion. While we attempted to use Zoom's live transcript function, we found the live transcript was often incorrect. Therefore, we took notes during the interviews on a shared document that contained our interview questions and then filled in the responses we received during the interview.

Afterwards, we organized the notes and identified key takeaways in a separate shared document. The shared document compiled the data we collected from those interviews into summaries for each interview, outlining important points and barriers and needs for digital pathology listed by each interviewee. Using the identified barriers and needs, we made a set of recommendations for implementing digital pathology and the eventual future of AI development in US hospitals. We made a document describing the research we found and presented our data in a written report.

Our team used a computer to design the survey and a software program called Qualtrics to distribute and analyze the survey. Respondents were able to complete the survey using either a phone or a computer. The team exported responses that yielded quantitative data to Excel for data organization and visualization.

3.5 Data Analysis and Visualization

We conducted a content analysis to identify concerns in the interview responses with regards to barriers and needs for digital pathology. For example, most lab directors and administrators identified cost as a large barrier, and determined the largest challenges for aetherAI to expand in the US based on these trends. We also compared responses and discussed possible reasons for differing opinions between pathologists from our interviews. We included specific quotes from interviews in the report to give a primary perspective on the way pathology and other labs are currently conducted and how those who work in labs see the field integrating with AI. The comparison between literature and primary interview responses was useful to see how our interviews fit into more general trends across the US and to back up or counter data we found.

3.6 Ethical Considerations

The main ethical issues that arose during our project involved informed consent from our interview and survey participants and preserving the confidentiality of our research contacts. Using Lune and Berg (2017), which discusses the details of informed consent at length, we ensured that the research subjects understood our project goals, the final result of our project, and how the information they provided would be used. To protect our research participants, we redacted names and specific identifying information from our findings and confirmed that our sponsor would not contact respondents without explicit consent. Although our sponsor expressed interest in getting in touch with some interviewees, we did not share contact information without clear permission from the interviewee, and we asked our sponsor not to connect with any of our research participants whose contact information might be inferred from our project.

When conducting our interviews, we adhered to IRB guidelines on informed consent. We carefully and clearly explained to our interviewee the purpose of our interview, what kind of questions we would ask, and how our team planned to use responses before obtaining consent. We asked for permission to video record or take notes in any meetings we had with the participants of our research and explained how our team would use those recordings and notes would. For the interviewees who wished to remain anonymous, or wanted the meeting to be confidential, we met their wishes and removed any identifying information, such as their name, email address, and job title.

The team took steps to collect informed consent and protect privacy of the project participants when conducting surveys as well. We received explicit consent from every survey respondent through a required Qualtrics question before the survey began. Consent was achieved by stating the intent and nature of the survey before the survey starts, and having each participant affirm that they understand and wish to continue the survey. We also had the surveys be

anonymous to prevent identifying answers. Information that we collected was kept secure and protected on a google drive shared between teammates.

4.0 Findings

Throughout a five-week period our team conducted 16 interviews via Zoom. Through the interviews, we were able to gain valuable insight into the pathology, economics, marketing, managerial, and computer science perspectives with regards to digital pathology systems.

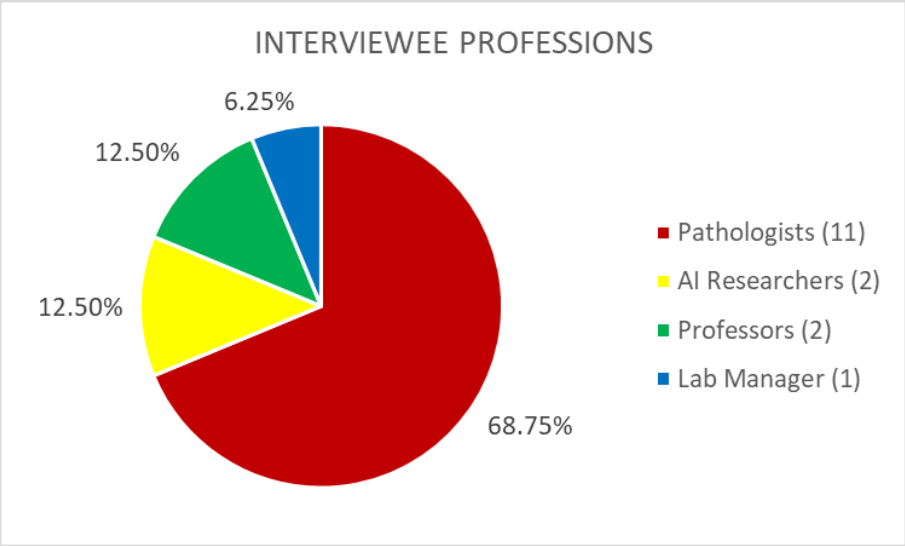

Figure 4.1: Interviewee Pool for Digital Pathology Research

As shown in Figure 4.1, the majority of our interviews (69%) were with pathologists followed by professors (12.5%) and AI researchers (12.5%). Of these professionals, the majority were from the University of Rochester (31%), followed by Worcester Polytechnic Institute (25%) and the Veterans Affairs VISN-1 healthcare region (13%) and Rochester Institute of Technology (13%). Figure 4.2 summarizes the interviewee pool in terms of institution below.

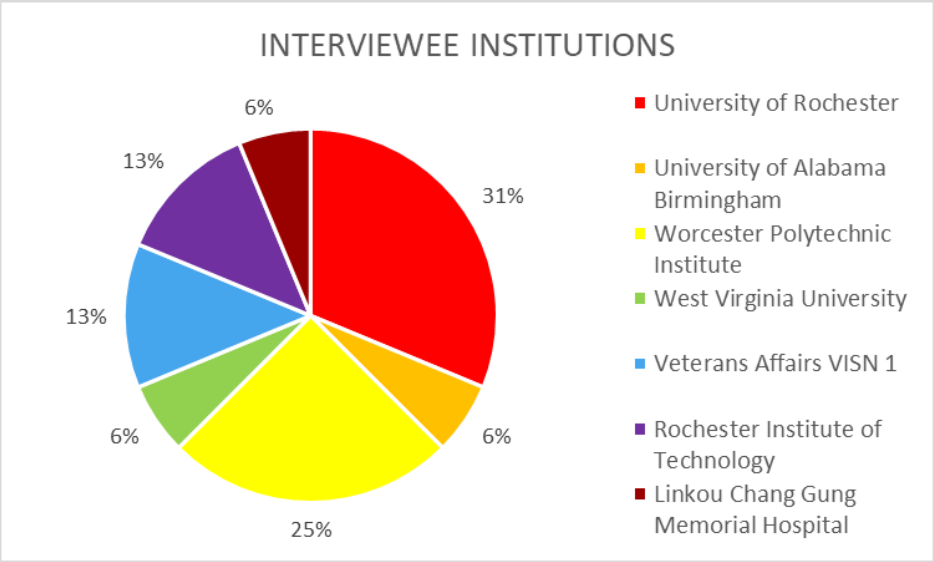

Figure 4.2 Interviewee Pool by Institution.

4.1 Digital Pathology Implementation Challenges

As shown in Figure 4.3, our team identified four recurring themes that many pathologists mentioned as challenges to implementation of digital pathology. Firstly, the necessary equipment is very expensive, so hospitals need significant funding. The cost concerned 54.5% of pathologists in our interviews, as displayed by Figure 4.3. Secondly, hospitals will need increased cybersecurity to protect digital files. 45.5% of pathologists had security concerns when considering a digital pathology program at their hospital. Next, many pathologists expressed frustrations with non-intuitive software and hardware, 72% in our study emphasizing this concern, and finally, pathologists are often indifferent towards digital pathology due to the lack of immediate or clear benefits, as 63.6% of our interviewees felt indifferent towards digital pathology implementation.

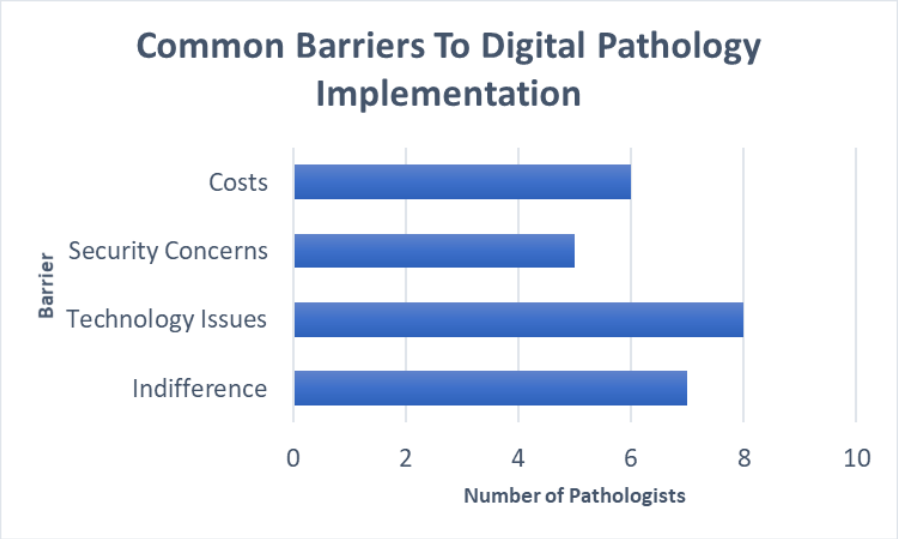

Figure 4.3: Recurring challenges to the adoption of digital pathology in the US,.

4.2.1 Financial Barriers

Our team found that challenges in adopting and implementing digital pathology often stemmed from the cost of the system. While there is an online database with lists of government grants given for research projects at individual hospitals by organizations like the National Institute of Health (NIH), which provided over 40,000 grants and $28 billion in 2021 for healthcare related research, hospitals still have a difficult time overcoming the cost barrier for digital pathology. Out of the eleven pathologists interviewed, six (55%) discussed the steep costs of digital pathology, referencing the expensive scanning equipment, software, and hardware required to run a fully digital pathology workflow. One pathologist emphasized the issue of cost for digital pathology implementation, "*It's very costly…we've laid the groundwork, but it is exceedingly expensive to get into digital pathology, and I suspect that's why a lot of groups are hesitant"* (Dr. Park, personal communication, 4/1/2022). However, about one-third of pathologists who mentioned costs viewed it as simply a necessary expense, saying that pathologists should not view digital pathology through a cost/benefit analysis lens, rather as a

necessity for the future. Meanwhile, in our interview with a pathologist who worked in VA hospitals, they noted that there are less financial restraints for government funded hospitals like the VA than for hospitals without government funding (Dr. Patterson, personal communication, 3/25/2022).

The most frequently mentioned cost in our interviews was the digital slide scanner and the cost of scanning with one respondent remarking,.“*It actually costs more to scan a slide. That’s a problem”* (Dr. Park, personal communication, 4/1/2022). Scanners used for digital pathology were present in all the labs we contacted, but each laboratory scanner had different levels of throughput. Throughput, in regards to the scanners, refers to the amount of slides that pathologists can scan at once. The higher the throughput, the more slides scanned at once. Unfortunately, higher throughput also means higher costs for the scanner, with high throughput scanners costing anywhere from $100,000 to $400,000 (Lujan 2021). A system without a high throughput scanner is still a significant cost, ranging from $30,000 to $250,000, not including additional costs for running the system, such as acquisition contracts or IT infrastructure (Patel 2021).

The software can be expensive as well, especially if the software works in tandem with the scanner, but different scanners offer different services with their scanners, causing a variance in costs. As Lujan (2021) points out, “some scanners are accompanied only by minimal software, while others are bundled with elaborate software platforms to host and organize large image sets and to manage many of the requirements of a digital workflow.” For some hospitals, depending on the scanner they select, costs could be exceptionally higher than another based on the choice of digital scanner.

More expenses arise when training pathologists and hiring new technologists for the new software and hardware programs associated with digital pathology. Most pathologists have minimal training in digital pathology, receiving limited and varied instruction from medical school (Elmore 2020). Lengthy and intensive training would be required to run the system optimally, stacking up high labor costs on top of the training resources. Dr. Park, having established a new digital pathology program at their institution, described the labor-intensive, time consuming process, "*it took us about two years to get the system up, get all our interfacing, storage worked out. It's a pretty extensive project"* (4/1/2022). Dr. Marriott continued the sentiment by discussing how new hires must be brought in to run certain equipment like scanners. "*You have to train technologists to scan the slides in, it doesn't happen automatically"* (03/16/2022).

Concerns over costs drive most hospitals away from investing in digital pathology company technology. In order to access the US market, companies must find hospitals willing to implement digital pathology at a steep cost. While consulting a professor of marketing at WPI, they advised an approach to digital pathology that may circumvent costs as a barrier for companies to provide their products. When consulted on the problems with costs, the professor pointed to large scale hospitals, like Massachusetts General Hospital, that have collaborations with reputable, well-funded institutions and larger budgets.

> *[Companies] have to go to these high-end, first-tier hospitals. They're [their] best shot at getting an audition for [their] technology, because smaller hospitals make less money, so they can't afford it…but more importantly, they can't afford the risk* (Professor Finch, personal communication, 4/6/2022).

The hospitals with well-known connections and larger budgets have the ability to take on high costs and wait for the benefit of AI in the future. The cost problem can be addressed by first

approaching large hospitals with sufficient government grants and private funding who will adopt the systems, develop it, and encourage smaller scale hospitals to implement digital pathology programs because, "*once you get [large hospitals] to put their stamp on it, everyone else follows suit"* (Professor Finch, personal communication, 4/6/2022).

4.2.2 Digital Pathology Technological Issues and Resistance

The technology currently in use in hospital pathology labs, including the computers, monitors, scanners, software, and lab equipment, is often lacking. Eight out of the eleven (72%) interviewed pathologists reported an issue with outdated, slow scanners, slower computers that were unable to run advanced software, not enough space on hard drives, or a combination of all three. As for the scanners, the lower throughput scanners that are typical in United States hospital pathology labs scanned a range of 5-10 slides at a time. Lower throughput scanners discourage pathologists from using digital pathology, as the low number of slides scanned at once makes for a slow, tedious process that halts lab productivity. Some pathologists told us that they analyze around 40-50 slides a day while others stated that they handle over 80,000 cases a year, which is an average of 200 cases a day. There was even one pathologist who oversees a team of 65 pathologists, who indicated that his institution received close to one million cases a year (Dr. Baker, personal communication, 4/6/2022). Due to the heavy caseload pathologists receive, adding an extra step for digital pathology hinders their already overworked schedules. As Dr. Reynolds said, *[Digitalization] means that at the beginning of the day, before any pathologist has a chance to look at them, you're going to be scanning, digitizing all these slides. It's gotta go pretty fast, because pathologists wanna get started* (Dr. Reynolds, personal communication, 3/16/2022). Another contact agreed, *The problem is the scanning time. You've got to remember, these [samples] get cut, stained, and, you know, we're dealing with an in-*

patient, it's on my desk like now…We don't want to wait. Two hours, three hours is a big difference (Dr. Bradley, personal communication, 4/11/2022).

The most common software pathologists reported using were Leica Biosystem's Aperio, Huron Digital Pathology's HuronViewer, or Inspirata's Dynamyx. The most negative opinions were of the HuronViewer program with Dr. McCormick, a pathologist whose institution specifically used Huron Digital Pathology's system. lamenting how the inconvenient interface does not allow users to stop annotating, pick up their pen, or save their annotations without closing the whole image (Dr. McCormick, personal communication, 3/15/2022). Each of these complaints strike where pathologists find issues with digital pathology – the systems are not easy or intuitive to use, making pathologists take longer to analyze slides than manual analysis due to technical problems. Several pathologists voiced these kind of concerns:

> *It's just slower, I don't have time to click and scroll…when I can just [look at the slide] with my hand and be done looking at it in a millisecond* (Dr. Marriott, personal communication, 03/16/2022).

> *Don't forget about my microscope, and how fast I can move a piece of glass across this [microscope]. I mean, there's no lag time* (Dr. Bradley, personal communication, 4/11/2022).

> *Unfortunately, glass is extremely fast, whole slide imaging is a little bit slower* (Dr. Cera, personal communication, 3/29/2022).

With technical problems slowing down the slide navigation, such as slow loading, low throughput scanning, interrupted analysis, and slow diagnosis and analysis process, most pathologists (72%) viewed digital pathology indifferently, as they feel it is not adding much benefit to their work. Responding to questions regarding their desire to implement digital technology in their labs they indicated:

> *Do I need an archive? Do I need to know, like, where all these breast biopsies are? I mean, we keep track of them right now.* (Dr. Bradley, personal communication, 4/11/2022)

> *As far as why do we need WSI? It's another layer, it's another step.* (Dr. Cera, personal communication, 3/29/2022)

Once pathologists scan the slides and process them in digital pathology software, pathologists require the digital images to have excellent resolution, near-instant loading times, an easy viewer, simple interface, and the ability to see the depth of the slide to compare to microscope manual analysis. These attributes are often missing in digital pathology programs, causing an unease and unfamiliarity with the programs. Dr. Patterson sums the situation up best saying, "*people are just not used to it"* (3/25/2022). Therefore, many pathologists would rather make a diagnosis from a physical slide rather than a digital one and are only comfortable using digital images for consultation, education, or slide organization at most as revealed by one pathologist who acknowledged:

> *Most of us don't feel comfortable…You need those cytologic details…Those…have severe consequences on the patient…Skin…that's not too bad. Let's say you underdiagnose or overdiagnose, but for lymphomas, you're giving this patient six weeks of chemotherapy. That has significant impact, so most of us would still prefer the glass slide* (Dr. Young, personal communication, 4/7/2022).

Fluid and morphologically complex samples, in particular, require more dimensionality, demanding multiple planes to fully analyze. Digital pathology, unfortunately, does not yet have the technology to achieve the in-depth analysis and programming fluid samples would need (Dr. Reynolds, personal communication, 3/16/2022). Interviewees suggested technologies yet to be developed, like fluid sample analysis, for digital pathology. Jill, an experienced histotechnologist with pathology training, for example, mentioned that developing a program that works with a dissecting microscope would be useful to pathologists(Jill, personal communication, 3/30/2022).

Path dependence was a strong barrier mentioned throughout our research, as most pathologists have extensive training with physical slides and little with digital methods. Physical slides are seen as the standard, while digital pathology is just emerging in the field with varying degrees of acceptance due to its disruption of decades-long workflows.

> *In terms of acceptance in the laboratory, the challenge isn't often so much the details of how to construct… a software and hardware that will allow you to do, to annotate and find it accurately and move it back, it's more in how does this new approach interface with… the ergonomics of how the pathologist actually does the work in order to get all these cases signed out in a day. [Because] everybody is under stress, the lab's really busy* (Dr. Reynolds, personal communication, 3/16/2022).

> *When you introduce a new system, and now you have to drive it with the mouse and steer around on the screen and click and drag the image?…That's a new paradigm, that's a new way of thinking that these people have to adapt to if they want to use this new technology* (Dr. Cera, personal communication, 3/29/2022).

Not every pathologist is open to starting a new "paradigm" or changing manual training to digital pathology workflows. Pathologists, especially those close to retirement, are not necessarily interested in learning new techniques, as one pathologist suggested,

> *There's different levels of resistance. Do I really want to get into that? I've got a great practice. I've been doing it for fifteen years, what's another five?... Then I can retire* (Dr. Cera, Personal Communication, 3/29/ 2022)

Another technological barrier often mentioned by interviewees for digital pathology was a storage system, like network storage server with high bandwidth, to store the huge sample slide files, typically saved in .svs files. The pathologists interviewed who had digital pathology programs either had local network drives or hard drives to manage storage. Literature echoes the concerns from pathologists for storage, saying "data storage of diagnostically used WSI data on consumer hard drives is inadequate" and "more funding needs to be obtained for key issues such

as the ongoing costs of image storage and more guidance could be provided as to how this is best achieved by which medium (e.g., cloud based, tape storage, or servers)" (Jahn 2020, Turnquist 2019). Out of the eleven pathologists interviewed, six listed storage as a concern for digital pathology implementation programs. Dr. Young in particular stated that storage is a "*big issue, those images are huge…someday [the storage space] is gonna get filled up…I don't think we have a good solution for that yet"* (4/7/2022). Most pathologists echoed this concern about the uncertainty of storage and handling digital slides once space on their current storage system is filled up. For example, one pathologist from the University of Alabama Birmingham showed us a two-terabyte hard drive filled to capacity with sample slide images. As a possible solution, one pathologist described the use of cloud computing, which had an added benefit of better cybersecurity.

Even if resistance to digital pathology was prevalent among interviewees, some pathologists did acknowledge the advantages of digital pathology towards education, consulting (telepathology), and staffing. Digital pathology can facilitate training of medical students because, *"now [the digital pathology certification exam] is all digitalized"* (Dr. Young, personal communication, 4/7/2022). Telepathology can be very useful as a way to get a second opinion from experts as well. Dr. Young mentioned, "*You show five different pathologists [a slide], you [might] get five different answers... if that's the case, what we do is we send [the digital slide] to the expert in the field"* (4/7/2022). Virtual consultation is a convenient benefit of digital pathology that is relatively easy to adopt, as compared to adopting a fully digitalized lab, since it doesn't disrupt workflow. Scanning and digitally sending a slide to an expert is considerably quicker than transporting a physical slide with more than 70% of pathologists we interviewed indicating that their institution uses, or is looking to use, digital pathology for consultations.

Sharing slides for collaboration or consultation is particularly beneficial to pathologists as noted by one pathologist who said, *"the physical scanning of them and getting them somewhere else, particularly for things that are very routine. I think it's gonna have an impact"* (4/11/2022). Staffing was another point where pathology could benefit from digitalization, as Dr. Cera mentioned, "*the shrinking labor pool is a problem across the globe…so efficiencies have to be found. WSI has a property that would allow it to do that"* (3/29/2022). Archiving slides in an online system to improve continuity and care for returning patients was another advantage of digitization with one pathologist stating, "*we'll be able to store [slides] digitally…We get to keep the images as a record, these patients, sometimes they end up at our hospital for more treatment* (Dr. Park, Personal Communication, 4/1/2022). On top of these benefits, once labs are fully digitized, meaning all slides are scanned and analyzed digitally, they might have the potential to analyze and finish cases more quickly. Dr. Park, for example, cut down on slide analysis time for fluorescent samples in their completely digitalized system. Additionally, on top of doing the work of more people, using digital slides could reduce strain on the eyes and hands from constantly working with a microscope.

4.2.3 Security Concerns

The transition to digital pathology requires a secure location to store digital slides with sensitive patient information. These digital slides can contain personal data that can create huge legal problems if they were leaked, raising a valid concern from pathologists and patients alike when considering digitalization.

In our interview with a pathologist with considerable influence in their lab's transition to digital pathology, we discussed their current setup regarding sensitive data storage. Dr. Cera is spearheading a newer digital program at their institution and mentioned that their lab's current

system does not have many security features. The lack of security features increases the risk of a cyber-attack in the form of ransomware.

> *A large university does have a data protection team, is it as big as Google's? Absolutely not… cloud computing is probably safer than a network storage* (Dr. Cera, personal communication, 3/29/2022)

One viable solution to this dilemma is outsourcing computing and storage to a larger company's services such as Amazon Web Services (AWS) or Microsoft Azure as these services and their companies have greater expertise and funding pertaining to data security.

It is important to note, however, that smaller hospitals likely won't have the funds to pursue advanced and expensive tools to defend from cyberattacks due to the nature of the free-market system and the how hospitals are funded. Additionally, there is an ethical risk of entrusting medical information to a large corporation. For example, if AWS is hosting the storage server for medical information, they would have access to that data which has the potential to compromise patient privacy and confidentiality. Both parties signing an agreement could promise confidentiality, however this cannot guarantee safety.

At the same time, our interviewees who work with the VA did not share similar concerns regarding network security since they are part of the government system, so the government supports and funds their security. This is more aligned with Taiwan's healthcare system, which similarly relies on government security of medical data. When asked to elaborate on their network storage, we were told their system is very persistent in protecting data.

> *[The] VA is very strict about sharing any information… the firewall for [the] VA is very very protective… in the end its good, but it's really difficult to share information outside the VA* (Dr. Young, personal communication, 4/7/2022).

> *Here at the VA… security issues, that's very important. We wanna make sure that any of these companies that we're working with, they're not lax on cybersecurity… Privacy, ransomware, all these other attacks and stuff like that that are happening…. a private hospital might not have the direct incentive to pay people to investigate or look into these devices closer* (Dr. Patterson, personal communication, 3/25/ 2022).

The centralization within the government system and commitment to protecting security, and how it is sometimes difficult to intentionally share data is indicative of a well-guarded network. This is consistent with what we found in our literature, where the VA is the exception to weak network security in the healthcare system.

4.2.4 Regulations and Guidelines

A consistent response throughout our interviews with pathologists highlighted that they do not use digital pathology and machine learning software in a clinical setting because they lacked approval from the United States Food and Drug Administration (FDA). Companies that make medical devices and software that will directly affect the health of people need FDA approval before they can sell and advertise their products. In our interview with Professor Finch, he said that acquiring FDA approval for a foreign a medical company, such as aetherAI, would be very difficult:

> *Without having US clinical data that passes the sniff test at the FDA, [US hospitals] won't think about it seriously, more than likely…People are not gonna support something like that unless there is US based healthcare organizations that have validated it, and that there's clinical data that comes out of the US, they just won't* (Professor Finch, personal communication, 4/6/2022).

Digital pathology has only begun to emerge in recent years because of the rigorous and strict process of FDA regulation. In multiple interviews with pathologists, they mentioned how the COVID-19 pandemic accelerated the approval process for digital pathology and increased

their need for digital pathology. For example, University of Alabama Birmingham found that COVID opened doors for their autopsy department, allowing them to create an online resource full of COVID-19 samples to share with other organizations and research teams. Another example was Dr. Park's pathology department, already in the middle of a transition to digital pathology. He found digital pathology to be a massive advantage for his team because, "A*ll conferences were remote, so we were ready, actually, to do that. So we could scan slides and have our tumor boards"* (Dr. Park, personal communication, 4/1/2022). With smaller in-person workforces during COVID, the ability for hospitals to practice telepathology became increasingly more essential. Digital slides allowed pathologists to look at slides from anywhere or to send them to another hospital for consultation or a second opinion. However, telepathology can only be used for consultation and not diagnosis:

> *If it is not… FDA approved to use this software to make an actual diagnosis when you are not there looking at the slide through the microscope, then you are being a consultant. So you can't make the diagnosis. You can say to the person on the other end that's driving the slide, 'Oh this is what I think it is', but it kinda sorta defeats the purpose… of making this an efficient process* (Dr. Reynolds, personal communication, 3/16/2022).

Overcoming FDA regulations is not the only regulation and guideline-based barrier to accepting new medical technology. The College of American Pathologists (CAP) is an organization made up of around 18,000 board-certified pathologists that define their mission as to "serve patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide". Every year, CAP releases a new set of guidelines for pathology. The majority of hospitals and pathologists will not use a new device or software if it does not follow the CAP guidelines.

Another set of regulations that companies must comply with are local regulations that are specific to each hospital in the United States. Hospitals have their own boards and local regulations for adding new technology to their system. As Dr. Park explained regarding their implementation process, "*We had about six or seven different groups that focused on implementation. You know, we have governance… we have kinda, the IT, storage, networking people, legal regulatory"* (4/1/2022). Digital pathology regulations in Massachusetts may be different than in New York because of different state laws. For hospitals in the VA healthcare system, there is a specific approval process they must undergo to ensure that they are abiding by the regulations in place. After companies are approved by the strict VA guidelines, they win a bid for a contract with the government for five years in the VA health system. After five years, the VA healthcare system will seek a new contract (Patterson 3/25/2022). One positive of these strict approval processes is that once a new technology is approved, any VA hospital can adopt and implement the technology.

5.0 Recommendations and Conclusion

Through our interviews with many different pathologists, we discovered that almost all medical institutions in the US are only using digital pathology for research, education, and telepathology. There are several reasons for resistance towards the adoption of digital pathology in a clinical setting, including the lack of FDA approved AI software, an expensive investment for digital pathology setup, pathologists' reluctance to change their workflow, and insignificant immediate benefit to the transition from traditional to digital pathology.

Overall, there are two options for marketing digital pathology and AI programs in the US. The first option, the more passive approach and the path of least resistance, is to allow sentiment to change in the industry and focus on areas where digital pathology would be most welcome. One of the largest sources of resistance to digital pathology is that it takes too much time to scan and analyze the slides due to pathologists' unfamiliarity with this new workflow and their distrust of new technologies. To circumvent this issue, aetherAI could focus more on services designed for research, telepathology, and education. These three functions involve less severe consequences than primary diagnoses, thus more pathologists are comfortable trying and acclimating to the new technology. The second option, the more active approach, is to develop a cohesive plan to change pathologists' and administrators' sentiments regarding digital pathology by including direct and creative ways to incentivize change. Among other strategies, aetherAI would need to provide clear, quantified returns on investment to adopting digital pathology and AI, undergo US testing and validation (which might vary, depending on the institution), adapt to differing cybersecurity and insurance systems, provide training and support for customers, and promote user-friendly interfaces with high resolution and multi-plane images. Along with these

two options, our team determined several recommendations for aetherAI to more easily enter the US market.

5.1 Focus on Research and Identify Well-funded Hospitals in the US

Research projects can help identify places where digital pathology and AI can be most useful, for example, comparing large areas of tissue samples, cell counting, and other tedious or time-consuming tasks. Research has successfully led to AI programs in clinical routine workflow, as shown by Paige Prostate. In order to break into the research market, aetherAI should reach out to large hospitals and institutions that are well funded. They can find these hospitals and institutions by analyzing the National Institute of Health website, which is an online record of all the NIH grants awarded towards research projects. The filtering functions on the website can constrain the results to projects studying AI in pathology or sort by categories like location, number of projects, or funding. The institutions with the most funding will be the ones that would likely be most open to adopting cutting-edge technology since there is a good chance they are also large hospitals with a strong reputation. These hospitals' wealth and credibility allow them to assume the risk of adopting new technologies, and large hospitals or institutions will have the largest number of active research projects, making them the easiest hospitals to collaborate with on a project. Additionally, once large reputable hospitals integrate new technology and prove that it is useful and safe, many other hospitals would follow suit. Hence, getting involved in digital pathology and AI research in the US is a feasible stepping stone to implementing digital pathology and AI into clinical workflow.

5.2 Focus on Telepathology and Education

Telepathology does not require significant changes to pathologists' workflow and provides easy connectivity between experts in the field through consultations. Several of our interviewees stated they are already using digital slides for consultations, thus, there are pathologists already familiar with digital systems and others who could benefit from telepathology. Once a lab has implemented telepathology technology, pathologists have the ability to familiarize themselves with the digital slides, which would make it easier to fully digitalize labs in the future.

Digitalizing slides for educational purposes is also useful since many students benefit greatly from remote learning, especially after the pandemic. Dr. Young mentioned that the certification exam for pathologists is already digital in certain areas, meaning there are new pathologists entering the field with basic familiarity with digital systems. Developing educational software for schooling has the potential greatly popularize aetherAI's systems among pathologists. If aetherAI could become a frontrunner in educational pathology, it gives them the huge advantage of having many pathologists already familiar with working with their software. A more digitalized education system will facilitate the process of phasing in new digital pathology; digital pathology would enter the medical field along with the next generation of pathologists. Through this method, experienced pathologists would not need to or feel as pressured to learn new diagnosis methods or alter their workflow, and aetherAI could wait for a natural change to digital systems while also taking initiative to popularize their technology.

5.3 FDA Approval and Systematic Implementation

The systems used for telepathology, research, and/or education do not need to be approved by the FDA because they are not being used in a clinical setting. However, FDA

approval is required for full clinical digitalization of a lab, and digital pathology programs need to undergo US-based healthcare organizations' clinical trials and validation for success in clinical diagnosis. Without this, it is highly unlikely that technology from outside the US will be picked up by any hospital, no matter how credible an external approval or clinical trial is. Programs from Leica and Huron achieving FDA approval paves the way for more digital pathology systems to gain approval in the next couple years, providing validation for digital pathology in a clinical setting. With increased exposure and approval, pathologists will simultaneously be more comfortable using a digital system while also having a greater incentive to make the transition.

Due to the large size and lack of cohesiveness in the US healthcare system, it could be prudent to focus on a particular city, state or region within the United States. For example, although the metropolitan Boston area and Philadelphia, Pennsylvania are well-funded and conducting a significant number of research projects (as seen in the NIH Funding Profile) they work independently of each other and operate separately. Within these small regions, however, institutions generally have consistent needs and capabilities, making the implementation of digital pathology simpler. Therefore, focusing on gaining a foothold in one area at a time could ease the process of expansion. Experience in expanding in more local areas can then provide insight into growing into other areas, and gaining a reputation in a renowned area like Boston would greatly increase the credibility of the product and company.

Another systematic way of introducing digital pathology into the US could be to work with the Veterans Affairs System. The VA pathologists we interviewed explained that the US is split up into 18 Veterans Integrated Services Networks (VISNs), and each of these regions, or VISNs, decides on their own which technologies they want to use and which companies they

would like to sign a contract with. The US government then funds any necessary modernization of a given VISN, and all hospitals in the VISN receive the new technology. Despite the fact that each VISN operates and makes decisions separately from the other regions, once any technology is approved in one VISN, it is automatically approved for all other VISNs. Therefore, if aetherAI's product were to be approved by an institution in the VA system, it would be approved for VA hospitals across the US, and the US government could help fund its implementation.

5.4 Limitations and Future Research Opportunities

The research our team gathered over the course of our project is not without limitations. First, we were unable to garner a large number of responses for our survey, leaving our research to consist of individual, subjective interviews. As a result, we were unable to report general trends within the pathology field beyond what we had learned from individual's experiences. The individuals we did interview, however, were experts in their fields, thus their perspectives can be assumed to be representative of opinions in the northeastern US. Secondly, we were not able to reach hospital executives and administrators as effectively as pathologists, which could have left out important perspectives on digital pathology. We were able to contact executives and administrators higher up in the hospital staff, but we had hoped for more input to round out the overwhelming opinions from pathologists. Administrators and executives would be able to give more perspective on the inner workings of implementation, including licensure, budgeting, and negotiation that pathologists may not be able to provide. Lastly, our study was focused largely on the east coast of the US, limiting the experiences we reported to one geographic area. A wider range of locations could provide insight into geographic differences that may exist and provide a broader view of the current state of digital pathology across the US.

Continuing this work, future projects can explore the next step of implementing digital pathology in the United States. Defining a marketing strategy based off our findings would be the logical next step for our project. We suggest research into medical device development and approval, as well as advertising and licensure, to best approach a marketing strategy for aetherAI's products. In addition, though we had defined individual's opinions in the northeastern United States, we expect future studies to include a more diverse set of professionals to understand the US market as a whole with general trends. Future studies can explore a wider range of healthcare professions and locations in the US. Interviews with east coast, midwestern, southern, and west coast hospital executives, and administrators could be included along with pathologists to give a well-rounded approach to the study of the US pathology system.aetherAI's technology in the US.

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Appendix A: Interview Informed Consent

I, _____, consent to participating in the research conducted by the Algorithmic Medicine group at Worcester Polytechnic Institute. I Understand that I have the right to withdraw from the interview or survey at any point and not answer any questions I do not wish to answer. I agree to the recording of my interview/survey participation, and I understand that I have the right to review the recording or transcript following the interview. I recognize that, should I wish to, I can choose to remain anonymous or keep any information confidential at any point. I acknowledge that the information gathered from my interview/survey will be used for research proposes about pathology laboratories in hospitals and their barriers to artificial intelligence technology.

I, _____, have read the paragraph above, and I knowingly and voluntarily permit the Algorithmic Medicine group at Worcester Polytechnic Institute the full use of the information I provide and authorize them to publish this information.

_____

(Signature)

Appendix B: Survey questions

Q1 Which of the following best describes your position?
▢ Pathologist (1)
▢ Lab technician (2)
▢ Lab assistant (3)
▢ Lab manager (4)
▢ Lab coordinator (5)
▢ Hospital executive (6)
▢ Other (please specify) (7) _____

Q2 What institution/region are you associated with? (optional)
_____

Q3 Roughly how many cases/slides do you receive per month?
o Enter here: (1) _____
o Not sure (2)

Q4 Roughly how many pathologists are there in your insitution?
o Enter here: (1) _____
o Not sure (2)

Q5 Please describe the current status of digitalization of pathology in your institution?
o Not digitalized at all (1)
o Partially digitalized (2)
o Fully digitalized (3)
o Not sure (4)

Q6 If you answered partially digitalized or fully digitalized to the previous question, please describe what aspects of your pathology procedure is digital.
_____

Q7 To your knowledge, what are some practical barriers in adopting digital pathology at all or transforming into a full digital workflow? For example, high cost of scanners, uncertain return on investment, unfamiliarity/inexperience with digital systems, etc.
_____

Q8 Is artificial intelligence (AI) used in any capacity in your pathology lab?
o Yes (1)
o No (2)
o Not sure (3)

Q9 If you answered yes to the previous question, please list the name of the AI technology.
o List here: (1) _____
o Not sure of the name (2)

Q10 Please rank on a scale of 1-5 each of the following concerns in your lab currently.

	1 - no concern (1)	2 - slightly concerning (2)	3 - moderately concerning (3)	4 - concerning (4)	5 - Very concerning (5)
Outdated Systems (1)	○	○	○	○	○
Understaffing (2)	○	○	○	○	○
Lengthy Procedures (3)	○	○	○	○	○
Expenses (4)	○	○	○	○	○

Q11 If any, please describe the main tasks you wish to have AI-assisted tools to help with.

_____

Q12 If you would like to speak more in depth about your responses, please provide your email below and we would be happy to reach out to you for an interview ☺

_____

Appendix C: Interview Questions

Pathologist Interview Questions

1. What is your current/previous position in your lab?
2. Can you briefly describe your day to day work?
3. On average, roughly how many cases/slides do you receive per month/per year?
4. Approximately, how many pathologists are there in your institution?
5. What do you believe to be the biggest frustrations you faced in your day-to-day work in the pathology lab?
6. What is your familiarity with digital pathology? Are you familiar with tile scanning with whole slide imaging in digital pathology?
7. What are you using currently for research in digital pathology in your lab? (Please describe the status of digitalization in pathology in your institution.*)
8. What kind of tissue do you receive most? What are the most received types of cancers in your daily routine or your institution?
9. What samples are the most time consuming?
10. Are there any AI technologies currently being used in your pathology lab?*
11. Have you experienced or tried any medical AI applications on the market in the US before? If so, would you mind sharing your experience?
12. Is slide annotations a problem in your lab?
13. Briefly describe the main pain points or labor-intensive tasks in pathological diagnosis that you wish to have AI-assisted tools to help on?*
14. When it comes to AI research, we found it difficult and tedious to use separated platforms in organizing, collecting slides to annotating images, and exporting them in structured format. Do you encounter the same situation and do you wish for a streamlined workflow?
15. Was there anything else you would want to improve in your lab?

Survey Respondent Interview Questions

1. What is your current/previous position in your lab?
2. Can you briefly describe your day to day work?
3. Are you planning on using AI made by your institution or outside contractors?
4. How are you planning on dealing with security problems?
5. On average, roughly how many cases/slides do you receive per month/per year?
6. Approximately, how many pathologists are there in your institution?
7. What do you believe to be the biggest frustrations you faced in your day-to-day work in the pathology lab?

8. What is your familiarity with digital pathology? Are you familiar with tile scanning with whole slide imaging in digital pathology?
9. What are you using currently for research in digital pathology in your lab? (Please describe the status of digitalization in pathology in your institution.
10. Can you expand on the practical barriers you listed in adopting digital pathology in your workflow?
11. You specifically mentioned understaffing and outdated systems to be major concerns in your lab. Do you find this to be an issue across most pathology labs? Do you think digital pathology could help with these issues?
12. Do you believe digital pathology techniques would be useful for education? For organization?
13. What kind of tissue do you receive most? What are the most received types of cancers in your daily routine or your institution?
14. What samples are the most time consuming?
15. Are there any AI technologies currently being used in your pathology lab?
16. Have you experienced or tried any medical AI applications on the market in the US before? If so, would you mind sharing your experience?
17. You mentioned several places where AI could be helpful to you in your lab. Would you like to expand on these?
18. Is slide annotations a problem in your lab?
19. Briefly describe the main pain points or labor-intensive tasks in pathological diagnosis that you wish to have AI-assisted tools to help on?
20. When it comes to AI research, we found it difficult and tedious to use separated platforms in organizing, collecting slides to annotating images, and exporting them in structured format. Do you encounter the same situation and do you wish for a streamlined workflow?
21. Was there anything else you would want to improve in your lab?

aetherAI Contact Questions

1. Can you briefly describe your day to day work?
2. On average, roughly how many cases/slides do you receive per month/per year?
3. Approximately, how many pathologists are there in your institution?
4. What kind of tissue do you receive most? What are the most received types of cancers in your daily routine or your institution?
5. What made you choose aetherAI?
6. Approximately how long was the learning curve/training period for aetherAI's program?
7. What were the biggest challenges when implementing aetherAI?
8. Do you feel your lab will benefit in the long run?
9. What are the most significant improvements that aetherAI has provided your lab?
10. What are the current frustrations with the technology aetherAI has provided your lab?

11. Has aetherAI's technology helped with slide annotations? If so, how?
12. Have you had any issues with storage space for the digital slides? How do you deal with the storage issue?
13. Is there anything else you would want to improve in your lab?

Lab Manager Questions

1. What does your work day look like?
2. What labs do you manage?
3. What software/programs do you work with in your lab?
4. What issues do you frequently encounter?
5. What is the most frustrating part of managing a software/program in your labs?
6. What does the learning curve/training period look like for new technologies in lab?
7. How often do you introduce new software/new technology?
8. What is your familiarity with digital pathology?
9. Do you have contact with any pathologists?
10. From your experiences with pathologists, do digital pathology programs seem to be frequent/helpful?

11. VA Pathologist Interview Questions

12. How would you describe your position?
13. What does your day to day work look like?
14. How many slides do you handle per year?
15. What frustrations do you commonly face?
16. What goes into your consideration when implementing a new technology?
17. What are learning curves like with new software?
18. What type of tissue does your lab handle most?
19. What differences do you find working in a VA medical facility versus a non-VA medical facility?
20. Are the systems in use and provided consistent across VA medical facilities in the United States?
21. Do you have familiarity with digital pathology? If so, what programs are you familiar with?
22. What aspect of your work do you think digital pathology could help you most?
23. Do you see digital pathology becoming the standard in the future? How soon?

Professor Interview Questions:

1. Briefly, what different companies and industries have you had experience and consulted in?
2. How does a company market to an institution like a hospital? How does privatization affect the process?

3. If a company is based outside of the US, how does this affect marketing strategy and how the company is received here? What other factors must be considered?
4. When it comes to implementation of new technologies, especially those that force a change in workflow, what do you find to be the biggest sources of resistance?
5. Given the economic differences between Taiwan and the United States, what role will the economy play in the implementation of a new medical technology?
6. What makes an implementation process successful for new technologies? What are things to consider when trying to build your brand?

AI Researcher Questions:

1. How did you begin your collaboration with digital pathology?
2. We saw your research worked with identifying different types of bladder cancer using pattern recognition. Could you share your opinion on the feasibility of machine learning taking over a pathologist's analysis and when that could happen?
3. What specifically is holding back these programs at the moment? Lack of trust? Lack of consistency? Lack of accuracy? Threatening job security?
4. If there were hesitation or doubt from pathologists, where do you think it came from?
5. How did you acquire your training set and what were the main difficulties?
6. Do you think hospitals will have difficulty gaining sufficient training and testing sets for machine learning? Especially considering privacy, disconnected associations etc.
7. Considering hospital network/data security being faulty at best, what are the major concerns of holding this data?
8. What is the next step for your research?

Lab Tech Interview Questions:

1. What were your previous roles that involved pathology?
2. What technologies have you used in the histology field? What worked best?
3. Have you ever used a digital scanner? Was it helpful?
4. Why would you not use a digital scanner?
5. What issues did you typically run into when working in a pathology lab?
6. What frustrated you the most?
7. How many slides did you typically go through?
8. What do you wish you had when analyzing slides?

Digital Pathology Pathologist Interview Questions

1. What is your current/previous position in your lab?
2. Can you briefly describe your day to day work?
3. Approximately, how many pathologists are there in your institution?
4. On average, roughly how many cases/slides does your lab receive per month/per year?
5. What kind of tissue do you receive most? What are the most received types of cancers in your daily routine or your institution?

6. In what ways do you use digital pathology in your lab?
7. What did the implementation process look like?
8. Was training pathologists with the new system an issue?
9. What are you currently using for digital pathology in your lab? (Please describe the status of digitalization in pathology in your institution.)
10. Can you describe the practical barriers you ran into with adopting digital pathology in your workflow?
11. Is privacy or cybersecurity a concern? What about liability?
12. Are there any AI technologies currently being used in your pathology lab?
13. Have you experienced or tried any medical AI applications on the market in the US before? If so, would you mind sharing your experience?
14. Briefly describe the main pain points or labor-intensive tasks in pathological diagnosis that you wish to have AI-assisted tools to help on?
15. When it comes to AI research, we found it difficult and tedious to use separated platforms in organizing, collecting slides to annotating images, and exporting them in structured format. Do you encounter the same situation and do you wish for a streamlined workflow?
16. Was there anything else you would want to improve in your lab?