Wearable AR Device for Improving Patient Experience During In-Office Procedures
(Technical Paper)

Adapting Healthcare Policy for Precision Medicine
(STS Paper)

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Precision medicine promises to revolutionize our approach to healthcare. Thanks to advances in genomics and computing, we will soon be able to create highly personalized disease treatment and prevention plans for each individual. That is, of course, assuming said individual is white and upper class. At the current rate, those who are poor and uninsured will not be able to afford these extraordinary new treatments, and people of color will not have access to the same level of personalization due to lack of research on their genetic profile (Konkel, 2020). The reduction of uncertainty brought about by precision medicine could very well undermine the business model for private health insurance, driving up prices across the board or leaving vulnerable individuals without coverage (Blasimme et al., 2019; Klitzman et al., 2014). These new technologies have the potential to be a tremendous force for good. But unless we address current disparities and inefficiencies in healthcare, many members of society may never see the benefits.

In addition to allowing for precision medicine, advances in medical technology have enabled many procedures that previously took place in the operating room to now be doable in a regular doctor's office. These in-office procedures (IOPs) have many advantages over operating room (OR) procedures, including increased patient safety, decreased cost, decreased procedure length, and better overall outcomes due to avoidance of general anesthesia. However, being kept awake during these IOPs is anxiety-inducing for many patients, which makes the procedure more challenging for the physician, and sometimes prevents successful completion altogether (Young et al., 2012). The technical deliverable for this project will seek to reduce this patient anxiety

through the creation of a non-pharmacologic sensory stimulation device. The device will incorporate an augmented reality (AR) application and an integrated vibroacoustic component that will reduce patient discomfort while still allowing the physician to communicate with the patient and carry out the procedure unencumbered.

Technical Topic

In-office procedures represent a cost-effective and safe alternative to operating room procedures for a myriad of disease processes across medical and surgical specialties. In-office procedures (IOPs) are defined as those performed under local anesthetic with no general anesthesia or sedation. As health care costs in the US have continued to rise, IOPs have proliferated across medical and surgical specialties and are rising in popularity (Hoffer, 2019; McCarthy, 2003; Rice et al., 2013; Saini et al., 2019; Shah, 2019; Young et al., 2012). There were over 12 million IOPs, such as dental surgeries and endoscopies, performed in the U.S. during 2009 alone (Urman & Shapiro, 2011). This figure does not include the millions of additional minor procedures, such as injections and wound dressing changes, that also occur each year in-office. The benefits of IOPs to medical professionals include higher procedural volume, decreased cost, and improved patient safety and outcomes through avoidance of general anesthesia and intubation. Benefits to patients receiving IOPs include decreased cost, decreased time needed for treatment, ability to drive home the day of the procedure, and improved patient safety.

The biggest barrier to the further proliferation and adoption of IOPs is the lack of non-pharmacological interventions to improve patient anxiety, stress, discomfort, and

perception of pain during these procedures. For many patients and their physicians, patient discomfort forces the conversion of what would otherwise be an IOP to become an operating room (OR) procedure, with attendant increases in risks to patients primarily related to general anesthesia and intubation, as well as significant cost increases. For example, in Otolaryngology—Head & Neck Surgery (OHNS), the mean total charges for office-based procedures is $2,737.17, while the same procedures cost $7,329.69 on average if conducted in the OR (Prickett et al., 2012). Furthermore, OR procedures add significant delays to patient treatment due to wait time for OR availability. Within the UVA OHNS Department, at any given time there can be over 100 patients on the waitlist to be seen in specialty clinics, which means patients could wait months before being evaluated. If patients cannot tolerate an IOP at the time of that eventual clinic visit, they will then need to wait another 2-4 months before a scheduled OR date. If IOPs were more tolerable by patients, procedural volumes and their benefits conferred to patients would greatly increase, while decreasing overall healthcare costs at the same time.

Currently, the standard practice for improving patient experience and tolerance during IOPs is to inject local anesthetic (ex. lidocaine) into the region to be operated upon, with or without additional use of items such as ice or distraction with music to help with perception of pain. Despite the largely unchanged standard practice of local anesthetic usage, there have been a few interesting developments within the field of pain management. The Gate Control Theory of Pain asserts that the central nervous system can only process a limited number of stimuli at one time. The theory postulates that non-painful stimuli, such as vibration, which activate non-nociceptive sensory

neurons can interfere with signals from pain receptors, thereby inhibiting or lessening the transmission of painful stimuli (Braz et al., 2014; Treede, 2016; Zhang et al., 2018). In testing this theory, clinical researchers have shown that the application of low-frequency vibration reduces a patient's perception of pain during injections and other IOPs (Mally et al., 2014; Sharma et al., 2011; Smith et al., 2004).

In addition to vibrotactile sensation, another mechanism to improve patient experience is virtual distraction. The virtual simulation that a patient experiences and interacts with provides a feeling of an alternate reality, and as attention is increasingly focused on that reality, perceived pain decreases (Legrain et al., 2009; Melzack, 1993; Sil et al., 2014). The most common approach has been the use of virtual reality (VR) by patients either before or during procedures (Bekelis et al., 2017; Chan et al., 2019; Eijlers et al., 2019; Frey et al., 2019; Gold & Mahrer, 2018; Hendricks et al., 2020; Hoxhallari et al., 2019). Uniformly these studies have shown decreased patient anxiety, decreased stress, improved comfort, and/or decreased perception of pain. Despite initial positive study results, use of VR and/or non-painful stimuli, such as vibration, to improve patient experience is rare and no medical devices combine these modalities.

The end goal of this technical project is to develop an augmented reality application and integrated vibratory device to improve the patient experience during IOPs. There are four biomedical engineering undergrads on the project team: Sarah Glatz, Rehan Chaudry, Chaeyeon Kim, and Tucker Cullen (the author of this prospectus). There are also three advisors: Logan McColl (an MD/MBA student that serves as the main point of contact), Dr. Claudia Gutierrez MD (a resident physician in

UVA's OHNS department), and Dr. James Danerio MD (a professor of medicine in UVA's OHNS department). The AR software component of this project will be developed on a ThirdEye Gen X2 mixed reality headset that will be acquired through grant funding. The vibroacoustic component will be designed using microcontrollers and other electrical components ordered from various online sources. Prototyping tools - including 3D printers and soldering equipment - are available in the architecture school's FabLab and in Stacy Hall (the biomedical engineering makerspace). The fall semester will mainly involve research, brainstorming, and equipment procurement. While the spring semester will involve prototype design and in-clinic testing.

STS Topic

After investing 13 years and $2.7 billion, scientists released the first fully mapped human genome in 2003 (*Human Genome Project FAQ*, 2020). This key accomplishment served as the springboard for countless other breakthroughs in genomics that are now reshaping how we approach medicine. Thanks to next-generation sequencing (NGS) technologies, sequencing an individual's genome now costs less than $1,500 and can be completed in less than two days (Wetterstrand, 2020). Advances in computing - such as increased computer memory, the development of faster processors, and improved bioinformatics algorithms - have made it possible to access and analyze this vast amount of data so that it can play a role in clinical decision making (Cabral, 2019). These advances are making medicine more personalized. When these technologies are employed effectively, doctors no longer need to guess which drug will work best for a patient or what conditions they are most at risk for. Treatment

plans can be specifically tailored to an individual's genome to ensure the best possible outcome. However, these technologies are not entirely without concern.

There are still a few key issues that policymakers need to address before society can reap the full benefits of personalized medicine. The first issue is in regards to economics. According to the CDC, 32.8 million Americans under the age of 65 are uninsured (CDC, 2020). It is possible that genomics will exacerbate this issue, since personalized medicine does not fit with how health insurance is currently structured in America. The reduction in uncertainty that is obtained through genetic analysis could undermine the business model of private healthcare, driving up premiums or leaving genetically at-risk individuals without coverage. With the passage of the Genetic Information Nondiscrimination Act (GINA), lawmakers have blocked health insurance companies from using genetic information to make coverage, underwriting, or premium setting decisions (NIH, n.d.). This legislation protects at-risk individuals from being denied coverage based on their genetic makeup. While GINA is undeniably a step in the right direction, it may not be enough as genetic testing becomes more widespread. Under GINA, increased genetic testing could lead to increased “adverse selection” due to informational asymmetry (Blasimme et al., 2019; Cardon & Hendel, 2001). Adverse selection is where higher risk individuals disproportionately purchase health insurance plans, forcing insurance companies to either go out of business or drive up prices for all customers, thereby making healthcare less affordable. Personalized medicine will have a profound effect on healthcare, and we will need multi-faceted policy solutions beyond what is stipulated in GINA if we are to include the most vulnerable members of the population in this healthcare revolution.

The other central issue that must be addressed is the lack of diversity in genetic research. As of 2018, 78% of the individuals studied in genome wide association studies (GWAS) were of European descent (Sirugo et al., 2019). Comparatively, 10% of those studied were of Asian descent, 2% were of African descent, and only 1% were Hispanic. All other ethnicities make up <1% of GWAS study participants. This lack of study cohort diversity means that any findings generated via most past GWAS can realistically only be applied to people of European descent, leaving out vast swaths of the population. This critical diversity issue must be addressed before all individuals benefit from precision medicine. Otherwise, the technology will merely serve to deepen the racial and ethnic disparities that already permeate American healthcare (Imhoff, 2020).

Precision medicine will affect almost all aspects of healthcare, and as such, many groups will play a role in its implementation. At the center of this discussion lies the doctor-patient relationship. Decisions about an individual's health will become more data-driven. As such, patients will be able to take a more active role in their own healthcare, and doctors will become experts in data analysis as opposed to being repositories of medical knowledge themselves (Abrahams et al., 2005). The development of precision medicine will also take the collaboration of many stakeholders, such as engineers, scientists, business people, and the like. Not only will society need people discovering new functions of various genes, but it will also need people developing ways to process and analyze vast troves of information, and ways to translate these findings to effective medical recommendations. Then to regulate the technology and ensure that it is being used responsibly, policymakers will need take a

proactive approach towards precision medicine and reform our healthcare system to best fit this new era.

Since precision medicine is still in the early stages of implementation - but quickly becoming standard – it is helpful to look at it through the lens of technological momentum (Hughes, 1994; Johnson & Wetmore, 2008). This science, technology, and society (STS) framework, first proposed by Thomas Hughes, states that for a technology to be initially accepted it must fit within the current context of society, but once it is well established it becomes more "deterministic" and starts to influence society itself. Some critics of this theory claim that at its core, this framework is just technological determinism. But Hughes refutes this claim, emphasizing that technological momentum is time dependent and that the initial period of social constructivism cannot be ignored (Hughes, 1994).

The central question in the proposed STS paper is: in what ways will the healthcare system in the United States need to adapt in order to accommodate advances in personalized medicine and ensure equal access for all? This question will be explored through a variety of sources including scientific articles about precision medicine, current laws and policy proposals relating to genetic information, STS literature, and opinion articles written by domain experts. Some keywords that will be used to find sources include: "health insurance," "genomics," "genetic discrimination," "GINA," "personalized medicine," and "healthcare disparities." These overarching keywords cover both current and foreseeable issues in healthcare. Most relevant sources are available through online databases or through government websites. Research will be conducted throughout the rest of the fall semester and into the winter.

Conclusion:

As technology continues to rapidly advance medicine it is critical that the patient experience stays at the forefront of all decisions. All individuals should be able to benefit from the latest treatments, not just the privileged few. The STS paper proposed here will explore the ways in which this healthcare equity can be achieved by adapting current policies to meet the needs of personalized medicine. If society is not careful, these recent technological advances could lead to widening disparities and new forms of discrimination in medicine. But if the system is intentionally redesigned to protect those most vulnerable, an incredible amount of good could come from this shift towards data-driven decisions and individualized healthcare.

The technical portion of this project also puts the individual patient front and center. The project aims to improve the patient experience during in-office procedures through the development of a multi-sensory stimulation device. This will make IOPs more accessible to those who struggle with procedure-related anxiety, and will streamline the procedure for the attending physician since they will be operating on calmer patients. Both projects proposed here, the STS thesis and technical capstone, will serve as steps towards a future where healthcare is both more effective and more accessible to all individuals in society.

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