Development of a Microplate Accessory for Improved Bacterial Growth

The Unaddressed Role of Religious Beliefs and Emotional Damage in Violations of Informed Consent for Medical Procedures

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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.

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General Research Problem: Revising Old Medical Practices to Greater Serve the Whole of Society

How can out-of-date technologies and practices reduce the effectiveness of medical innovations in benefitting all of society?

The American biotechnology market is currently valued at $1 trillion and is expected to grow to $3 trillion by 2030 (Ltd, 2022). Innovations in healthcare-related technologies, therapeutics, and processes have led to billions of lives being saved and many deadly diseases being cured. As biomedical knowledge improves, technologies and methodologies operated by healthcare professionals must be scrutinously evaluated to ensure maximum benefit to society as a whole. Medical practices have an average shelf life of 5.8 years, necessitating constant innovation in the biotechnology space to remain clinically relevant (Shekelle et al., 2001). Using this metric, one technology that has become outdated is the microplate. Microplates are used to culture, or grow, bacteria that make products vital to the medical, agricultural, and culinary fields. However, they have remained the same for over 30 years and are currently lagging behind other bacterial culture methods (Mishra, 2020). To address this, the technical project will aim to create a lid with baffled extrusions that improves the current microplate culture system to create more effective bacterial products.

In addition to microplates and other technologies, aspects of medical practices can also become outdated when left unchanged for too long. One such practice is informed consent. Although considered the cornerstone of medical ethics (Kakar et al., 2014), issues informed consent when dealing with emotional distress and religion have been identified (Tham et al., 2022). These two ideas were the premise of the *Salandry v. Bryk* (2008) case, in which the

Supreme Court of New York ruled that emotional distress brought about by the violation of a patient's religious beliefs did not constitute compensable damage in informed consent cases. The cited precedent for this decision dates back to 1961 (*Battalla v. State of New York*, 1961), making it one of the oldest unaltered provisions of informed consent in America (Bazzano et al., 2021). Opinions about the prevailing precedent vary across several groups, including religious organizations, civil rights activists, hospitals, courts, and lawmakers. The STS project will analyze the role of these groups in the *Salandy v. Bryk* case to evaluate the current view and effect of emotional damage in breaches of informed consent.

In this Prospectus, proposals for both projects will be developed with the goal of understanding how out-of-date medical practices can negatively affect people in America.

Design of a 3D Printed, Universal 96-Well Plate Baffled Lid to Improve the Growth of Bacteria in Culture

How can the characteristics of baffles extending into wells increase the oxygenation, distribution, and growth of cultured bacteria?

Bacterial cultures are important for a variety of biomedical research applications. They are the foundation of microbiological studies used to investigate the growth, antibiotic susceptibility, and response to stressors that bacteria exhibit (Krishnamurthi et al., 2021). Because of this, the bacterial culture market has grown rapidly over the last few years and is expected to more than double in value by 2032 (Research, 2022). The majority of this market comes from quantifying the number of bacteria in cultures. One of the most commonly employed bacterial quantification methods involves growing bacteria in microplates. A microplate is a flat plate with small cylindrical vessels called wells in which liquid can be stored, with 96-well

microplates being dominant in bacterial research. The advantage of microplates over other enumeration formats is that automated, high throughput, rapid measurements of concentration can be taken with a technique called spectrophotometry, where the absorbance of light passed through a sample is measured and directly correlated with concentration of the sample (Auld et al., 2004). Yet, concerns about the accuracy of microplates in representing physiological bacterial growth have been raised. Studies have shown that microplate readers yield the least reliable bacterial counts of all popular quantification tools (John et al., 2003; Pan et al., 2014). This disparity is due to inadequate dissolved oxygen and dispersion of bacteria inside the wells leading to suboptimal growth conditions (Fisher et al., 2021). Consequentially, these inaccuracies result in flawed data being utilized to develop life-saving drugs, diagnose deadly disease, and understand the role bacteria play in biology.

Several solutions have been offered to enhance the proliferation of bacteria grown in 96-well plates. Of these, two prominent proposals have been altering the frequency and amplitude of microplate shaking inside spectrophotometers and adding sharp corners to the wells in the microplate (Lattermann et al., 2014). Both of these changes are meant to agitate clumps of bacteria built up at the bottom of the wells, causing them to become more well-mixed within the media and allowing for a greater uptake of oxygen by the culture. Although these methods were successful at increasing the rate of oxygen transfer to the bacteria (Lattermann et al., 2014), problems with their application have made them infeasible to implement. First, many different models of spectrophotometers and 96-well plates are commercially sold. With the solution proposing to change the shape of the wells, systematic changes to all of those models would be needed. This would be expensive and time-consuming for both manufacturers and consumers. Also, spectrophotometry involves measuring the amount of light transmitted through a bacterial

culture. When changing shaking patterns or well geometry, light is interfered with and spectrophotometric measurements cannot be taken (Lattermann et al., 2014). Since the primary motivation of 96-well plate cultures is for growth curve and quantification analysis, a design that interrupts this is unusable. Therefore, a solution is needed to increase oxygen transfer rate, mixability, and proliferation that is universal to all 96-well plates and shakers and does not disrupt spectrophotometry. This technical project seeks to create that solution by making a baffled lid that can be placed on top of 96-well plates.

The baffled lid will be produced in two phases: design of the lid itself and testing of the lid. Starting with the lid design, the first step is to fabricate the baffles. Baffles are extruded sections of the lid that extend into each well of the plate. To optimize the geometry and size of the baffles, several iterations are to be made using Fusion 360 CAD software. Evaluation criteria include durability, 3D printability, and light scattering. Durability will be analyzed with Finite Element Analysis simulations run in Fusion 360. Baffles that pass will be 3D-printed via the Elegoo Saturn Resin 3D printer. Print time, required supports, and reproducibility will all be investigated to select the optimal baffle designs. Finally, the Cerillo Stratus spectrophotometer will compare the optical density measurements of media in 96-well plates with and without the baffled lid. If the values are the same, the baffle geometry and size will pass. After this phase, the lid as a whole will be evaluated for snugness of fit to 96-well plates and overall plate-lid height. A snug fit is important to reduce media evaporation, while the overall height must be small enough to fit inside of commercial spectrophotometers.

Lid schematics that meet the previous criteria will undergo testing for efficacy of oxygenation, dispersion, and bacterial growth. Oxygenation of the system by the environment will be tracked by the conversion of sulfite to sulfate catalyzed by cobalt. Dispersion can be

visualized utilizing gram staining of the cultures in the wells. Gram staining utilizes a colorimetric stain to preferentially dye bacteria so they can be distinguished under a microscope (Ponnusamy et al., 2012) The number of bacteria over a fixed volume will be used as a metric of success.. The final test will quantify bacterial growth using the SpectraMax 250 spectrophotometer. For all three tests, a higher value will denote greater success, meaning that the baffled lid prototype that maximizes these values will be selected as the final design. This design will be paired with 96-well plates to improve the growth of bacteria, making the products created from bacterial research more effective and beneficial for all of society.

The Unaddressed Role of Religious Beliefs and Emotional Damage in Violations of Informed Consent for Medical Procedures

How do different American social groups view and get affected by the current implementation of informed consent in matters of religion and emotional distress?

Informed consent in America has protected patients' rights to choose whether or not to receive medical interventions for over a century (Kumar, 2013). It was adopted to increase the autonomy of the people and decrease the power of physicians in making treatment-related decisions. When physicians violate a patient's decision, compensation is meant to be awarded based on the potential or actual harm to the patient (Paterick et al., 2008). Yet, the definition of harm with respect to informed consent has become a controversial topic, as seen in the Supreme Court case of *Salandy v. Bryk*. Here, it was ruled that emotional harm brought about by disregard for a patient's religious beliefs does not constitute a violation of informed consent. Some groups, such as religious organizations and civil rights activists, strongly oppose this decision. Others, including physicians, lawmakers, and the courts, see it as a necessary and correct choice. This

STS project will analyze these groups' opinions on the status of emotional distress and religion in informed consent through use of the *Salandy v. Bryk* case. Compiling this data could reveal whether the current precedent is more harmful or helpful to society.

Background

Over 40 million major surgeries are performed every year in America, all of which require informed consent to be given by the patient (Dobson, 2020). The five required elements that must be explained during informed consent discussions are: "(1) the nature of the procedure, (2) the risks and benefits of the procedure, (3) reasonable alternatives, (4) risks and benefits of alternatives, and (5) assessment of the patient's understanding of elements 1 through 4" (Shah et al., 2022). These elements were told to Joan Salandy, a patient of Kingsbrook Jewish Medical Center who underwent knee replacement surgery from Dr. Eli Bryk. Salandy consented to the knee operation but stated she refused to get blood transfusions as they went against her beliefs as a Jehovah's Witness (Gohel et al., 2005; *Salandy v. Bryk*, 2008). When blood transfusions were performed anyways, Salandy sued Kingsbrook and Bryk for violating her right to informed consent and causing her emotional distress (Dikic et al., 2013). In a contentious verdict, it was decided that Salandy had no grounds for the suit since damages cannot be awarded without fear of physical harm or injury. Religious groups and civil rights activists vehemently opposed this decision, stating that emotional distress should be included in harm as it violates their rights and beliefs. On the other hand, physicians, law-makers, and courts maintained that emotional distress should only be prosecutable if it is related to a patient's fear of physical danger or injury. This STS research will inspect the reasoning behind each group's stance and how it influences the equity of informed consent by looking at the Salandy v Bryk ruling case.

Literature Review

Previous studies have investigated the justification of the *Salandy v. Bryk* ruling and the responses of several groups to the outcome. The court's verdict was based on a precedent that was set in 1961 by the Battalla v. State of New York case (*Battalla v. State of New York,* 1961). In this case, it was decided that a plaintiff may only be compensated for emotional distress caused by a physician's negligence if they had a reason to fear harm or physical injury (Tebano, 2008). Since Salandy was in no danger, the violation of her religious beliefs and subsequent emotional distress were irrelevant to the case. Social groups have varying opinions on this matter. The most neutral opinion comes from the court. The final decision made by the Supreme Court was based on *stare decisis,* which is the doctrine stating courts will uphold previous decisions when ruling on cases (*Stare Decisis,* 2021). Courts will only overrule a precedent when there is "special justification or strong grounds" to do so, which according to the justices was not the case in *Salandy v. Bryk* (Nigro, 2022). Legislators and politicians have historically been in favor of the *Salandy v. Bryk* ruling as well. They believe it would be infeasible to implement laws on emotional harm because it could never be fully proven or disproven (Hanna & Vanclay, 2013). Speculation has also been made that political hesitancy to enact emotional harm laws stems from the largest lobbyist in America: the healthcare industry (Wouters, 2020). Healthcare workers, especially physicians, are strongly against the idea of emotional harm being cause for negligence because it would hinder their ability to do their job. Two previous studies found that over 50% of doctors were scared to perform preventative lung cancer screenings based on the emotional harm it could cause the patient (Ersek et al., 2016; Henderson et al., 2019). Additionally, physicians state that it would be impossible for them to predict whether or not a

patient would experience emotional distress due to the surgery being provided, making them more skeptical to offer high-risk procedures that could be life-saving (Dikic et al., 2013).

In opposition to the opinions summarized above, two social groups have been outspoken about their displeasure with the *Salandy v. Bryk* ruling: religious groups and civil rights activists. Joan Salandy was a Jehovah's Witness, and the disregard for her religious beliefs outraged religious communities. Jehovah's Witnesses professed that the emotional pain suffered by Salandy was far worse than any physical or earthly pain she could have sustained (Katz et al., 2016). This is because eating blood in any form is considered a sin that will eternally damn a soul after death, and blood transfusions are considered a form of "blood feeding", which counts as eating blood (West, 2014). Other religions, such as Buddhists and Christian Scientists, have also professed their distaste for the enforcement of informed consent because it goes against their religious beliefs (Tham et al., 2022). Civil rights activists view the problem from a more constitutional lens, noting that the *Salandy v. Bryk* verdict directly violates people's First Amendment rights to freedom of religion (Butzier & Stevenson, 2014). Further, they believe the 1961 precedent is outdated because it was decided at a time before religious freedom was considered outside of Christian denominations (Beckman, 2009).

The stances of the groups mentioned above will be compiled to capture the overall opinion on emotional distress in informed consent. This data could be used to address the actant's concerns and come up with the best solution for everyone involved.

Methods: Evidence/Data Collection and Analysis

Data on the opinions of the current state of emotional distress in informed consent exemplified by the *Salandy v. Bryk* case will be collected for five selected groups: religious

organizations, civil rights activists, physicians, lawmakers, and the court system. To establish the overall stance of each group, published studies, ethnographic research, newspaper articles, blog posts, and testimonies from the *Salandy v. Bryk* case will be analyzed. One part of this analysis will be determining the justification for the group's ideology based on social and cultural factors. The other will be examining the direct impact the *Salandy v. Bryk* ruling has on the groups and how it informs their stances. Analysis of the participating parties' positions will help illuminate the overall impact of the *Salandy v. Bryk* verdict in America.

Conclusion

The goal of this STS project is to assess the ramifications of the *Salandy v. Bryk* ruling on emotional distress in informed consent. To do this, varying opinions from highly impacted groups will be analyzed and evaluated to understand their influence on society. With this information, future work that considers stances of every group can be used to create more equitable informed consent laws. Through completion of the technical project, a microplate accessory that improves bacterial growth within 96-well plates will be produced. The resultant increase in bacterial growth will make microbiological studies using 96-well plates better at representing actual bacterial growth, leading to more robust, reliable data. Both of these projects confront the much larger issue of complacency within the medical field. The *Salandy v. Bryk* verdict was made based on a precedent set over 60 years ago in 1961. Although its shortcomings with respect to emotional distress and religious beliefs have been scrutinously documented, the precedent has remained intact. Similarly, poor growth conditions reported in 96-well plate cultures have been reported for over a decade, yet no revisions to the technology have been made. These projects bring to light the inadequacy of outdated practices, and if built upon, could result in long overdue changes being implemented.

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