Development of a Microplate Accessory for Improved Bacterial Growth
(Technical project)

A Systematic Review of Operation Smile and Their Definition of Efficacy and Accessibility
(STS project)

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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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Introduction

There is a lack of basic surgical care worldwide with 34.8% of the global population receiving only 3.5% of all surgical procedures (Grimes & Lane, 2013). This disproportionately affects billions of individuals that live in low-income and middle-income countries (LMICs). One way to address this problem was the creation of international surgical organizations or non-governmental organizations (NGOs). These organizations typically come from high-income countries (HIC) and prepare short term volunteer based medical missions in LMICs (Martiniuk et al., 2012). Operation Smile is an international medical not-for-profit organization that provides free surgeries for patients with cleft lip and palate in LMICs (Magee et al., 2012). Cleft lip and cleft palate are craniofacial abnormalities that affect one in every 500 children born. This birth defect can affect a child's nutrient intake and speech and it is recommended that surgery is performed within the first 12 months of life (CDC, 2020). Since their founding in 1982, Operation Smile expanded from treating hundreds of patients to about 13,000 patients in 2020 alone (*Operation Smile*, n.d.). They are headquartered in the United States and their impact on the world is thanks to their large volunteer base from over 30 countries. They are committed to providing safe, sterile surgical environments and post operative care for children and adults that suffer from this genetic abnormality.

Short term medical missions usually provide a very temporary solution to the ongoing surgical burden of disease. Despite this wide scope of care and their impact in these low income regions, NGOs are often criticized. These criticisms include the lack of a sustainable solution and post operative care, limited local engagement etc. (Nagengast et al., 2021). Since Operation Smile is one of the longest running surgical NGOs, their model has evolved to address these issues. They started to utilize local volunteers and taught local medical personnel how to perform

these operations and maintain them afterwards. In addition they have adopted a multidisciplinary medical approach that utilizes nutritionists, psychosocial therapists, orthodontists, and speech pathologists to make sure that the patients are able to thrive post operation (Bermudez et al., 2013). To increase the longevity of their impact, Operation Smile also has established 27 care centers in 18 countries that they work in (*Operation Smile*, n.d.). Although there is a lot of room for improvement, Operation Smile's model attempts to increase the global accessibility of quality surgical care.

The technical portion of my thesis will consist of the design and prototyping of a 96-well microplate accessory that increases oxygenation in the wells. The STS portion will evaluate the efficacy of Operation Smiles model of care through ethical frameworks. Although these topics are very loosely related, it is imperative to evaluate both medical systems and medical technologies and the ethics surrounding them.

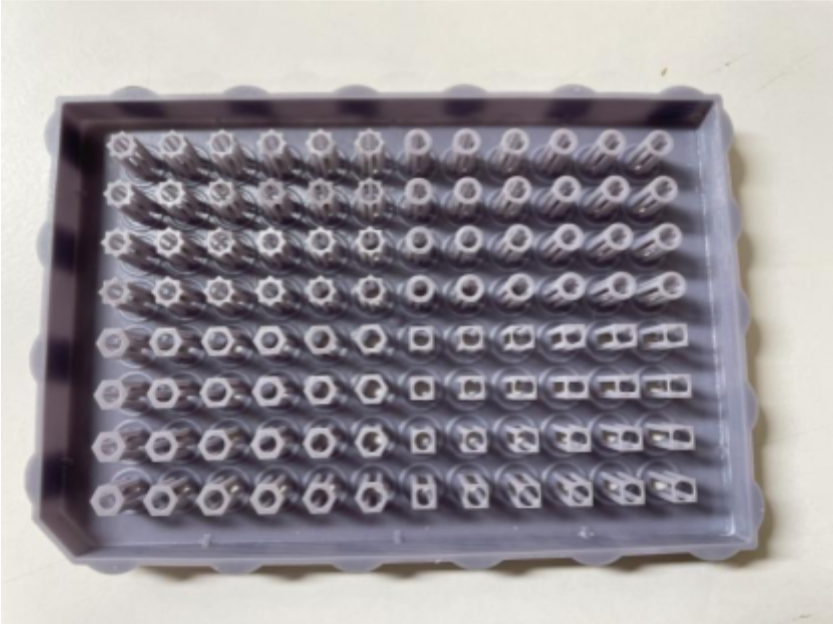
Technical Topic

The global bacterial culture market was valued at $1.89 billion in 2021 and is expected to grow to $2.91 billion by 2030 (Research, 2022). This is due to the importance of bacterial cultures in microbiological studies to investigate virulence factors, antibiotic susceptibility, and the response of bacteria to various environmental and chemical stressors (Krishnamurthi et al., 2021; Kurokawa & Ying, 2017). Accomplishing these tasks requires quantifying bacterial concentration and growth patterns over time, which is most commonly done using spectrophotometric measurements taken by microplate readers. One such microplate reader has been invented solely for this purpose: the Cerillo Stratus. The Stratus takes automated, high throughput optical density measurements of bacteria grown in 96-well plates. Bacterial growth

curves generated by microplates such as the Stratus have become one of the most common tools to analyze culture growth (Shukor & Shukor, 2014). Yet, the accuracy of these machines in representing actual bacterial proliferation has been questioned due to low oxygen transfer rates (OTRs) and poor mixability that fail to mimic natural biological environments (Fisher et al., 2021). Several solutions have been proposed, including alteration of microplate shaking parameters and creation of wells with sharp corners (Lattermann et al., 2014). While these solutions have shown success in increasing OTR and mixability, they also have several problems. There are many variations of shakers however, the most commonly used in lab settings and in the actual spectrophotometer are orbital shakers. In addition there are multiple types of 96-well plates that can be coated, opaque for fluorescence readings, standard. This makes a uniform implementation of these changes unfeasible. Further, light scattering due to irregular well geometries has been recorded, which decreases the accuracy of the optical density measurements (Lattermann et al., 2014).

Our goal is to create a device to increase OTR and mixability that is universal to all 96-well plates and shakers and does not interfere with spectrophotometric measurements. To address these issues we plan to design a universal 96-well plate lid with baffles entering each well. As seen in Figure 1, the lid is designed with extrusions from the bottom face that enters each of the wells, that we refer to as baffles. These baffles are designed with sharp edges that promote mixing of the wells in conjunction with an orbital mixer typically found in standard spectrophotometers (Lattermann et al., 2014). The design of the baffles intentionally have a hole down the middle of it to make sure that it does not disrupt optical density measurements.

Figure 1
3D printed microplate lid with baffles



The technical portion doesn't correlate with the STS problem extremely well, however engineering ethics should be applied to the design of any technology. Whether that be a specific device or a whole system, viewing these through ethical frameworks is essential. It discusses important factors that are often not a priority, in the minds of engineers and can help make important decisions related to the design.

STS Topic

Ethical frameworks provide a set of principles and guidelines for determining what is right or wrong in a given situation. In the case of Operation Smile, an ethical framework can be used to evaluate the organization's actions and determine whether they are morally justifiable. The introduction outlines some of the problems and solutions that Operation Smile has addressed over its lifetime, but are these the most effective? Do their efforts benefit the most people

possible? To answer questions like these I am considering three main ethical frameworks in this paper: Utilitarianism, Kantian theory and rights ethics.

Utilitarians core principle is to act as to bring about the greatest amount of happiness and that anything that doesn't, or produces unhappiness, is bad (Johnson, 2020). It focuses solely on the outcome of an action, disregarding anything else prior. One criticism of Utilitarianism is inability to quantify human happiness (West, 2008). There can also be extreme variation in personal experiences of happiness; however, for my topic I believe there will be a more definitive feeling of happiness and unhappiness. Kantian Theory contrasts utilitarianism and focuses on the intent behind those actions. It emphasizes the importance of acting from duty and what we owe morally to others. It is commonly used in medical ethics but some think that consequences of actions should not be ignored (Annas, 1984). Finally, rights ethics is the idea that human rights are fundamental and that actions must always consider these rights whether they optimize good or not (Schinzinger & Martin, 1999). Common criticisms of right ethics is that it ignores morally significant human attitudes such as community, care and compassion which I think will be important to consider when used in this paper (Kapoor, 2019). I chose these three specifically because I thought they each provide relevant logic in the context of international surgical organization.

I plan on applying these theories to major issues surrounding international surgical NGOs which include sustainability of the care after the mission is over, supplementary issues such as technological needs, challenges of using volunteers, and determining end points of care (Howe et al., 2013). There is almost an endless list of ethical challenges like these due to insufficient global standards and documentation in general (Roche et al., 2017). Operation Smile is a

trailblazer in the field of international surgical organizations and these ethical frameworks can help me assess the aspects of Operation Smile that lead to that success.

Research Question and Methods

This paper will seek to answer the questions: How does Operation Smile model define efficacy and accessibility and how does that model hold when looked through the scope of theoretical ethics? This is an important topic because Operation Smile, and NGOs, are often seen as good producing platforms and a lot of charitable resources are donated to them. With so much time and resources allocated to them it is essential to assess them with ethical theories in mind. I plan to address this question through a literature review because it is the most effective for the scope that I am trying to cover.

I am first going to gather information from Operation Smile's yearly reports, official website, and papers from their research and outcomes department. This will help me answer the first part of my research question and allow me to elaborate on their definition of efficacy and accessibility. This literature review will then also utilize other sources pertaining to ethics and the effectiveness of international surgical organizations. These sources are primarily found on the National Institutes of Health's PubMed. I will then compile the information and use it to lay out the key concepts of the ethical framework and then apply that to what Operation Smile has accomplished. Since Operation Smile works on a global scale I am using data and reports on missions in multiple LMICs but I will be using written material from the past 20 years. I will also be using resources that report on both the visitors and the hosts perspectives to avoid bias in the conclusions that I make.

Conclusion

With billions of people lacking basic surgical care, international surgical organizations continue to be fast growing assistance to the problem. Organizations like Operation Smile provide surgical care for hundreds of thousands of individuals and it is imperative that they are assessed for their efficacy and with ethics in mind. I want to emphasize that the intent of this paper is not to criticize Operation Smile but to rather evaluate their systems and models for care. Once successfully completed the STS portion could help other NGOs define efficacy and accessibility and implement that into their work. In addition, viewing these topics through ethical frameworks can create the standard of care for NGOs. The result of the technical portion is very different but the process of designing and producing a microplate accessory can reemphasize the importance of ethical theory in the design of medical systems and devices.

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