VISUALLY-ASSISTED SPLIT TIP CATHETER FOR ACCURATE POSITIONING AND SURFACTANT ADMINISTRATION FOR PREMATURE NEONATES

THE SOCIO-TECHNICAL WEB OF MEDICAL PRODUCT SAFETY FOR NEONATES

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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

According to the NIH, 2.5 million infants die around the world each year. More than half of these deaths are preventable and are due to a disregard of the Convention on the Rights of the Child (CRC). When the CRC was adopted by the United Nations General Assembly in 1989, it declared that children's health was a human rights issue (Rosa-Mangeret et al, 2022). Article 24 of the CRC states that children have the right to access the "highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health." (United Nations, Adopted 1989). However, infant care, or neonatal care, is flawed as most medical devices and technology used for this population is not specifically made for them, and rather adjusted from technologies made for adult patients (Taha et al, 2023). According to a study conducted by Hwang et al, many pediatric devices are approved with trials conducted in patients under the age of 18, as the FDA considers patients between the ages of 18 to 21 to be pediatric (Hwang et al, 2014). Adaptation from adult medical technology and lack of specific validation for neonatal use is specifically seen in the case of surfactant administration for preterm infants immediately following birth. Surfactant administration is crucial to preterm infant survival to reduce respiratory distress, as underdeveloped lungs are unable to produce surfactant naturally. This process requires a clinician to use a standard intratracheal catheter to directly administer exogenous surfactant to the preterm infant's lungs, and risks unilateral administration which may worsen respiratory conditions or result in death.

In consideration of the CRC's goal to ensure the highest quality of pediatric healthcare for children, I propose the development of a visually-assisted, split-tip intratracheal catheter specifically intended for use in preterm infants. This design will eliminate the risk of worsening the health of the infant while also providing clinicians with real-time assurance of catheter

placement and surfactant administration. Because the challenge of ensuring the highest standard of healthcare for all humans, including the smallest and youngest humans, is sociotechnical in nature, it demands attention to both technical and social aspects to be accomplished successfully. This technical project will require a network of various technical, social, and conceptual resources which will support its goal to create a technology that is validated within preterm infants for the specific purpose of serving preterm infants. To analyze this network of resources, I will utilize the STS framework of actor-network theory to investigate the controversy of Johnson & Johnson baby powder, a talc-based powder that allegedly contained asbestos, a proven carcinogen. In particular, I will examine how the complex relationships between various human and non-human actors contributed to the destabilization of Johnson & Johnson's reputation in the public eye.

Technical Project Proposal

According to the World Health Organization, more than 10% of infants are born before 37 weeks of pregnancy and are considered preterm. Preterm birth is categorized by gestational age, where extreme preterm is considered under 28 weeks of gestation, very preterm is considered between 28 to 32 weeks of gestation, and moderate to late preterm is considered 32 to 37 weeks of gestation. Premature birth is the leading cause of child death under the age of 5 globally, and survivors are subject to a lifetime of disability (World Health Organization, 2023). The most common cause of infant mortality in preterm infants is neonatal respiratory distress syndrome (RDS), occurring in 24,000 infants born in the US each year. RDS presents almost immediately after birth, and predominantly occurs in preterm infants with underdeveloped lungs. If left untreated, symptoms of RDS will worsen and lead to respiratory failure (Yadav et al, 2023). Preterm infants presenting RDS are unable to produce surfactant, which coats the alveoli,

or air sacs, in the lungs to reduce surface tension and prevent lung collapse as the infant begins breathing in air following birth. To manage and treat respiratory distress syndrome, many different methods are used. Some of these methods include antenatal corticosteroids, assisted ventilation and exogenous surfactant therapy. Antenatal corticosteroids are administered to mothers at risk of premature delivery to increase survival rates of the infant and reduce incidence of RDS by accelerating lung development before birth. However, antenatal corticosteroids may also increase risk of stillbirth or other issues during delivery (Roberts et al, 2017). Assisted ventilation includes the use of continuous airway pressure (CPAP) where air is delivered through small tubes inserted into the infant's nose or trachea to provide steady oxygen flow that supports the infant as they breathe on their own (March of Dimes, 2021). Although these technologies are effective in the treatment and prevention of RDS, neither target the cause of RDS at its source. The most direct method of intervention is exogenous surfactant delivery, which is administered via endotracheal tube (ETT) and a thin intratracheal catheter. This catheter is ideally placed in between both lungs to target them equally. Consequences of poor placement can be grave and lead to unilateral surfactant administration which can result in airway obstruction, chest air leak, increased respiratory distress or even death. Many institutions will wait until an X-ray is completed to confirm accurate positioning of the intratracheal catheter to administer surfactant. This method of verification requires unnecessary radiation exposure for these infants, and deprives clinicians of valuable time under critical circumstances (Yadav et al, 2023).

The standard technique of surfactant administration is inefficient in providing an immediate response to reducing RDS occurrence in preterm infants due to the amount of time between birth and intubation. The aim of this technical project is to improve on the existing standard of care for surfactant administration by creating a visually-assisted catheter with a

split-tip mechanism to ensure accurate positioning to accelerate this process and increase survival for preterm infants. By implementing a method of visualization using a micro camera, clinicians will be able to verify catheter placement in real time, eliminating the need for additional time and an X-ray before surfactant administration. Along with the split-tip capability, the catheter will be able to reach both lungs simultaneously without risk of unilateral administration. To develop this catheter, a design will first have to be developed within CAD software to create a model of an optimized product that prioritizes ideal visual aid placement and fluid flow within the size constraints. Materials will need to be sourced from the UVA hospital as well as manufacturers of medical grade cameras and additional resources. These materials will then need to be assembled using soldering techniques to create a suitable product that can be tested on a simulated patient. This testing will verify ease of use for clinicians as well as validation of materials to be biocompatible in accordance with relevant ISO medical device standards.

STS Project Proposal

Johnson and Johnson Baby Powder has been a household staple since the late 1800s. It is most commonly used to treat diaper rash for infants and is a popular personal skincare product. The main ingredient used in Johnson and Johnson's Baby Powder is talcum powder, which is derived from talc, a naturally occurring mineral that sometimes contains asbestos. Asbestos is a group of fiber minerals that is carcinogenic when inhaled. The FDA began testing talc products in 1976 after traces of asbestos were found in talc powder, yet Johnson and Johnson's Baby Powder had tested positive for asbestos contamination in 1957. Johnson and Johnson claimed that there was no asbestos within any sample of their product produced in the years preceding FDA regulation of products containing talc powder. However, Johnson and Johnson's testing

allowed traces of asbestos to remain undetected within the fraction of talc they tested (Girion, 2018). Since then, over 50,000 lawsuits have been filed against Johnson & Johnson alleging that their Baby Powder caused several forms of cancer in its users (Roush, 2024). For years, Johnson and Johnson was marketing to and profiting off of endangering infants and their families in addition to all other users of their highly versatile product. A Reuters investigation revealed that many documents disclosing asbestos-positive tests were kept private from the FDA and the public in efforts to hinder asbestos regulation in talc products as well as research into health risks related to talc (Girion, 2018). This evidence against Johnson and Johnson was brought to light after users speculated that the Baby Powder caused their cancers and began a series of investigations into Johnson and Johnson's testing and documentation processes (Roush, 2024).While these litigation efforts were certainly the key catalyst in the revelation of Johnson and Johnson's efforts to avoid being caught in deceiving the FDA and the public, there is a diverse network of various factors that allowed this endangerment to occur. For a technology to become a controversy as complex as the one Johnson and Johnson faced with their Baby Powder, there must be interdependence between each factor involved that plays a role in disrupting the network to gain the overwhelming public response to this case of corporate malpractice.

To frame my analysis of the controversy of Johnson and Johnson's Baby Powder, I will use the science, technology and society (STS) framework of actor-network theory (ANT). Actor-network theory was developed by Michel Callon, Bruno Latour and John Law to describe a specific approach to analyze innovation as "something that is performed" rather than used (Cressman, 2009). This theory outlines engineering as building a network of resources where all technical projects are composed of human and non-human actors that work together to accomplish a specific goal. The actor-network includes technical, social, natural, economic and

conceptual actors that influence the trajectory, success, and failure of a specific innovation. Additionally, I will draw on Michel Callon's concept of translation, which explains the formation and maintenance of a particular actor-network. (Callon, 1984) This concept will be used to further investigate the roles of different actors that failed to regulate Johnson and Johnson's Baby Powder before it caused suffering to its users, and consequently caused the demise of Johnson and Johnson's reputation. The evidence I will utilize to support my argument will predominantly be taken from news media articles and corporate accountability reports, such as the investigation conducted by Reuters.

Conclusion

To address the challenge of ensuring the highest standard of healthcare for all humans, including the smallest and youngest of them, my technical project aims to design and develop a catheter specifically meant for use in premature infants that provides the highest regard for clinician efficiency and patient safety in order to prioritize the improvement and treatment of respiratory distress syndrome. Additionally, my STS project aims to investigate how the controversy of Johnson and Johnson's Baby Powder came to be due to the intricate relationships among technical, social, and conceptual actors. This investigation can effectively guide regulators to understand how interdependence between different relationships can lead to endangerment of consumers and therefore avoid their neglect. Through the parallels that shape medical device development and regulation of standard consumer items, we can work towards innovation that prioritizes each group specifically and ensure quality of life and healthcare for all.

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