MEDICAL MISTRUST AND DEVICE DESIGN: BUILDING NEW BRIDGES OVER DECADES OLD GAPS IN CARE IN THE AFRICAN-AMERICAN COMMUNITY

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William Sande

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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.

ADVISOR

Catherine D. Baritaud, Department of Engineering and Society

MEDICAL MISTRUST AND DEVICE FEAR REMAIN PRESENT ISSUES WORSENED BY COVID-19 YET METHODS OF ALLEVIATION REMAIN ELUSIVE

Medical mistrust is characterized as a lack of trust in medical institutions, processes, and professionals. Medical mistrust is a present and common issue within America, especially in light of the COVID-19 pandemic and subsequent efforts for mass public vaccination. Despite these efforts, at the time of writing this paper, 20% Americans lack at least one dose of a COVID-19 vaccination and 30% have not completed the primary series (CDC, 2020). This issue is particularly poignant in African-American communities where medical mistrust is common and likelihood of vaccination is low (Allen et al., 2022; Williamson & Bigman, 2018). Increases in medical mistrust were significantly associated with a decrease in the likelihood of receiving a vaccination (Thompson et al., 2021). Beyond a reluctance to vaccinate, medical mistrust can also manifest as fear of various medical devices or techniques, such as needles or anesthesia. Often, this mistrust and fear is rooted in a lack of familiarity with the object of fear, as seen with non-medical professionals displaying greater fear toward such objects as compared to medical professionals (Celik & Edipoglu, 2018; Kindler et al., 2000; Shafer et al., 1996). Medical mistrust can also lead to an underutilization of healthcare services, reducing familiarity, and in turn increasing fear and mistrust, leading to a vicious cycle (LaVeist et al., 2009).

In spite of general knowledge of this issue, an effective solution has not yet been established. Part of this problem is that studies concerning medical mistrust often use varying metrics, hampering comparison between them (Benkert et al., 2019). Additionally, the source of medical mistrust in African-American communities is often attributed to notable stories of malpractice such as the Tuskegee study where 400 African-American men were unknowingly infected with syphilis to be studied over a 40-year period, however, it appears to be more likely that medical mistrust within African-American communities is due to larger, systemic issues

rather than the impact of a single story (Brandon et al., 2005; Jaiswal & Halkitis, 2019). Fear of medical devices faces a unique problem in that those who use or experience them, patients, often do not interact with them until the usage occurs, reducing opportunity to develop the kind of familiarity that would alleviate fear. In order to address medical mistrust, properly understanding the issue and preventing the vicious cycle of mistrust leading to underutilization in turn causing more mistrust are paramount.

This STS paper intends to characterize the issues of device fear and medical mistrust in order to propose a solution. This analysis is done within the framework of the social barriers between patients and medical devices altering how a device is perceived within the mind of the patient and the solution is proposed under Actor-Network Theory (ANT) (Latour, 2005) where the role of engineers in the device design pipeline is examined and alterations proposed in order to create a solution. Properly understanding the relationships between how the image a patient has for a medical device and the role an engineer has in that process is critical to formulating solutions to device fear medical mistrust, which is directly related to the technical portion of the project which focuses on the creation of a medical device designed to be used alongside anesthesia.

The technical paper describes the development and construction of an oral airway device intended to be used in facial plastics surgery. Surgery is typically performed under general anesthesia where a patient is fully paralyzed, however, facial plastics may be performed under monitored anesthesia care (MAC) where a patient is partially anesthetized and partially conscious (Taub et al., 2010). Because facial plastics surgery deals with the soft tissues of the face, traditional intubation techniques, such as placing a tube down the throat of the patient, are undesirable as they distort the soft tissues of the face (Halloran et al., 2011; Jaisani et al., 2015).

Given that sufficient oxygen for MAC can be delivered via nasal cannula, surgeons may place a nasal cannula in the mouth of a patient. While this is easier to establish and gives an easier recovery for patients, it risks obstruction during the surgery as the patient may move their mouth or otherwise obstruct airflow from the device. This technical project describes the creation of a device which protects the cannula lines from deformation and obstruction and provides additional stability when placed in the mouth, without distorting the soft tissues of the face.

The tight coupling of the STS and technical paper allows for unique perspectives to be offered in engineer role analysis. Proper understanding of the development of medical mistrust and device fear allow for the creation of effective solutions. Contextualizing the process of medical device development within the greater scheme of device fear development similarly allows for more relevant changes to the development process to be proposed. Medical mistrust remains a clear and present issue in modern society, both from the perspective of health of the mistrustful and from the perspective of those who are not as the health of society becomes evermore interconnected.

MEDICAL MISTRUST IN THE AFRICAN-AMERICAN COMMUNITY

Medical mistrust has been traditionally studied in minority, specifically African-American, communities however this has led to poor explanations of origin (Williamson & Bigman, 2018). This focus in research led to the proposed explanation that medical mistrust in the African-American community was specifically due to singular events which became well-known and established/enforced pre-existing biases in the community against medical institutions and individuals. In contrast to this explanation, research has shown that African-Americans do not have significantly greater knowledge of the Tuskegee study which would support the aforementioned explanation, yet higher levels of medical mistrust remain (Brandon et al., 2005). More recent explanations of medical mistrust tend to instead favor the explanation that the experiences of marginalized groups in society contribute to mistrust of institutions, including medical institutions (Benkert et al., 2019; Jaiswal & Halkitis, 2019).

Such disparities and failures in care include medical professionals believing that African-Americans experience less pain than white Americans and the resulting decrease in treatment efficacy, gaps in maternal mortality rates between African-American and white American mothers, and failures to admit to specialty medical departments for racial minority groups as compared to white patients (CDC, 2022; Eberly et al., 2019; Hoffman et al., 2016). While patients may not be aware that these experiences are indicative of broad social trends, these experiences are nonetheless common and well-known in the African-American community, informing their views of medical institutions and individuals, contributing to medical mistrust.

Traditional framings of medical mistrust often place the responsibility in resolution onto the affected communities. Even within the term “mistrust,” there lies the implication that the

thoughts and beliefs of the community or individual are incorrect or inaccurate. Given the well-studied disparities mentioned previously, this would be an incorrect implication to make. Concerns in the African-American community about the medical system mistreating African-American patients are well-placed and thus the responsibility for resolution is placed on medical institutions, rather than patients, as Jaiswal et. al. (2019) explains:

> Medical mistrust, and conspiracy beliefs in particular, have been conceptualized as a 'cultural barrier,' insinuating that such mistrust is a characteristic of populations of color in the United States. This framing is problematic and likely racist in that it situates the onus to overcome medical mistrust on the population experiencing structural, social, political, and economic exclusion and marginalization, rather than the institutions and entities that have created environments that engender mistrust and sustain institutionalized inequalities. (p. 81)

By understanding the root cause of medical mistrust as resulting disparities in care leading to accurate assessments by African-Americans, we can better understand how to resolve such an issue.

DEVELOPMENT OF DEVICE FEAR

Much like the above discussion on the development of medical mistrust in the African-American community, device fears can often be based in the association of negative experiences with specific locations or objects. In the case of the African-American community, this is found with negative medical experiences shaping a general view of medical institutions. In the case of device fear, this is found with negative medical experiences shaping a general view of the device or technique in question.

Needle fear, a specific case of device fear concerning hypodermic needles, is exceedingly common with needle fear occurring in up to 50% of adolescents and 30% of young adults, which

is especially concerning as the usage of needles for injections is one of the most common medical procedures (McLenon & Rogers, 2019). This fear decreases with age and can result in patients avoiding certain medical procedures.

Needle phobia tends to present with fainting in 75% of those affected. This experience often causes those affected to become anxious not just of the needle, but also of the experience they would have with the needle in fainting. This causes further avoidance of medical procedures, potentially endangering their health, and reinforcing their anxiety around the device (Jenkins, 2014). The remaining 25% of needle phobia, those who do not present with fainting, may result have a negative association with needles at a young age, Jenkins (2014) describes as:

> a patient who recalls being held down as a child while receiving vaccinations, or undergoing anaesthetic, will have learned a paired association of 'needles plus doctors equals pain and distress'. Therefore, being back in that situation produces distress, to the extent that sufferers will simply avoid the situation. (p. 5)

Much like the experiences of the African-American community described above, a learned association between a certain device or institution with a negative experience can cause anxiety, fear, and mistrust of that device or institution.

MEDICAL DEVICE DESIGN NETWORK

Within Actor Network Theory (ANT), a network is composed of actors, which are both humans with agency within the system and non-humans such as pieces of technology (Walsham, 1997). This network has multiple actors with varying interests, goals, and roles that define how each actor behaves within the greater system. In the case of medical device design, the network is comprised of engineers who design the devices, the companies and investors who employ, fund, and direct engineers, government officials and regulatory entities who set the standards by

which engineers work under, physicians who often make requests or present needs to engineers or companies for needed devices, and finally patients who receive the usage of medical devices via government entities or physicians, as described in Figure 1 below:

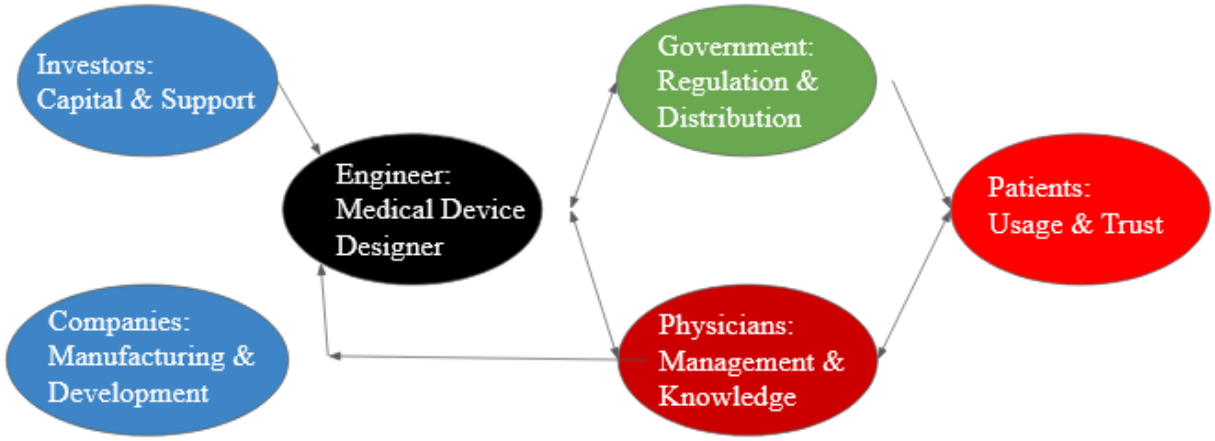

Figure 1: Actor Network Model of Current Relationships in Medical Device Design. Red represents those who utilize medical devices, blue those who invest and profit from them, black those who design from them, and green those who regulate from them. This model demonstrates the lack of connection between patients and engineers (Sande, 2023a).

Figure 1 also depicts the technical aspect of the project. The technical team represents engineers who received input primarily from physicians as to the needs of the device and from the Federal Drug Administration (FDA) in the form of existing, publicly available regulations which constrain the device. Though patients will be the ultimate users of the device, the technical team was not able to communicate directly with them, relying on second-hand information from physicians. Engineers under similar restrictions are then required to either make assumptions about the patient experience, what patients value in device design, or rely on the information provided by physicians, who have a fundamentally different role in and understanding of the device-patient interaction than patients do affected by their own implicit biases.

From a physician's perspective, a medical device is functional. It is a tool that exists to serve a purpose. The physician, as a result of their education and qualification, are able to

understand the mechanisms and intent behind the device. This demystifies and makes a medical device mundane in nature. This does not fully alleviate any fear or anxiety a healthcare professional may have regarding medical devices or techniques, but it does lessen it as can be observed with the significant difference in preoperative anxiety between healthcare professionals and non-healthcare professionals regarding anesthesia (Celik & Edipoglu, 2018; Shafer et al., 1996).

To a patient, a medical device is a foreign object which contains an unknown purpose that works through an unknown method. The general public is not as informed as healthcare professionals or engineers as to the how and why of medical devices which lends them an air of mystery that can easily lead to fear. For example, vaccinations are a medical device which have received much fear throughout their history, such as British parents refusing to vaccinate against pertussis in the 1970s in response to reports of associated negative symptoms or, more notably, a paper published in 1998 by Andrew Wakefield published in The Lancet which attempted to support a connection between the measles, mumps, and rubella vaccinations and the development of autism in children (Hussain et al., 2018). This latter report was fully discredited with time, however, anti-vaccination sentiments remain strong. A 2020 Gallup poll found that while only 10% of Americans are certain that vaccines cause autism, 46% were unsure, leaving only 45% to be certain vaccines do not cause autism, which is the mainstream scientific consensus position (Reinhart, 2020).

In this perspective, patients are those most at risk when using medical devices. If a device malfunctions, patients are most likely to be harmed. If using a device is inherently uncomfortable, patients are most likely to receive that discomfort. During the usage of a medical

device, a patient may not be aware of the underlying process of a medical device or have preexisting misconceptions about what a device is intended to do, leading to anxiety and fear.

SOLUTIONS TO MEDICAL MISTRUST AND DEVICE FEAR

INSTITUTIONAL SOLUTIONS FOR MEDICAL MISTRUST

Both medical mistrust and device fear vary in cause between individuals, but as established above, both are often rooted in negative experiences associating a negative emotion with the device or experience. Another source of mistrust and fear is the unknown nature of medicine to non-healthcare professionals. Exposure to the objects of fear in positive manners appears to be helpful, so this paper proposes a similar solution for medical mistrust and device fear.

Cognitive behavior therapy utilizing a systematic desensitization program appears to be useful in alleviating needle phobia (Jenkins, 2014). This is done by exposing patients to the object of their fear in controlled settings which can lead to new positive experiences and new positive associations with the object of fear in the mind of the patient. Another study from Krijin et. al. found in 2004 that exposure therapy using virtual reality technology was effective at reducing stress related to fears of heights and flying (Krijn et al., 2004). Alterations in device design also represent a promising avenue for reducing anxiety associated with device usage. A 2007 study from Kettwich et. al. demonstrated a significant reduction in stress related to needle fear by using syringes decorated with “simple colorful representative designs” (Kettwich et al., 2007).

Exposure therapy could be utilized for medical mistrust by ensuring that the negative experiences racial minority groups have within the medical system are minimized and new, positive experiences replace them. The positive feedback loop of negative experiences driving

patients away from the medical system reinforcing mistrust would be interrupted if patients have a positive experience with the medical system. Specifically working to ensure that medical professionals are aware that African-Americans do not experience less pain than white Americans, closing the gap in maternal mortality rates, and ensuring equal access to specialty departments in hospitals between racial groups offer these positive experiences in controlled settings that could act as a form of exposure therapy for medical mistrust.

NETWORK ALTERATIONS FOR IMPROVING DEVICE FEAR

The primary issue with the aforementioned medical device design network is that patients are disconnected from engineers and thus unable to provide necessary feedback to ensure that medical devices are designed in such a way as to facilitate positive experiences in patients. This is particularly harmful as patients are most at risk for suffering from poor device design. The ideal alteration would be to provide an avenue for patients to directly communicate with engineers during the design process, as depicted in Figure 2 below:

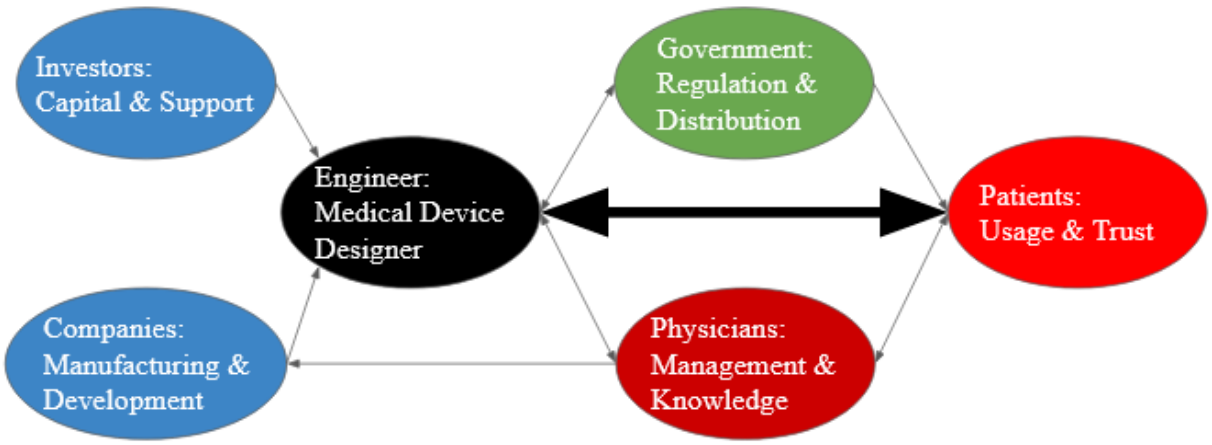

Figure 2: Altered Actor Network Model of Current Relationships in Medical Device Design. Red represents those who utilize medical devices, blue those who invest and profit from them, black those who design from them, and green those who regulate from them. This model shows how engineers receive input from every source in device design, now including patients (Sande, 2023b).

This change could be done by providing access to focus groups of intended end-users for engineers to collaborate with during the design process or allowing patients to submit direct feedback to designers following usage of a device to improve future models. As shown by the Kettwich study, alterations to medical devices are capable of alleviating associated stress and anxiety. Choosing to include patients in the design process would help ensure such alterations perform their intended role. Beyond alterations to the device, this would provide opportunities for patients to be positively exposed to medical devices and to be included in the development process, enhancing understanding and reducing the air of mystery surrounding these devices.

IMPLICATIONS OF REDUCED MEDICAL MISTRUST, DEVICE FEAR, AND FUTURE PATHS OF RESEARCH

Given the widespread nature of medical mistrust, any positive effect in reducing it would go far to improve patient experiences in the medical system and the general health of the country. Disparities in healthcare along racial and ethnic lines resulting from differences in treatment by the medical system are well-documented, well-known and expansive such as the gap in mortality rates between African- and white Americans (Williams & Rucker, 2000). Medical device fear is common and may prevent patients from accessing medical care services but can be alleviated via positive exposure (McLenon & Rogers, 2019; Thurgate & Heppell, 2005). This exposure to medical devices can occur via alterations in the medical device design network by including patients in the design process via direct connections to engineers.

Future research would ideally concern the impacts of exposure therapy at an institutional level and the efficacy of programs designed to encourage those distrustful of the medical system to willingly experience it again. The greatest barrier in this practice would be initiating the

process as the positive feedback loop of negative experiences would reduce the opportunities for medical institutions to attempt to establish new, positive experiences with patients. Future research would also do well to study the impacts of patient inclusion in the medical device design process on the future stress induced by medical device usage in patients, both for those included in the process when using other medical devices and those not included in the process when using the altered medical device.

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