Value Sensitive Design in Medicine

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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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Value Sensitive Design in Africa

Africa has the world's leading mortality rate and most of these deaths are caused by infectious diseases(Deaton & Tortora, 2015). The easiest way to prevent these deaths is through vaccinations(*Vaccine-Preventable Diseases*, n.d.). There are massive obstacles that stand in the way of widespread successful vaccination campaigns in Africa that include supply chain issues, medical professional training, and public trust(Vouking et al., 2019). To address these concerns and increase vaccinations and protections in sub-Saharan Africa a Rebecca Walton, PhD, in the Department of Human Centered Design and Engineering at the University of Washington designed a "Last Mile Vaccination" system that better equipped health workers with data tools that helped them understand what communities needed to be prioritized and to make travel most efficient as vaccines need to be kept at constantly low temperatures. Walton used an ethical theory that doubled as a design methodology known as Value Sensitive Desing (VSD) in her system creation and implementation that she believes was key to the success of her work in creating a system that is still in effect and has been integrated into further communities(Walton & DeRenzi, 2009). VSD was an integral part of this application that has aided health care workers and patients alike. The implementation of VSD into everyday health care, specialty care, and current biomedical ethical theories would serve to bolster a positive patient outcome by integrating patient values with designer and practitioner expertise.

Introduction to Ethical Theories: Biomedical Ethics and Value Sensitive Design

Biomedical ethics according Raanan Gillon, an editor for the *Journal of Medical Ethics* and former president of the British Medical Association, can "…offer a common, basic moral analytical framework and a common, basic moral language" and furthermore, "… help doctors and other health care workers to make decisions when reflecting on moral issues that arise at

work."(Gillon, 1994). Biomedical ethics consists of 4 pillars that are beneficence, nonmaleficence, autonomy, and justice. HIPPA, informed consent, and many other benefits that are afforded to citizens of the United States spring from these pillars(Varkey, 2021)[1]. The principle of beneficence is that it is the physician's responsibility to strive to improve the patient's quality of life, to prevent harm, and overall to act for the benefit of the patient. Nonmaleficence is the responsibility to do no harm. As for autonomy, Kant says that every man has intrinsic and unconditional worth and therefore should be able to exercise his or her self-determination; this is woven into the pillar of autonomy that seeks to respect the basic human rights of patients by obliging physicians to fully inform patients of potential treatments and truthful prognosis[2]. The pillar of justice is often referred to as "distributive justice" and aims to disperse resources and care in an equitable way. This is an incredibly weighty pillar to uphold and there are a plethora of models that attempt to provide a path toward justice in healthcare, but

[1] A vigorous overview of biomedical ethics and its application in modern and historical contexts. "Ethics is an inherent and inseparable part of clinical medicine [1] as the physician has an ethical obligation (i) to benefit the patient, (ii) to avoid or minimize harm, and to (iii) respect the values and preferences of the patient" Varkey, B. (2021). Principles of Clinical Ethics and Their Application to Practice. *Medical Principles and Practice*, *30*(1), 17–28

[2] There are several caveats to the pillar of autonomy. Some are well stated by Varkey, "The principle of autonomy does not extend to persons who lack the capacity (competence) to act autonomously; examples include infants and children and incompetence due to developmental, mental, or physical disorder.", or in consideration of different populations and peoples, "…some minority populations hold views different from that of the majority white population in need for full disclosure, and in decisions about life support (preferring a family-centered approach)" Varkey, B,(2021).

a guiding model splits justice into three categories that are distributive, rights based, and legal justice(Gillon, 1994)[3].

Modern biomedical ethics has its roots in the Percivalian code that was coined after its creator, Thomas Percival who emphasized the importance of the physicians obligation to service, but also a fervent endorsement of paternalism[4] within patient interactions(Library, n.d.). The objective of medical paternalism is the benefit of the patient(Murgic et al., 2015). At its core is that the physician's opinions, knowledge, and decisions are always going to be more informed in a medical sense than the patients' own decisions. In its application physicians apply care without explicit consent or present patients with catered sets of information that they believe to be important regarding treatments options, medicines, clinical trials, or any number of things that they are the expert in. In its extreme, referred to as strong paternalism, it is the opposite of patient autonomy as a physician could certainly obfuscate any information to guide a patient down a path that the physician thinks best or perform large operations without explicit patient consent. This is a highly controversial characteristic of the doctor patient relationship and has

[3] A consideration of these three factors "The best moral strategy for justice that I have found for myself as a health care worker is first to distinguish whether it is I or an organization, profession, or society itself that has to make a decision. For example, "how should I respond to a particular patient who wants an abortion?" is distinct from, "what is this hospital's organizational view on abortion?" and "what is the medical profession's collective view on abortion?" and "what is society's view as expressed in law and practice?" Gillon, R. (1994). Medical ethics: Four principles plus attention to scope. *BMJ*, *309*(6948), 184.

[4] Paternalism is defined by the American Medical Association's Journal of ethics as, "… an action performed with the intent of promoting another's good but occurring against the other's will or without the other's consent [13]. In medicine, it refers to acts of authority by the physician in directing care and distribution of resources to patients." Drolet, B. C., & White, C. L. (2012). Selective Paternalism. *AMA Journal of Ethics*, *14*(7), 582–588.

been subject to much debate (Buchanan, 1978; Chin, n.d.; Drolet & White, 2012; Komrad, 1983). Many see it as a necessity within the medical world as physicians are experts in their field and a level of trust is necessary for positive patient outcomes(Komrad, 1983), while others vehemently oppose what they see as paternalisms twisting of the truth(Buchanan, 1978).

I would argue that some degree of paternalism is required and necessary for physicians to provide the best possible medical care in a timely and professional manner. Many would be familiar with weaker examples of paternalism that benefitted them such as a doctor setting their bone back into place, administering C.P.R., or even just performing a routine examination without ever being explicitly granted permission by the patient. Physicians in those situations are certainly operating off perceived values that patient might hold of life and wellbeing. The shortcoming with biomedical ethics and medical paternalism's efforts to uphold those ethics, is that physicians do not have an intricate understanding of the patients' values. Paternalism could be applied more fairly in its endeavor to meet and uphold the foundations of biomedical ethics if physicians had a more developed knowledge of what patients hold dear. It is my position that Value Sensitive Design could be implemented in patient care situations to improve patient outcomes.

Value Sensitive Design

Value sensitive design (VSD) is an ethical theory and methodology championed and created by Batya Friedman that seeks to develop an in depth understanding of human values and weave them into the design process in a comprehensive and exhaustive manner (Friedman & Hendry, 2019). As Batya puts it best "Value Sensitive Design is a theoretically grounded approach to the design of technology that accounts for human values in a principled and comprehensive manner throughout the design process", VSD seeks to explicitly include users'

values into each part of a design process, in order to shape a more valuable, meaningful, and lasting technology or service (Borning & Muller, 2012)[5]. This theory implements a tripartite methodology[6] that is iterative and additive in hopes of bettering some design through multiple trials. To introduce this methodology, imagine Olympia by Manet. The paint colors do not exist separately or are mutually exclusive from the other, rather they are layered and accent each other. Manet did not use white or black paint just once, but rather their use is seen all over the work in various forms. Some details are precise, as if a knifes edge laid it upon the canvas, other details are brutal and less inconspicuous. Some details or themes resonate through the entire painting and are central to its identity and presence in our mind like the unabashed seductiveness of Victorine Meurent, who dares us to keep looking. Everything together creates the masterpiece. So, too, with VSD the iterations of the parts culminate to become more than just the sum of its steps. These steps, like brush strokes and smears, consist of conceptual, empirical, and technical investigations of value. These steps are constantly utilized and tweaked throughout the process in the hope of positively impacting a target population.

The conceptual investigation identifies the direct and indirect stakeholders in a technology and its use, and furthermore, their values that are meant to be upheld and strengthened by the system or technology. If a designer is crafting your new home and you value open spaces and scenic vistas, they would strive to incorporate those values into their design,

[5] A description by Muller of VSD acting as an "established theory and method for addressing issues of values in a systematic and principled fashion in the design process" Borning, A., & Muller, M. (2012). Next steps for value sensitive design, *Proceedings of the SIGCHI Conference on Human Factors in Computing Systems*, 1125–1134

[6] "Value Sensitive Design builds on an iterative methodology that integrates conceptual, empirical, and technical investigations", Friedman, (2019)

while also keeping in mind that you will have visitors that will have their own interaction with the home. The designer seeks to bolster the values of each stakeholder, but they must understand each other hence the investigation of conceptual values. The technical investigation commits to a tangible realization of the values of the stakeholders into some form of technology or service rendered. The same designer who understands the value of scenic views might create plans that place the home on the highest point of the property or include large sweeping windows that show the beauty of the property. These plans can be shown to an owner who can have their own interaction and reaction to them that can highlight existing values or illuminate new ones. The owner may realize that they prefer a shorter driveway, and this value can be realized again in new technical investigation. The empirical investigation is used to understand how well the design upholds user values using quantitative observations. For a doctor who has performed a knee replacement these quantitative observations might include how quickly was a patient able to return to a previous quality of life or how many stairs they can climb without pain. In this case if the conceptual investigation showed that the patients values centered around their freedom of movement, then the technical would create a surgery that seeks to achieve that, and the empirical would inform the designer of how well they met those values in a quantitative manner. These are not stand alone or sequential steps, but methods that can be iterative and each can be employed throughout the process. Each can inform the next or be molded by the last.

What is Value[7]? It is inherently intrinsic and unique to everyone, but people also identify with shared values in communities that they identify with. The concept of value has its roots in

[7] Value and success within healthcare have classically been defined by "the health outcomes achieved per dollar spent.", which the author would argue is too encompassing and relies only on preconceived notions of value without operating from a more stringent investigation of patient value.(Porter, 2010)

antiquity with philosophers like Plato, Averroes, and Aristotle stating that society and the individual should champion truth, beauty, the right, and logic. More modern theory tries to dissuade and distinguish fact from value as what "is" is not always what "should be" (*Principia Ethica, by George Edward Moore—A Project Gutenberg eBook*, n.d.). Values can be mundane or a lofty ideal of morality to be held in the highest regard. People often value the time they get to spend with family, a walk in the park, their morning caffeine, or some other vice. They could also be a torchbearer for prolife or prochoice causes as they identify with the values set forth or emphasized by those communities and organizations. Some values are placed above others by the individual or society. Some values are forgotten until the capability to exercise them is taken away. Many do not wake up with a sense of gratitude that we can walk or see the world around us, but simply imagine the alternative and it is easy to be reminded how important these abilities are. Values must be elucidated[8] and tested to have a deeper understanding of their meanings to each person. Once a greater understanding is achieved it can be thoughtfully incorporated and woven into daily life and innovation just like any other metric.

The Conceptual Investigation

The conceptual investigation seeks to identify the values of a patient or population that are relevant to the design, process, or drug being created(Cummings, 2006). Literature identifies 12 important constructs and ideas that offer a form of guidance to the would-be designer of a project. These include human welfare, ownership and property, privacy, freedom from bias,

[8] The nature of the tripartite methodology and iterative application of VSD is made necessary by the fact that "The investigation of intrinsic values is complicated by the fact that the value of a whole may be different from the sum of the values of its parts…", so a revisiting of values is a central tenant of VSD (*Principia Ethica, by George Edward Moore—A Project Gutenberg eBook*, n.d.)

universal usability, trust, autonomy, informed consent, accountability, calmness, identity, and environmental sustainability. It is important to understand that each of these contains nuances and depth beyond the surface that must be illuminated for each population. Human welfare can mean different things in the cases of a new invasive surgery compared to an ankle brace, as in their patients will have different ideas of expected welfare. The conceptual investigation examines how the relevant human values that are identified among a population are affected by the intervention and use of the design.

This step also identifies direct and indirect stakeholders that would be affected by the project(Friedman & Hendry, 2019)[9]. For example with the creation of a new medical records system in a hospital system in Uganda, the Ministry of Health was not consulted on the implementation of the system in the hospitals it had purview over(Walton & DeRenzi, 2009). The program was eventually shut down and concerns over privacy were cited by the Ministry. It is logical to say that indirect stakeholders were not deemed important under the design of this project. Alternatively, in the world of personalized medicine the stakeholders are the main concern and many treatments or interventions are tailored to the patient directly with things like nano medicine(Hoven, 2017), CAR-T cell therapy to actively fight blood and bone caners (Sterner & Sterner, 2021), or the creation of nocturnal seizure detectors using machine learning

[9] A direct stakeholder is someone who would interact with or impacted directly by a technology, service, or treatment, while indirect are only peripherally associated with the technology. A direct stakeholder might be the user of a brace or medicine while an indirect stakeholder may be their caretaker or even their physician. It is important to understand the values of both to foster better interactions with the technology or service. Cummings, M.L. Integrating ethics in design through the value-sensitive design approach. *SCI ENG ETHICS* **12**, 701–715 (2006)

(Andel et al., 2015). The inclusion and consideration of specific patient values and a comprehension of the stakeholder can create more nuanced and targeted treatments.

The Empirical Investigation

The less philosophical and rhetorical aspects of this methodology must be considered with the same rigor. Conceptual designs need to be evaluated for validity, weight, and success. Empirical investigations are used to understand how the technology will be used in a human context. Depending on the project, the full gambit of widely accepted scientific research methods and protocols could be applicable. These include interviews with subjects, measurements of success, qualitative and quantitative metrics, experimental practices like placebo and treatment groups, blind studies, clinical trials, and surveys. In this step it is critical to question and evaluate the subjects on how their values have been supported or diminished by the design, whether there are tradeoffs, or how they've had to adapt their behaviors to fit the design. These questions will inform the next iteration of the design and hopefully improve the results of the design. For example, in the creation of the braces for the technical part of this project the team documented performance metrics[10] of the users while wearing similar braces and asked patients how they perceived the results in relation to several metrics that covered accomplished mobility, return to strength, and ease of use.

[10] Several quantitative tests were conducted to empiracly investigate how previously acquired valued had been met or upheld by the brace. These tests included: Knee Outcome Survey – Activities of Daily Living Scale (KOS-ADLS), a Global Rating Score (GRS) of knee function, maximal volitional isometric contraction (MVIC) to ascertain strength of both limbs pre and post-op, hop tests to understand limb symmetry indexes as seen in(Goodstadt et al., 2013).

The Technical Investigation

Technical investigations seek to uphold user value with actual features of the technology. This may seem like empirical investigations, but this process is a more proactive design method that seeks to satisfy the values of the user that are identified in the conceptual investigations. For example, a university in Finland sought to install solar panels on the roof of one of their main buildings and they prided themselves on being "green" and culturally rich with a deep heritage and mindfulness of their prestige and image. Building on these conceptual investigations of value, technical investigations of prototypes and designs were drafted that did their best to uphold the conceptual values while also meeting economic and time constraints(Friedman & Hendry, 2019). After numerous meetings with architects and direct and indirect stakeholders in the project to exhaustively evaluate conceptual values and ways that humans interact with these designs, installation of the array was accomplished, and empirical investigations sought to understand how successful and thorough previous investigations were. After numerous iterations of each of these techniques, the university was left with an array that accomplished many of the values it set forth in the very beginning of the project. The iteration of the methodologies benefitted the university by first seeking to understand and then ensure that their values were met and upheld throughout the project.

Literature Review & Findings

Biomedical innovation is meant to improve people's lives. In pursuit of this there are many endeavors that bear fruit such as the creation and approval of nearly 42 novel drugs a year since 2013 (Commissioner, 2023). New and innovative procedures like employing ultrasound to

break the blood brain barrier has potentially overcome what has historically been the main impediment in the effectiveness of many drugs that could be used to fight crippling diseases like Alzheimer's (Konofagou et al., 2012) or the determination of a method that could take a terminally differentiated stem cell of the skin and alter it into a cell that could turn into any cell in the body[11] (Takahashi & Yamanaka, 2006). Potential treatments of debilitating injuries sustained on the battlefield are also on the rise with the investigation of implantable devices that help the body heal (Corona et al., 2014; Wu et al., 2012). Transplants of blood and even various organs from other animals to a human patient (Xenotransplantation) has been around for centuries (Cooper, 2012), but the recent initially successful transplantation of a pig heart to a Lawrence Faucette has taken us leaps and bounds past wiring up frog blood to an aristocrat(*2023 News - UM Medicine Faculty-Scientists and Clinicians Perform Second Historic Transplant of Pig Heart into Patient with End-Stage Cardiovascular Disease | University of Maryland School of Medicine*, n.d.).

There is no shortage of innovation for good in science, but there is often a disconnect between the stated goals of innovation and the values of those whom it is meant to serve. There

[11] Stem cells are unspecialized cells in the organism that differentiate into all cell types in the body. During embryonic development stem cells are referred to as totipotent meaning they can differentiate into all cells in the body. As the organism matures the stem cells lose "potency" and can differentiate into fewer cell types. Zakrzewski, W., Dobrzyński, M., Szymonowicz, M., & Rybak, Z. (2019). Stem cells: Past, present, and future. *Stem Cell Research & Therapy*, *10*(1), 68. As cells differentiate down their paths they become terminally differentiated and are no longer capable of changing cell types; this was until Yamanaka and others discovered a way to bring those terminally differentiated cells back to the top of the ladder into a state of pluripotency, which can form any of the three germ layers of the early embryo. Takahashi, K., & Yamanaka, S. (2006). Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors. *Cell*, *126*(4), 663–676.

are some tragic examples of this disconnect that have been well documented within many of our lifetimes. AIDS was once the No. 1 cause of death in men ages 25 to 44 (*40 Years of AIDS*, 2021), and it was nearly 8 years after its discovery, and thousands of deaths, before any approved drugs came to market. AZT was a failed cancer medication that was found to stop the AIDS virus in a statistically significant amount of subjects (*The First AIDS Drugs | Center for Cancer Research*, n.d.). AZT was also incredibly toxic and caused the deaths of many young men and women even in initial trials. If it did not kill you, many felt severely poisoned by the drug and had little to no quality of life, (*The Story Behind the First AIDS Drug, Approved 30 Years Ago*, 2017). Patients felt that their lives had been disregarded and believed doctors considered them lucky to even be alive and many discontinued their role in trials to enjoy the rest of whatever life they might live with the disease instead of continuing to take a drug that destroyed their quality of life. The drug and its use were designed to prevent death, but it ignored everything in between life and death.

Medications are supposed to solve some problems, yet they often create another. We are currently living through an opioid epidemic that has claimed nearly 83000 lives in 2023 alone(*Provisional Data Shows U.S. Drug Overdose Deaths Top 100,000 in 2022 | Blogs | CDC*, 2023; *Understanding the Opioid Overdose Epidemic | Opioids | CDC*, 2023). This epidemic was manufactured and marketed by Purdue Pharma and the Sackler family(Keefe, 2021), who are now on hook for many billions of dollars after numerous lawsuits brought against them by their victims(*Fate of Billions for Opioid Victims From Sacklers Rests With Supreme Court - The New York Times*, n.d.). Purdue Pharma knowingly misled doctors and patients alike into prescribing and taking these medications despite explicit knowledge of the risks of addiction and dependency. The values of these patients were not ascertained in palliative care, which may have

elucidated an aversion to powerful drugs or risks to addiction of each patient. It is now common practice to have patients intricately involved and educated on their own palliative care(Crawford et al., 2002). In a particularly damning example of their marketing of these drugs is an ad from 1998, paid for by Purdue, that was meant for doctors to show their patients who were apprehensive of taking the medications prescribed to them. A striking line from the ad that has landed Purdue and the ad agency in court is: “Some patients may be afraid of taking opioids because they are perceived as too strong, or addictive, but that is far from actual fact. Less than 1% of patients taking opioid actually become addicted.”.

In the tragedies above there existed a throughline that was the failure to incorporate patient and consumer value into their design and implementation. It may seem that Doctors were acting off assumed values that set a minimum bar of survival or numbed pain, but maybe there was more to each of those patients than those extremes. AZT and its trials have led to decades of antiviral drug discovery (*Antiretroviral Drug Discovery and Development | NIAID*, 2024) and opioids at large help chronically and acutely ill patients lead normal lives (Hui & Bruera, 2016), but each of them has in the past been applied unethically and without deep consideration of patient value. Had VSD been applied it might have in the very least shown the physicians that their patients may have had a more intricate set of values than the minimum values of survival and numbness.

The central tenants of medical care are to promote health and well-being, prevent diseases that cause pain and suffering, and the prolonging of life(Callahan, 1998). Medical professionals take the Hippocratic oath which centers around 4 ethical pillars that guide them in their interactions, research, and care for patients. Beneficence, nonmaleficence, autonomy, and justice constitute these 4 pillars and are themselves riddled with nuance and their own set of

prescribed value systems that seek to improve the quality of life of patients(Varkey, 2021). There are several methods that seek to interweave these pillars and ethical standards into everyday care including soft or hard paternalism (Chin, n.d.), care ethics (Maio, 2018; Schneiderman et al., 1994), and other models that champion the autonomy of the patient and informed consent(Miles, 2005). Value sensitive design is a worthy addition to these longstanding ethical frameworks because it can allow for a more stringent incorporation of patient values into their daily care. There are many real-world examples of how VSD has been integrated into projects and how it has helped further the goals of those projects.

As mentioned earlier the CommCare project in Africa that aimed to better integrate patient information and disseminate it more effectively to vaccine distribution centers(Walton & DeRenzi, 2009). The group from Washington University was able to investigate what kinds of data was used and implemented by vaccine distribution center in order to complete their goals, then gathered an understanding of the needed technical aspects of a project that would increase the efficiency of distribution centers including analytical tools, training for streamlined on boarding, and cooling technologies for the vaccines and more. Finally, they were able to test how effective these methods were at contributing to the success of the distribution centers and health ministries goals of increasing vaccination statuses within their communities. They believe that their application of VSD was pivotal to the overall success and longevity of the project, as their systems are still in place it shows that values and standards continue to be met by the system, which also can evolve and be modified if the values change or goals reform around new needs. The integration of the user value into the design of this project undoubtedly elevated the performance of the system, so is the value in VSD.

Another study that implemented VSD for its support of human value was a research forum that sought to elevate a form of ambulatory care for seniors in rehabilitation programs for patients with disabilities caused by CNS[12] malfunction(Mueller et al., 2018). The group from the University of Siegen was attempting to evaluate the efficacy of digital devices in aiding health care workers in their daily treatments of seniors in health care centers. The goals of the project were to improve the integration of these devices that could assist in the care and create more effective treatments for the seniors by accruing valuable data and presenting it after being processed by software that could suggest treatments informed from even larger data sets. At the same time they were evaluating the technologies efficacy in this endeavor they also had to evaluate and understand the values that the patients had. Many of these devices were wearable and or interactive so the user-device relationship was intimate and full of nuance that deserved to be paid attention to. Had VSD not been in place a massive relationship between user and device may have been neglected. With VSD the group was able to better incorporate and improve upon features of the device that elevated the values of the users, which included a return to their previous quality of life, the ability to stand up free of help, and their privacy. The group believes that VSD was pivotal to their project and created a relationship of trust that is often neglected in senior care.

Trust is a massively important aspect of user interaction with medical devices. Trust that the system can be relied upon would seem an obvious value of the user, but this user value can be overlooked by designers. A group in the Netherlands decided to incorporate these values using

[12] There are a plethora of diseases that cause degeneration, malfunction, or loss of function in the central nervous system, which is defined as the brain and spinal cord. Typically, these diseases are degenerative in nature and cause a loss of a basic quality of life. In some cases, they can be abated with medications, but many still suffer from the side effects and lose motor functions or sensory aspects are highly impaired. Ambulatory and other physio adaptive forms of physical therapy can be implemented to build strength and regain some quality of life. (*Overview of Nervous System Disorders*, 2021)

VSD as a guiding framework in their creation of an at home nocturnal seizure detector(Andel et al., 2015). When stakeholders were asked about some of their most explicit values, many were elucidated, but namely health, trust, autonomy, accessibility, and reliability were among the chief concerns. These values then informed the design and iterative improvements upon the design that culminated in a device that was able to detect a seizure and alert a caregiver for a safer environment to be created for the user in the event of an episode. Users reported a peace of mind that was cultivated by the device and that was absent from their interactions with other devices or from life without the device. It seems that the initial investigation of value was integral to the eventual success of the device among its users.

All these examples involve a system seeking to garner a deeper understanding of a user value and integrate those predetermined values into some system that seeks to elevate them through continued use. Other healthcare concerns could absolutely be bettered by the application and implementation of VSD into their practice as it serves to create trust, foster longevity, and improve the efficacy of a system or device for some user.

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