Using Care Ethics to Examine the Retracted Article by Andrew Wakefield, et al.: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

STS Research Paper
Presented to the Faculty of the
School of Engineering and Applied Science
University of Virginia

By

Rebecca Byrd

April 13, 2020

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.

Signed: ____

Approved: ____ Date _________________________
Benjamin J. Laugelli, Assistant Professor, Department of Engineering and Society

Introduction

Vaccines have been used for over 220 years to protect humans against certain biological diseases and viruses, such as polio, smallpox, and measles. Some of the developed vaccines have been so effective that the World Health Organization (WHO) has considered the diseases to be globally eradicated, like smallpox. However, there have been a few incidents which have caused the general population to lose trust in the scientific community, including the 2010 retraction of a paper published in the scientific journal, Lancet (Wakefield et al., 1998). The paper, titled "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" (1998), stated that there is a relationship between the measles, mumps, and rubella (MMR) vaccine, that is first given to children around the ages of 12-15 months, and the development of autism (Center for Disease Control, 2019). Wakefield, et al. were found guilty of ethical violations, as they conducted intrusive studies on the children in the study without obtaining the necessary clearances (Rao & Andrade, 2011). However, solely viewing this case as an error in scientific testing methods will undermine the ethical issues of reporting falsified or biased data to the public. Current scholars fail to mention Wakefield's duty to the scientific community, in addition to the general public, to report accurate scientific facts so that patients can make informed decisions. If we do not continue to uphold standards for the scientific community then society will lack the understanding of the importance of novel scientific innovation.

I will examine the case of the retracted paper written by Andrew Wakefield, et al. through the ethical framework of care ethics to show that the researchers can be held morally responsible for the recent resurgence in the anti-vaccination movement. I will illustrate this claim by examining the principles of healthcare ethics, as proposed by Tom L. Beauchamp, focusing on how the researchers had a duty of care to the medical community, but neglected to uphold the principles of nonmaleficence, beneficence, and justice that are essential for ethical medical care (Ashcroft et al., 2007).

Background

The first vaccine was developed in 1796 by Edward Jenner when he discovered that milkmaids who had previously contracted cowpox did not develop smallpox (College of Physicians of Philadelphia, n.d.). Vaccines are a mixture of antibodies, adjuvants, and stabilizers for a specific disease or subset of diseases that work together to cause a limited-scope immune response that can create memory immune cells that help the body respond faster and more effectively if the person is ever exposed to the live virus (Center for Disease Control, 2018).

Although many consider the development of vaccines to be one of the greatest feats of modern medicine, there have been incidents which have caused the general population to lose trust in the scientific community. This includes the Cutter Incident, in which live polio virus was administered to over 200,000 patients instead of the inactivated form of the virus, resulting in over 40,000 people being diagnosed with the paralyzing disease (Lambert, 2006).

Herd immunity is defined as a population's resistance to the spread of a contagious disease when a certain percentage of the population has been exposed to the disease, either by vaccination or by having previously contracted the disease (VaccinesToday, 2015). The vaccination rate needed to achieve herd immunity is typically above 80%, and can be upwards of 90% for more contagious diseases such as measles. (Bowes, 2016; Center for Disease Control, 1993). When people begin to distrust the scientific community and vaccination rates decrease, the threshold for herd immunity will be in danger of not being reached. This puts a large number of people and communities at risk for highly contagious and preventable diseases.

Literature Review

Many academics have examined Wakefield's study that related the MMR vaccine to autism diagnoses, and none have been able to replicate the data he produced. A significant portion of their analyses focus on the fallacies in Wakefield's scientific testing method and the ethics of unauthorized invasion of patient information during the study.

Rao and Andrade explain that this case was a scientific blasphemy, stating that Wakefield's extremely small sample size of 12 children and the uncontrolled nature of the experimental design led to the study's fraudulent conclusions (Rao & Andrade, 2011). They also examine the unethical nature by which Wakefield received funding for his study. Upon retractions from 10 of the 12 co-authors on the paper, *Lancet*, the medical journal that published the article, revealed that Wakefield had failed to disclose his financial interests. It was later discovered that his study was financially supported by lawyers who were engaged in lawsuits against vaccine-producing companies, who had motive for novel "scientific" results that conveniently aligned with their case. Their argument also focuses on the implications of the study, including the waste of time and resources that were spent on trying to repeat and verify the data that Wakefield had produced. However, the scholars failed to address the ethical implications of publishing invalid scientific facts and how Wakefield failed to execute his duty of care to both his patients and to the general public.

Fiona Fleck analyzed Andrew Wakefield's actions as they apply to the ethics of research article publication (Fleck, 2004). In particular, she wants editors to be able to ensure that all conflicts of interest relating to the author's research are declared, in order to prevent biased and untruthful results from being published. Wakefield's study was financed by lawyers who had personal interest in the results of his study. This was potentially a cause for the biased and flawed results. Although Fleck mentions that the ethics of the research method were flawed, she fails to mention how Wakefield's actions impacted the global anti-vaccination movement.

These scholars believe that Wakefield was unethical in his motives and scientific practices, but fail to address the duty of care that Wakefield, as a doctor and researcher in a position of authority, owes to the greater public. By addressing this duty of care produced by the asymmetrical relationship between doctors and patients that scholars fail to address, I will shed light on the moral obligations of doctors to people who do not know as much about the medical field.

Conceptual Framework

The morality of Wakefield's actions can be examined using care ethics as it relates to the analysis of asymmetrical relationships. Care ethics, initially inspired by the work of Carol Gillian, is an ethical framework that emphasizes the importance of relationships in moral decision making. She states that morals are not developed by learning general moral principles -- it is the relationships you have with people that influence how you act. The care ethics framework also suggests that recognition of vulnerability and dependence play an important role in living morally, "especially if the relationships are asymmetrical, such as the relationship between a doctor and patient" (van de Poel & Royakkers, 2011). This is the exact relationship being examined in this case study, as doctors have a greater knowledge of the medical field than the majority of the world. Further, in every relationship, the level of care we expect to owe and/or receive is a result of the recognition of the types of relationships we are a part of and the current situation we are in. This can be applied to the doctor-patient relationship to mean that patients expect to receive a higher level of care from their doctors than they owe back to the doctor.

Tom Beauchamp defined three elements of healthcare ethics principles that help us better understand how care ethics can be applied and interpreted in the medical field. These principles are: nonmaleficence, beneficence, and justice. Nonmaleficence in the context of the healthcare field means that doctors and other healthcare professionals should minimize the amount of risk of harm to a patient while working to better the patient's current quality of life (Ashcroft et al., 2007). Beneficence in the medical field is similar to nonmaleficence, but exceeds the scope of nonmaleficence in the sense that it is more concerned with the intentions behind a doctor's actions rather than the amount of harm that they do or do not inflict upon the patient. Although this is not a requirement by law, moral doctors, as they are viewed through care ethics, are ones who aim to help every single one of their patients to the best of their ability. Beauchamp states "every civilized society is a cooperative venture structured by moral, legal, and cultural principles of justice that define the terms of cooperation" (Ashcroft et al., 2007). Here, he indicates that every person deserves the right to make an educated decision about their health based on facts that are fair and accurate. Additionally, Beauchamp states that justice in the healthcare field implies that every similar case should be treated with the same amount of attention and respect.

The following analysis will examine the case of Andrew Wakefield's publication of the later retracted article titled, "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" through the context of care ethics based on the asymmetrical relationship between a doctor and their patient(s). I will use Beauchamp's healthcare ethics principles of nonmaleficence, beneficence, and justice to measure Wakefield's ability to follow through with these responsibilities that come with the duty of care that he owes. Because of the global nature of healthcare and disease, Wakefield's duty of care extends not only to his patients, but also the general public, due to the interconnectedness of today's society.

Analysis

Wakefield, et al. failed to deliver care ethics to the general public via violation of Beauchamp's principles of healthcare ethics. The American Council for Graduate Medical Education (ACGME) lists six core competencies for all medical doctors, including patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice (ECFMG, 2003). The actions of Wakefield, et al. directly violate these competency requirements that reinforce the ideas behind Beauchamp's *Principles of Health Care Ethics*. The following sections highlight areas where Wakefield, et al. failed to fulfill their duty of care by examining three of Beauchamp's principles of healthcare ethics with respect to care ethics: nonmaleficence, beneficence, and justice.

Nonmaleficence

Nonmaleficence means non-harming or inflicting the least harm possible to reach a beneficial outcome (Sundean & McGrath, n.d.). Through the lens of care ethics, nonmaleficence implies that people will help one another by optimizing outcomes while simultaneously minimizing the amount of potential risk of harm. One of the most quoted principles in the history of health codes is *primum non nocere*, or "above all, do no harm." This implies that medical professionals must treat their patients to the best of their abilities by giving the patient the best possible quality of care. Wakefield et al. failed to act with nonmaleficence, as they caused harm to the patients in the study, the greater medical and scientific communities, and the general public. Wakefield's maleficence, therefore, was a cause behind the resurgence in the anti-vaccination movement.

While Wakefield did not physically harm the children in his study long-term, he acted unethically as he performed the study without obtaining the necessary consents from the parents and/or guardians of the children participating in the study, thereby violating the children's privacy. In a video of a speech that Wakefield gave at a meeting of parents of children with autism in 1999, it was disclosed that Wakefield unethically paid children at his son's 10th birthday party £5 ($8) each to give blood samples to use for his research (Harrell, 2010). Wakefield claims that he made up these details to "amuse his listeners" (Dyer, 2008). Whether or not this detail of his experimental process is true does not affect the fact that Wakefield was unethical with respect to care ethics. If the statement is true and he did collect blood samples at the party, he failed his duty of care to the children at the party and their parents by using their blood samples without appropriate consent. If the statement is false, then Wakefield failed his duty of care and respect to the parents at the speech by misleading them and providing false information. In both cases, Wakefield violates the duty of care that is owed to the children and their parents due to their asymmetrical relationship.

Wakefield also harmed the reputation of the scientific and medical communities as details of his experimental methods were released. In addition to his unethical sample collection methods, it was later discovered that his patient sample was not representative of the general population; many of the participants were associated with lawsuits against vaccine-producing companies for prior potential injury caused by vaccination. This means that the results of his study are inconclusive, and it is therefore inappropriate and unethical to draw any significant scientific conclusions from the results of this study.

The ethical implications of Wakefield's study being published in an accredited medical journal, such as *Lancet*, can be expanded from his patients to the general public. By publishing that there is a correlation between the MMR vaccine and autism in what is widely considered to be a credible source, the general population is then led to believe that the results have been proven to be accurate. This highlights the need to view scientific publications through a framework such as care ethics. Without this framework, it is difficult to distinguish whether the researchers can ethically be held accountable for the publication of false data. As the study became increasingly publicized, the anti-vaccination movement began to gain momentum, especially in Wakefield's home country, the United Kingdom. By 2002, MMR vaccination rates dropped to 83% in the UK, significantly below the WHO recommended 95% vaccination rate needed in order to achieve herd immunity and reduce the likelihood of outbreaks (Fleck, 2004). Decreasing vaccination puts those with weakened immune systems, such as children who are less than one year old and the elderly, at high risk for developing very preventable diseases.

Beneficence

Beneficence in the context of Beauchamp's Principles of Healthcare Ethics is defined as the moral obligation to act for the benefit of others. Because of the experimental nature of science and medicine, it is impossible to "do no harm" all the time as stated in Beauchamp's Nonmaleficence Principle. Instead, scientists and physicians should strive to have a "positive balance of goods over significant inflicted harms" (Ashcroft et al., 2007). This is where the principle of beneficence exceeds the scope of nonmaleficence. Beneficence is an essential skill for doctors to have when treating patients because the patient's welfare should be of utmost importance when they are being treated. This includes preventing harm to patients, helping patients find financial assistance when needed, and assisting patients gain access to healthcare or research protocols. Additionally, can also beneficence include weighing the benefits against the risks of potential treatment plans for each and every patient. This helps the doctor, or respective healthcare professional, maximize the end result for the patient. In order to hold Wakefield accountable, we must first state that the scientific community has a moral responsibility to conduct ethical scientific studies and accurately inform the public of their findings.

The notion of beneficence that involves reducing substantial harm to patients can be further expanded to vaccinations. While vaccination may cause a patient immediate, short-term harm, the temporary pain and swelling are inflicted on the patient with the goal of preventing the patient from being infected from a contagious, deadly disease. This is especially true for people with weakened immune systems who benefit greatly from the immunity provided by others. Josh Nerius discovered that he had never been vaccinated for measles, mumps, and rubella when he was diagnosed with measles in May 2016 which felt like "the worst flu [he'd] ever had" (Nerius, 2019). Nerius' case of measles is especially dangerous for any person that is not vaccinated because the disease can linger in the air after a cough for up to two hours and infect 90% of the people around them who are not immune (Centers for Disease Control, 2019). When Wakefield's study was published, it caused people to resist vaccination and led to an increase in the risk of preventable communicable diseases. This shows that Wakefield violated the principle of beneficence, as his study encouraged patients to resist vaccination and put themselves at risk for harm in the future.

Applying the humanitarian-based principle of beneficence in the healthcare field implies that the physician or healthcare professional should work to help the patient improve or maintain their current quality of life. When publishing his research study, Wakefield failed to balance the potential risks of him inaccurately obtaining data against the benefits of his potentially novel research findings. The discovery that his research sample was biased led many to believe that he was financially incentivized, as opposed to having humanitarian incentives.

Justice

Beauchamp states that a person in any society has the right to be treated justly and fairly, according to what is fair, due, or owed (Ashcroft et al., 2007). According to care ethics, the asymmetrical relationship between a doctor and a patient indicates that the doctor owes a duty of care to the patient because of their greater breadth of knowledge about the human body and medical field. Justice in the context of the healthcare field means that citizens have the right to be correctly informed, especially when the concerned information involves their own health. Wakefield violated Beauchamp's principle of justice when he falsified and created data published in his research. He unethically and unjustly misinformed citizens all over the world, causing people to make crucial health-related decisions based on this data.

Those who listened to the data that Wakefield published and chose not to vaccinate either themselves or their dependents were then, unfairly, at a greater risk for disease than those who chose to get vaccinated. Wakefield's actions also impact patients with weakened immune systems because, in the case of an outbreak, the disease would spread quickly among those who are not immunized, therefore increasing the chances that people with weakened immune systems would get infected. One community where this is especially apparent is Ashland, Oregon, where 28% of children go to school without any vaccinations (Palfreman, 2010). In 2014, Ashland experienced an outbreak of chicken pox due to their low vaccination rates. Because of their skepticism about vaccines, largely because of the results published in Wakefield's article, this community is at constant risk of other highly infectious and potentially serious diseases like measles and whooping cough. The actions that the parents of Ashland have taken show that Wakefield failed to follow through on his duty of care by failing to allow them to make an accurately informed decision. Communities like Ashland that are not willing to vaccinate their children will likely fail to understand the importance of any new vaccines in the future, including the ones being developed for the coronavirus (COVID-19) pandemic. The repercussions of Wakefield's publications create unnecessary obstacles for healthcare officials as they try to globally eradicate deadly diseases.

While examining Wakefield's actions through the lens of care ethics points to the conclusion that Wakefield can be held morally responsible for the significant decline in vaccination rates in the United Kingdom, it is important to consider opposing viewpoints. An article published in *Pediatrics and Child Health Journal* states that further research has shown that there are currently no known direct links between the MMR vaccine and autism; rather, there is a temporal relationship, instead of a causal relationship, between MMR vaccination and the development of autism (MacDonald & Pickering, 2007). Although Wakefield's claim has so far proven to be false, the journal states that the temporal relationship between autism diagnosis and MMR vaccination gave Wakefield and his fellow researchers good reason to believe that his discovery was a significant scientific innovation.

Conclusion

The morality of Wakefield, et al. can be shown using the care ethics framework to conclude that the researchers are morally responsible for the rise of the anti-vaccination movement as a result of publishing falsified data that was a result of research that was conducted unethically. The publication of Wakefield’s research caused people all over the globe to doubt the safety and efficacy of vaccines and has put at-risk populations in danger of contracting highly contagious diseases that are easily prevented through vaccination. Beauchamp’s three principles for healthcare ethics -- nonmaleficence, beneficence, and justice -- provide the grounds for evaluating the researchers’ actions and the further implications on society. While the published article was later retracted by the journal, the effects of the research still affect society today. This case highlights the unfortunate middle ground that exists between publishing novel scientific research and abiding by the law. In order to understand the significance of novel scientific research in the future, we must effectively reprimand those who violate ethical guidelines that have widespread implications for society.

Word Count: 3461

Bibliography

Ashcroft, R. E., Dawson, A., Draper, H., & McMillan, J. (2007). *Principles of Health Care Ethics*. John Wiley & Sons.

Bowes, J. (2016). Measles, misinformation, and risk: Personal belief exemptions and the MMR vaccine. *Journal of Law and the Biosciences*, *3*(3), 718–725. https://doi.org/10.1093/jlb/lsw057

Center for Disease Control. (1993). *History and Epidemiology of Global Smallpox Eradication*.

Center for Disease Control. (2018). *Understanding How Vaccines Work*. 2.

Center for Disease Control. (2019, December 24). *MMR Vaccination | What You Should Know | Measles, Mumps, Rubella*. https://www.cdc.gov/vaccines/vpd/mmr/public/index.html

College of Physicians of Philadelphia. (n.d.). *Timeline | History of Vaccines*. Retrieved February 27, 2020, from https://www.historyofvaccines.org/timeline#EVT_48

Dyer, O. (2008). Wakefield admits fabricating events when he took children's blood samples. *BMJ : British Medical Journal*, *336*(7649), 850. https://doi.org/10.1136/bmj.39553.506597.DB

ECFMG. (2003). *ACGME Core Competencies—ECHO Resources*. ECFMG. https://www.ecfmg.org/echo/acgme-core-competencies.html

Fleck, F. (2004). MMR controversy raises questions about publication ethics. *Bulletin of the World Health Organization*, *82*, 311–312. https://doi.org/10.1590/S0042-96862004000400017

Lambert, P.-H. (2006). A successful vaccine that missed its target. *Nature Medicine*, *12*(8), 879–879. https://doi.org/10.1038/nm0806-879

MacDonald, N., & Pickering, L. (2007). Autistic spectrum disorder: No causal relationship with vaccines. *Paediatrics & Child Health*, *12*(5), 393–395.

Rao, T. S. S., & Andrade, C. (2011). The MMR vaccine and autism: Sensation, refutation, retraction, and fraud. *Indian Journal of Psychiatry*, *53*(2), 95–96. https://doi.org/10.4103/0019-5545.82529

Sundean, L., & McGrath, J. (n.d.). *Ethical Considerations in the NICU*. Medscape. Retrieved March 1, 2020, from http://www.medscape.com/viewarticle/811079

VaccinesToday. (2015, February 7). *What is herd immunity?* VaccinesToday.

https://www.vaccinestoday.eu/stories/what-is-herd-immunity/

Wakefield, A. J., Murch, S. H., Anthony, A., Linnell, J., Casson, D. M., Malik, M., Berelowitz, M., Dhillon, A. P., Thomson, M. A., Harvey, P., Valentine, A., Davies, S. E., & Walker-Smith, J. A. (1998). RETRACTED: Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *The Lancet*, *351*(9103), 637–641. https://doi.org/10.1016/S0140-6736(97)11096-0