General Research Problem: Intravenous Cannulation

Intravenous insertions and effect on patient care

Intravenous (IV) insertions can be a painful experience for many patients, including both those that are afraid of needles and those that are turned away from blood donation. Some patients with healthy veins that roll or are difficult to envision are labelled as 'tough sticks', necessitating the improvement of IV cannulation (needle insertion) for the comfort of the patient and ease of the medical practitioner. This technology could be modified physically and improved to provide better patient care. A controversial societal implication of IV insertions in blood drawing is the Food and Drug Administration's deferral period for men who have sex with men for blood donation. This policy was introduced to prevent the spread of disease, but is now considered by many to be a discriminatory practice. This policy must be reevaluated to ensure the safety and liberties of the American public. The examination of the physical and societal impact of the technology and methodology of IV insertions is important to the improvement of patient care and treatment in the United States.

Modification of Intravenous Cannulation for Improved First Pass Rates

Intravenous cannulation, or the insertion of a needle into a vein, is used often in the medical field. Common procedures such as catheter insertion, drug delivery, and blood drawing all depend on IV insertion. This means many patients are stuck with a needle for IV cannulation, and about 40% of patients are stuck more than once, which causes discomfort and even a lack of trust for the medical practitioner (Cooke et al., 2018). A successful first attempt at sticking the patient, also known as a first pass, is an important part of a patients' effective treatment. We are attempting to modify the cannula, or needle, used in these intravenous procedures in an effort to improve first pass rates for all medical practitioners performing this procedure.

Currently, methods such as ultrasound, near infrared (NIR), and transillumination technologies are used to find a vein in patients that are considered 'tough sticks', normally as a last resort when a vein has not been found (*NIR vs. Ultrasound vs. Transillumination for Vein Access*, n.d.). While these are useful, they can be time consuming, expensive, and logistically difficult to perform, requiring additional trained teams of medical practitioners. In addition, locating a vein is not always the issue in the case of a 'tough stick'. Many other reasons for 'tough sticks' exist, including 'rolling veins', movement of the patient, patient phobias, dehydrated patients and varying skin thickness. Simpler methods such as tourniquets, warm compresses, elevation, and relaxation can help a medical practitioner perform this procedure, though these methods are less effective than the previously mentioned visualization techniques and also do not necessarily address the wide range of difficulties associated with IV cannulation.

A survey of medical practitioners that perform these intravenous procedures will be performed in order to gauge the major issues and areas in need of improvement for the needle. Physical modifications to guide even the most inexperienced medical professionals through the intravenous insertion, such as a mechanism to guide the needle or a simpler method for

visualization of the veins would follow, based on the major issues medical professionals find with current methods determined by the survey. Testing on IV practice arms will then be used to determine whether or not the modifications improve first pass rates among both experienced and inexperienced medical professionals.

The Deferral Period for Blood Donation and the LGBTQ Community

Ethicality and Efficacy of the Policy

During the AIDS epidemic in the United States, the Food and Drug Administration (FDA) banned men who had sex with men (MSM) from donating blood in an effort to further prevent the spread of disease. In 2015, the ban was lifted and replaced by a deferral period of 12 months, requiring that MSM not donate within 12 months of their last sexual encounter with a man (Center for Biologics Evaluation and Research, 2019). This research will address whether this policy is ethical using a basic set of bioethical principles and compare it with two other potential policies.

This policy affects three major stakeholders addressed in this research: those receiving blood transfusions, MSM and Lesbian, Gay, Bisexual, Transgender, Queer + (LGBTQ+) activist groups, and governmental agencies tasked with regulating the safety of the blood supply (such as the FDA or the Center for Disease Control, which tests all blood donations for transfusion transmittable infections) (Center for Disease Control, 2019).

A similar ban on Haitian and sub-Saharan immigrants donating blood was a result of the widespread fear in 1990 of the AIDS epidemics and that heterosexual intercourse was the main course of transmission in Haitians and the incidence of HIV in Haitian immigrants was thought to be higher. This policy, while merely a suggestion by the FDA, was followed by most major blood banks and deemed racist, illogical, and discriminatory by Haitian groups and even physicians (Lambert, 1990). It was replaced later that year with self-reported questions to determine if a potential donor had engaged in ‘high risk behavior’ in the previous six months, as those with AIDS may not test positive six months after contracting the virus (“U.S. to Lift Haitian Blood Donor Ban,” 1990).

Notably, there have been many strides in blood testing since the 1990 ban by the FDA was abolished (*Highlights of Transfusion Medicine History*, n.d.). In 2002, the FDA licensed the nucleic acid amplification test (NAT) for detecting HIV. This test was more sensitive and able to detect HIV sooner, but cost more than previous methods (Hans & Marwaha, 2014). Currently, tests for Hepatitis B and C, human T-lymphotropic virus, syphilis, West Nile virus, Zika virus, and HIV are run on every donation to prevent TTIs and protect those receiving blood transfusions.

Arguments for the deferral policy, by the FDA and politicians, focus on the issue as one of public health while those protesting the policy, such as LGBTQ groups and some politicians, argue that the policy is an infringement on civil liberties. These arguments are informed by a higher incidence of HIV and other TTIs in MSM and a previously overturned ban on Haitian

immigrants donating blood, respectively (Sturrock & Mucklow, 2018; Zhou & Berkman, 2019). Some LGBTQ groups also argue that this policy promotes distrust between MSM and medical practitioners, and has exacerbated the spread of HIV as a cause of that distrust (*Ban the Ban*, 2018). Arguments have also been made that prohibiting (or deferring) entire populations from donating blood unnecessarily limit an already dangerously small donation pool (American Red Cross, 2019). In contrast, some argue that the prevalence of HIV in MSM is a public health risk that overshadows a shortage of blood for transfusions.

The FDA, in moving from a permanent ban to a deferral period for MSM in donating blood, proposed multiple potential policies to replace the permanent ban. The two additional policies included in this research are the previously changed outright ban on MSM donations and a no-action policy, which would rely solely on laboratory testing to screen out TTIs in blood donated by MSM. Each of these policies has their own ethical implications. If the FDA were to advise against deferrals, there would be a potential four-fold increase in HIV transmissions from blood transfusions.

In order to compare these policies, I will conduct research to inform the bioethical matrix, a basic bioethical principle that takes into account the stakeholders and four fundamental pillars of bioethics. The first of these is autonomy, ethically, procedures should not be performed on an unwilling patient; autonomy is also something that needs to be considered with respect to the donors in these policies, as most of the donation process is voluntary and self-reported. Second is non-maleficence, which ensures that there is minimal harm coming to the patient or stakeholders involved. Third, beneficence means that procedures are intended to help patients involved. Finally, justice in terms of these policies will focus on the legality and possible discriminatory aspects of these policies.

This topic presents a fundamentally ethical dilemma, with basic arguments that the public health is paramount or that civil liberties are of the utmost importance to the American people. A thorough examination of the arguments presented by these groups, observational studies performed in other countries such as Australia and the UK with similar or alternative policies, and legal precedents for the civil liberties related to this issue should provide a comprehensive overview of the topic to inform the question of the ethicality of these policies.

Conclusion

Intravenous cannulation is an important aspect of many areas of public health, and is one that can be improved upon. This procedure can be difficult for many patients, and a successful first pass is optimal. Modification of the cannula used for IV insertion will better the experience of both patients and medical practitioners. The mitigation of ‘tough sticks’ and improvement of first pass rates will decrease the time and energy required for IV insertion. Societally, in the case of blood donation, the FDA’s policy deferring MSM from donating is in need of review. Evaluation of this deferral policy and other potential policies is necessary to inform decisions about public health and about civil liberties. The efficacy and ethicality of this deferral period is

important, as much of the American public is affected (as members of the LGBTQ community, as recipients of blood donations, and as blood donors). The technical and societal importance of IV insertions and blood donation in public health cannot be overlooked and require reevaluation to achieve better patient treatment.

References

American Red Cross. (2019, July 9). *American Red Cross Issues Emergency Need for Blood Donors*. American Red Cross Blood Services. https://www.redcross.org/about-us/news-and-events/press-release/2019/american-red-cross-issues-emergency-need-for-blood-donors.html

Ban the Ban: An argument against the 12 month blood donation deferral for men who have sex with men. (2018, November 28). GLAAD. https://www.glaad.org/amp/ban-ban-argument-against-12-month-blood-donation-deferral-men-who-have-sex-men

Center for Biologics Evaluation and Research. (2019, March 14). *Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products*. U.S. Food and Drug Administration. http://www.fda.gov/regulatory-information/search-fda-guidance-documents/revised-recommendations-reducing-risk-human-immunodeficiency-virus-transmission-blood-and-blood

Center for Disease Control. (2019, May 8). *Blood Safety Basics | CDC*. Center for Disease Control. https://www.cdc.gov/bloodsafety/basics.html

Cooke, M., Ullman, A. J., Ray-Barruel, G., Wallis, M., Corley, A., & Rickard, C. M. (2018). Not "just" an intravenous line: Consumer perspectives on peripheral intravenous cannulation (PIVC). An international cross-sectional survey of 25 countries. *PLoS ONE, 13*(2). https://doi.org/10.1371/journal.pone.0193436

Hans, R., & Marwaha, N. (2014). Nucleic acid testing-benefits and constraints. *Asian Journal of Transfusion Science*, *8*(1), 2–3. https://doi.org/10.4103/0973-6247.126679

Highlights of Transfusion Medicine History. (n.d.). Retrieved October 31, 2019, from http://www.aabb.org/tm/Pages/highlights.aspx

Karamitros, G., Kitsos, N., & Karamitrou, I. (2017). The ban on blood donation on men who have sex with men: Time to rethink and reassess an outdated policy. *The Pan African Medical Journal*, *27*. https://doi.org/10.11604/pamj.2017.27.99.12891

Lambert, B. (1990, March 14). Now, No Haitians Can Donate Blood. *The New York Times*. https://www.nytimes.com/1990/03/14/us/now-no-haitians-can-donate-blood.html

NIR vs. Ultrasound vs. Transillumination for Vein Access. (n.d.). Retrieved October 3, 2019, from https://www.veinlite.com/blog/post/nir-ultrasound-transillumination-vein-access/

Sturrock, B. R., & Mucklow, S. (2018). What is the evidence for the change in the blood -donation deferral period for high-risk groups and does it go far enough? *Clinical Medicine*, *18*(4), 304–307. https://doi.org/10.7861/clinmedicine.18-4-304

U.S. to Lift Haitian Blood Donor Ban. (1990). *Washington Post*. https://www.washingtonpost.com/archive/politics/1990/12/06/us-to-lift-haitian-blood-donor-ban/23468adf-8348-46d9-beb7-6c5a010dc801/

Zhou, L., & Berkman, R. T. W. (2019). Ban the ban: A scientific and cultural analysis of the FDA's ban on blood donations from men who have sex with men. *Columbia Medical Review*, *1*(1). https://doi.org/10.7916/D8HX1BST