Donate with Pride: Updated FDA Blood Donor Criteria and Reducing LGBTQIA+ Stigma

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## Abstract

The United States trails other countries in the global north in adopting LGBTQIA+ inclusive legislation and policies. This was especially evident in the outdated and stigmatizing FDA blood donation deferral guidelines before May 2023. This project aims to bring awareness to the 2023 updates to the FDA's blood donation guidelines to normalize LGBTQIA+ donations and subsequently reduce stigma. The dissemination methods used include social media posts, face-to-face presentations, handouts, and scannable QR codes with links. These were utilized to provide the LGBTQIA+ community and the public with awareness of these updates as they were not widely covered by news media. The results of this project were measured by the quantity of audience members reached through each of the aforementioned methods with a total of over 700. This project sought to promote word-of-mouth familiarity and discussion of the new policies to promote LGBTQIA+ inclusion and participation in the blood donation process. This advanced the goal of national awareness of the new guidelines and the reduction of stigma against the LGBTQIA+ community. The University and Medical Center IRB prescreened this project and did not require an IRB review.

## **Key Words**

LGBTQIA+, blood donation, stigma, inclusion, pride, men who have sex with men (MSM), transwomen, quality improvement, FDA donor deferral.

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Background

Men who have sex with men (MSM) have been deferred from blood donation since the AIDS epidemic in the 1980s. Until recently, the United States had not updated blood donation protocols to reflect the advances in blood product screening and HIV detection accuracy. The United Kingdom, Canada, Mexico, Israel, and several other countries have updated their blood donation guidelines and risk assessments to be more inclusive of the LGTBQIA+ community, including MSM, bisexual men, and transwomen years before the United States. LGBTQIA+ advocacy groups such as Pride, Banned4Life, and Parents, Families, and Friends of Lesbians and Gays (PFLAG) have partnered with legislators across the country to advocate for changes that would allow MSM to donate blood. In January of 2023, the Food and Drug Administration (FDA) released recommendations for updates to the donor eligibility risk questionnaire which could be used by all blood donation entities such as the American Red Cross. The proposed updates to the guidance included unbiased language and individualized risk assessments not based on sexual preference alone. These modifications were finalized and released for implementation on May 11, 2023.

A North Carolina LGBTQIA+ advocacy organization remains committed to supporting, educating, and advocating for the LGBTQIA+ community in alignment with their national organization's mission. This North Carolina LGBTQIA+ advocacy chapter's efforts to advocate for the LGBTQIA+ community include vocal opposition to the FDA blood ban and the promotion of inclusive changes to the protocol. The chapter's National Board of Directors formally adopted this mission in January of 2023. Jettisoning the current FDA blood ban promotes equality and inclusion along with reducing stigma through individual risk-based

assessments rather than stereotypes and assumptions based on sexual preference (PFLAG, 2023). Before the guideline updates, MSM were automatically required to defer blood donation for three months after sexual contact with a male partner regardless of monogamy and/or low-risk sexual behaviors. Repealing the deferral policy for MSM, bisexual men, and transwomen allows the LGBTQIA+ community more autonomy to donate vital blood supplies. An individual risk-based assessment and donation history questionnaire administered to all blood donors address the components of the LGBTQIA+ advocacy organization's mission statement to promote a caring, just, and affirming world for those within the LGBTQIA+ community. In addition, changes to the current blood donation policy met the organization's adopted core values of accountability, bravery, growth, community and collaboration, and inclusivity and belonging (PFLAG, 2023).

While not currently a Healthy People 2030 objective, the goal of increasing the number of people who donate blood is in the developmental stages (Office of Disease Prevention and Health Promotion [ODPHP], n.d.). Research and data are actively being collected to support this being officially added to the goals of the U.S. Department of Health and Human Services (DHSS) Office of Disease and Health Promotion (OASH) Healthy People 2030's objectives (ODPHP, n.d.). The data collected through the Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) Study have helped to move this initiative forward by providing data to substantiate expanding the donation criteria for MSM. Like Healthy People 2030, the state of North Carolina does not currently have established goals for blood donation. However, they do support the proposed changes to the current blood deferral requirements for MSM. In January 2023 the North Carolina Department of Health and Human Services (NCDHHS) released a statement of support for the FDA's decision to modify the current blood donation policies to a more inclusive and individualized risk-based assessment. NCDHHS Secretary Kody H. Kinsley

and State Health Director and Chief Medical Officer Dr. Elizabeth Cuervo Tilson penned a letter of support for these changes. Health officials from the District of Columbia and nine different states signed the letter in solidarity with Secretary Kinsley and Dr. Cuervo Tilson (NCDHHS, 2023). National and state recognition of the need to ensure an inclusive blood donation screening policy supports LGBTQIA+ advocacy groups, such as PFLAG, who actively advocate for reducing stigma and creating a safer and more inclusive world for the LGBTQIA+ community and those who love them.

The revision of the current stigmatizing and discriminatory blood donation protocols contributes to the Triple Aim of healthcare in all three areas: improving the health of our population, improving the patient experience, and reducing costs (Bodenheimer & Sinsky, 2014). Enabling MSM, bisexual men, and transwomen to donate much-needed blood supplies improves the health of our population at large. Mass shootings targeting the LGBTQIA+ community at Pulse nightclub in Orlando, Florida, and Club Q in Colorado Springs, Colorado have been a call to action for LGBTQIA+ persons. Even so, MSM, bisexual men, and transwomen who wanted to offer their donations were prohibited from doing so. Increasing the national blood supply would provide resources throughout the country that could be readily available in the event of such tragedies. In addition, the COVID-19 pandemic further highlighted the need for increased blood donations. Revision of the current donation protocols improves the patient experience by providing LGBTQIA+ persons with the autonomy to donate blood and blood products. The support of the American Red Cross helps to improve the patient experience through advocacy for inclusivity and ensuring safe and compassionate spaces to donate blood and blood products. The reduction of cost is achieved by increasing the national blood supply. Adequate supply increases the broad availability of blood and decreases the urgent transport of blood to areas of need,

saving crucial time and money. Patients who require blood transfusions will spend less time in the hospital if there is sufficient supply, thus decreasing the amount of money spent on lengthy hospital stays and potential hospital-acquired complications. Removing the stigma of MSM blood donations will allow for more blood to be donated which will help to offset the national blood shortage in addition to the benefits of expanded inclusivity. The undertaking of revising the current blood donation policies is a collective effort between the FDA, blood donation centers, legislators, the LGBTQIA+ community, and LGTBQIA+ advocacy groups. It is the goal of these entities to accomplish a reduction in donor stigma. Success would bring additional benefits such as improvements in patient experience, promotion of public health, reduction of health care costs, and progress toward a more inclusive, just, and compassionate world for the LGBTQIA+ community.

#### Problem Statement

MSM, bisexual men, and transwomen encountered unjust opposition, judgment, and long-held stigma about blood donation and HIV transmission risk that is based solely on their sexual orientation while heterosexual individuals who practiced high-risk sexual behaviors have been allowed to donate without restriction. The delay in updates to the FDA blood donation guidelines prevented advances in equality, upheld stigmas, and substantiated discrimination against the LGBTQIA+ community. Although the updates have been active since May 2023, there has been little to no media coverage. The partnering North Carolina chapter of an LGBTQIA+ advocacy group requested this project be implemented to supplement the lack of awareness in accordance with their mission and values specifically addressing their support for updated inclusive and affirming FDA guidelines for blood donation.

# Purpose Statement

In partnership with a North Carolina chapter of an LGBTQIA+ advocacy group, the purpose of this quality improvement project was to launch a public health awareness campaign. The purpose of this awareness campaign focused on bringing awareness to MSM, bisexual men, transwomen, and others historically deferred and/or banned from blood donation of the updated FDA individualized risk-based screening to reduce the stigma surrounding this population and empower future donations. This project was designed as an awareness campaign aimed at disseminating FDA updates to the public to promote the spread of information through personal circles, families, and social groups. Additionally, this campaign had the benefit of potentially increasing blood donations which could minimize the current national blood shortage.

## **Current State of Knowledge**

According to the American Hospital Association (2023), the previous blood donor deferral policies for MSM have unfairly prevented this population from donating vital blood. With the updates in technology and HIV detection accuracy, the restrictions on MSM were outdated, discriminatory, and resulted in unnecessary and harmful stigma (Skelly et al., 2023). The American Red Cross, OneBlood, and Vitalant blood centers conducted the ADVANCE Study which was used to evaluate the effect of potential changes to the United States' blood donation policy. While the peer review process of this research has yet to be completed, the results indicate that individual donor questionnaires can identify MSM with low-risk sexual behaviors who are eligible to donate blood (Custer et al., 2023). The initiatives of the United States lag that of several other countries, such as the United Kingdom, which have changed their donation policies for MSM with success and without increased transmission risk to blood recipients (Sturrock & Mucklow, 2018).

In May 2023 the Association for the Advancement of Blood & Biotherapies (AABB) released updated FDA-recommended deferral guidelines for implementation. They included permanent deferral for any person having clinical or laboratory evidence of HIV/AIDS or who is currently taking medication to treat HIV infection. A 3-month deferral period was retained for donors who have had more than one sexual partner in the past three months and anal sex, had a new sexual partner in the past 3 months and anal sex, or have taken oral medication to prevent HIV infection (Post Exposure Prophylaxis [PEP] or Pre Exposure Prophylaxis [PrEP]). The deferral recommendation was removed for MSM who do not fall into the above categories (AABB, 2023).

## **Current Approaches to Solving Population Problem(s)**

Blood donation centers were encouraged to implement the FDA's revised guidance for the industry immediately. This guidance is not legally enforceable unless stated but reflects the most current scientific data supporting the revisions (Food and Drug Administration, 2023). The AABB provides the updated blood donor history questionnaire document (DHQ v4.0) which includes 41 questions assessing donor health at the time of donation, medications, donation history, and high-risk sexual behaviors. It does not include questions about gender identity, sexual orientation, or sexual preference. This document was written in alignment with the FDA's updated guidance. The AABB also offers a library of resources for education on implementing the updated blood donation guidelines. It was recommended that these resources be reviewed and utilized by blood collection centers for immediate implementation of the updated blood donation guidelines following their release (AABB, 2023).

The updates to blood donor eligibility are not currently receiving news media attention.

They have also been absent from social media. GLADD released an article in early 2023

describing the updates and celebrating a 40-plus-year fight for equality. Outside of LGBTQIA+ advocacy groups, news media outlets have not yet covered the updates. A North Carolina chapter of an LGBTQIA+ advocacy group aimed to collaborate and disseminate this information to the local LGBTQIA+ community and beyond in the form of an awareness campaign. The approach to this campaign involved community outreach in the form of group meetings, attendance at LGBTQIA+ advocacy events, and social media posts. These methods aimed to connect with the LGBTQIA+ community safely and compassionately to encourage their autonomy for blood donation. Education was provided to individuals and audiences about the updates to the FDA's guidance, eligibility criteria, and deferral periods.

## Methodology

The Iowa Model of Evidence-Based Practice was used to guide quality improvement project development, implementation, and dissemination. The Iowa Model's algorithm provided a stepwise approach to identifying issues and/or opportunities, collecting relevant data and evidence, designing the intervention, integrating and sustaining the change, and disseminating the results. The Iowa Model also allowed for teams to be formed to collaborate for practice changes. This collaboration included collecting and reviewing relevant evidence, developing a means of implementing identified changes, and seeing the implementation through completion (Iowa Model Collaborative, 2017). The use of the Iowa Model allowed for identifying the issue of revised, inclusive changes to blood donation protocol and deferral periods. This prompted the collection of relevant data supporting said changes, identifying a breakdown in communication to the LGBTQIA+ community, and a collaboration with a North Carolina LGBTQIA+ advocacy organization.

#### Interventions

The lack of news media coverage necessitated quality improvement interventions in the form of an awareness campaign. Although many lawmakers, LGBTQIA+ advocacy groups, and individuals nationwide have worked tirelessly in support of the FDA updates the media has failed to bring attention to this important achievement. Updates to the guidelines are less effective without the public's knowledge and subsequent utilization of their new capability for donation. The intervention methods used to implement this project included face-to-face presentations with and without PowerPoint, printed material, QR code scanning, and social media posts. All interventions were used to bring awareness to the FDA blood donation guideline updates.

Face-to-Face Presentations. Face-to-face presentations and informal conversations were conducted to increase awareness of the FDA updates. When possible, PowerPoint slides were included to supplement presentations, add a visual component, and concisely showcase key information. The information included in these presentations were examples of how language was edited to be more inclusive and gender neutral focusing instead on high-risk sexual behaviors that prompt deferral and their subsequent deferral timelines. Additionally, website addresses were provided to allow the audience access to more detailed information after the conclusion of the presentation. Face-to-face presentations ended with question-and-answer sessions which allowed for ensuring clarity and understanding.

**Printed Materials.** Fliers were distributed at LGBTQIA+ advocacy events and provided at local businesses to offer to patrons. These handouts were titled "Donate with Pride" which was printed in color to reflect the rainbow of the Pride Flag signifying unity with the LGBTQIA+ community. The information succinctly alerted the recipient of the FDA updates and included

three QR codes to scan for additional information. Fliers were distributed across North Carolina in various locations including Mooresville, Statesville, and Asheville.

Social Media Posts. Facebook and Instagram were the social media platforms chosen for this awareness campaign quality improvement project. A single post using text, graphics, and QR codes was posted on personal, LGBTQIA+ advocacy groups, and a North Carolina college's Facebook and Instagram pages. There same post was used for both social media platforms. Data totals were calculated 24 hours after the posting was live. Included in the total were the number of views, clicks, comments, and shares. Before the conclusion of the implementation process, the posts were reviewed and data were added if the posts had received additional views, clicks, or shares.

QR Code Scanning. QR codes were included in the handouts, PowerPoints, and social media posts. It was intended that these codes would provide the audience or viewers with additional resources including the American Red Cross's LGBTQ website, local American Red Cross blood drive locator, and AABB's updated Donor History Questionnaire v4.0 (DHQ v4.0) reflecting current screening questions asked of each donor to determine eligibility and deferral status. Each QR code was labeled with a brief description of its contents to prompt the recipient to the knowledge they desired.

## **Results**

Following the implementation phase of this quality improvement project, data were collected and categorized by type of exposure categorized by intervention modality. Social media posts resulted in 551 exposures to the FDA updates which made up 74% of all awareness. This data revealed social media as being the most effective way to raise awareness. In total, 151 fliers were distributed which was 20% of total disclosures. Face-to-face presentations,

conversations, and discussions totaled 23. This method comprised 3% of all information awareness attempts. Only 22 total QR code scans were completed during the implementation phase of this project. With only 3% of the exposures, this and face-to-face interactions were the least effective method of disseminating awareness.

The efficacy of this project was measured by the quantity of new awareness provided to individuals of the FDA blood donation and deferral guideline updates through verbal presentations, social media posts, QR code scanning, and printed material. In all, 747 viewers or audience members were provided awareness of the FDA updates. These exposures can be assumed to provide awareness to an even larger audience through word of mouth, sharing of social media posts, and handouts taken and shared. It is expected that any resultant increase in donations of blood by LGBTQIA+ persons will take continued awareness efforts and time.

# **Implications**

This project aimed to launch a public health awareness campaign to educate MSM, bisexual men, transwomen, and others historically deferred and/or banned from blood donation about the updated FDA individualized risk-based screening to reduce the stigma surrounding this population and empower future donations. This can be achieved through LGBTQIA+ advocacy groups posting on social media, local legislative leaders publishing a press release, or national/local news media channels running a story about the FDA updates. Healthcare practitioners also provide a unique opportunity to reach a wider audience. This information could be disseminated during annual wellness visits or as a poster or handout in the office.

Opportunities for new and continued partnerships with LGBTQIA+ advocacy groups provide an outlet to reach more individuals who are committed to reducing LGBTQIA+ stigma. This project can be adapted to any audience and can be modified to offer various types of information.

Additionally, an increase in blood and blood product donations would serve to lessen the nation's blood shortage. The LGBTQIA+ individuals and historically deferred donors have the potential to provide life-saving quantities of blood through their donations. The AABB (2024) details how the quality and safety of donated blood are maintained with the inclusion of LGBTQIA+ donors. This information negates biases and opinions and provides evidence and support for their inclusion. Van Remoortel, et al. (2020) provides that there is no increase in transmission risk from LGBTQIA+ donors. With this understanding, we can reasonably assume that an increase in LGBTQIA+ donors would have the additional benefit of supplementing the national blood supply and increasing the availability of blood and blood products to potential recipients.

## **Conclusions**

The updates to the FDA blood donation guidelines have been in place for nearly a year. Since that time the topic has received little news media coverage. Although LGBTQIA+ advocacy groups, legislative leaders, and individuals have worked tirelessly on this change there are minimal efforts to inform LGBTQIA+ donors of these updates. This hinders the potential increase in blood and blood product donations from eligible donors, maintains the national blood shortage, and hinders the destignatization of the LGBTQIA+ community. This project employed face-to-face presentations and conversations, handouts, QR codes, and social media posts to bridge the gap between the FDA updates and audience awareness. This quality improvement project can be reused an unlimited number of times by a variety of presenters in the form of an awareness campaign. The media could adopt these efforts to reach a wider audience.

Additionally, blood donation centers could offer printed materials to donors at community blood drives. LGBTQIA+-friendly blood drives could be held to provide a safe and inclusive

environment for community members and promote donations. As efforts continue to make this information more widely known, we can anticipate a normalization of LGBTQIA+ blood donations and, in turn, a reduction of LGBTQIA+ stigma overall while promoting future donations that build the national blood supply and prevent further shortages.

## References

- American Hospital Association. (2023, January 31). FDA issues draft guidance updating blood donation policy. <a href="https://www.aha.org/special-bulletin/2023-01-31-fda-issues-draft-guidance-updating-blood-donation-policy#:~:text=The%20Food%20and%20Drug%20Administration,who%20have%20sex%20with%20MSM">https://www.aha.org/special-bulletin/2023-01-31-fda-issues-draft-guidance-updating-blood-donation-policy#:~:text=The%20Food%20and%20Drug%20Administration,who%20have%20sex%20with%20MSM</a>
- Association for the Advancement of Blood & Biotherapies. (2024). How the blood community ensures the safety of blood in the United States. <a href="https://www.aabb.org/for-donors-patients/about-blood-donation/how-the-blood-community-ensures-the-safety-of-blood-in-the-united-states">https://www.aabb.org/for-donors-patients/about-blood-donation/how-the-blood-community-ensures-the-safety-of-blood-in-the-united-states</a>
- Bodenheimer, T., & Sinsky, C. (2014). From triple to quadruple aim: Care of the patient requires care of the provider. *Annals of Family Medicine, (12)*6, 573-576.

  <a href="https://www.annfammed.org/content/12/6/573.full#:~:text=https%3A//doi.org/10.1370/afm.1713">https://www.annfammed.org/content/12/6/573.full#:~:text=https%3A//doi.org/10.1370/afm.1713</a>
- Custer, B., Whitaker, B., Pollack, L., Buccheri, R., Bruhn, R., Crowder, L., Stramer, S. L., Reik, R., Padney, S., Stone, M., Di Germanio, C., Buchacz, K., Ender, A., Lu, Y., Forshee, R., Anderson, S., & Marks, P. (2023, January 1). HIV risk behavior profiles among men who have sex with men interested in donating blood: The assessing donor variability and new concepts in eligibility (ADVANCE) study. medRxiv.

  https://www.medrxiv.org/content/10.1101/2023.04.08.23288320v1
- Food and Drug Administration (2023). Recommendations for evaluating donor eligibility using individual risk-based questions to reduce the risk of human immunodeficiency virus transmission by blood and blood products. U.S. Department of Health and Human

Services, Center for Biologics Evaluation and Research. <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-evaluating-donor-eligibility-using-individual-risk-based-questions-reduce-risk-human</a>

- Iowa Model Collaborative. (2017). Iowa model of evidence-based practice: Revisions and validation. *Worldviews on Evidence-Based Nursing*, 14(3), 175-182. doi:10.1111/wvn.12223
- North Carolina Department of Health and Human Services. (2023, January 27). *NCDHHS*statement on FDA's proposal to expand eligibility for blood donation. North Carolina

  Department of Health and Human Services. <a href="https://www.ncdhhs.gov/news/press-releases/2023/01/27/ncdhhs-statement-fdas-proposal-expand-eligibility-blood-donation">https://www.ncdhhs.gov/news/press-releases/2023/01/27/ncdhhs-statement-fdas-proposal-expand-eligibility-blood-donation</a>
- Office of Disease Prevention and Health Promotion. (n.d). Increase the proportion of people who donate blood BDBS-D01. *Healthy People 2030*. U.S. Department of Health and Human Services. <a href="https://health.gov/healthypeople/objectives-and-data/browse-objectives/emergency-preparedness/increase-proportion-people-who-donate-blood-bdbs-d01">https://health.gov/healthypeople/objectives-and-data/browse-objectives/emergency-preparedness/increase-proportion-people-who-donate-blood-bdbs-d01</a>
- PFLAG. (2023). What we stand for: <a href="https://pflag.org/policystatements/">https://pflag.org/policystatements/</a>
- Skelly, A., Kolla, L., Tamburo, M. K., & Bar, K. J. (2020). Science over stigma: the need for evidence-based blood donation policies for men who have sex with men in the USA. *The Lancet Haematology*, 7(11), 779-782.
  - https://www.thelancet.com/journals/lanhae/article/PIIS2352-3026(20)30326-4/fulltext
- Sturrock, B., & 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, Vol* 18(4), 304-307. doi: 10.7861/clinmedicine.18-4-304.

Van Remoortel, H., Matthysen, W., Avau, B., Compernolle, V., Vandekerckhove, P., & De Buck, E. (2020). Is sexual risk behaviour associated with an increased risk of transfusion-transmissible infections in blood donors from Western and Pacific countries? A systematic review and meta-analysis. *Vox Sanguinis*, 115(2), 107-123. <a href="https://10.1111/vox.12874">https://10.1111/vox.12874</a>