Name of Policy: **Lookback Program** **Policy Number**: 3364-100-45-17 **Approving Officer**: Chief Executive Officer, Chief Medical Officer **Responsible Agent**: Blood Transfusion Services Director **Scope**: The University of Toledo Medical Center and its Medical Staff	UTOLEDO HEALTH **Effective date:** 01/23/2025 **Original effective date**: 09/10/1997
Key words: Blood transfusion, lookback program, FDA, AABB, donors testing positive.	

☐	New policy proposal	☐	Minor/technical revision of existing policy
☐	Major revision of existing policy	☒	Reaffirmation of existing policy

(A) Policy statement

The Blood Transfusion Service ("BTS") participates in Lookback programs in accordance with the requirements of the Food and Drug ("FDA") administration, AABB (formerly American Association of Blood Banks), College of American Pathologists ("CAP") and the American Red Cross ("ARC").

(B) Purpose of policy

To prevent infectious disease transmission and identify transfusion recipients that may be candidates for testing and counseling services.

(C) Procedure

The American Red Cross has a policy to notify the University of Toledo Medical Center ("UTMC") Blood Transfusion Services of blood units from donors who now test confirmed positive for anti-HIV-1/HIV-2 or HIV NAT, anti-HCV or HCV NAT, HBV DNA NAT, WNV NAT, or anti-HTLV-I. Recipients from the previous donations are considered "at risk" and must be identified and offered testing. If confirmed positive, the recipient is offered counseling to reduce the possibility of spreading infection. Testing services are provided by American Red Cross Blood Services, Western Lake Erie Region ("ARCWLE").

1. The Lookback program is initiated by the ARCWLE following confirmation of donor's positive tests.
2. ARCWLE will notify the University of Toledo Medical Center Blood Transfusion Services ("BTS") Director by letter, identifying the **implicated** blood units.
3. The UTMC BTS Director or designee ascertains the final disposition of the implicated blood units. If the unit was transfused, the recipient's name, hospital identification number and the attending physician are recorded on the ARCWLE form and the completed form is returned to the ARCWLE Medical Director.

4. The UTMC BTS Director notifies the attending physician, referring physician, or primary care physician in writing and provides the physician with a copy of the ARCWLE notification form. Information concerning resources for testing and counseling services will be provided to the physician. The resources include but are not limited to:

    a. HIV Clinical Nurse Specialist (AIDS Resource Team – ART)

    b. HIV Psych Clinical Nurse Specialist (ART)

    c. Infection Control Practitioner

    d. ARCWLE

5. The UTMC BTS Medical Director notifies the Risk Management department. If the recipient's physician is unwilling or unavailable to contact the recipient, Risk Management (in collaboration with the AIDS Resource Team or the Infection Control Practitioner in the case of HCV) will contact the recipient on the physician's behalf. Required written documentation will be processed as determined by the Department of Health and Human Service's policy 42 CFR Part 482 for HIV notification, or the most current FDA Guidelines on recipient notification related to donor testing for HCV. Current ARC guidelines will be followed for other viral tests.

The physician must contact Risk Management to clarify legal issues related to disclosure of any individual other than the recipient (it is not appropriate for the physician or UTMC to determine that the recipient or appropriate individuals should not be informed).

(D) References

1. AABB Standards for Blood Banks and Transfusion Services, current edition.
2. Centers for Disease Control and Prevention. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infections and HCV-Related Chronic Disease. MMWR 1998; 47(No. RR-19): [inclusive page numbers].
3. "Lookback" for Hepatitis C Virus (HCV): Product Quarantine, Consignee Notification, Further Testing, Product Disposition, and Notification of Transfusion Recipients Based on Donor Test Results Indicating Infection with HCV. August 2007.

Approved by:

/s/

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Daniel Barbee
Chief Executive Officer

1/23/2025

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Date

/s/

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Michael Ellis
Chief Medical Officer

1/23/2025

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Date

Review/Revision Completed by:

HAS
Lab Utilization Review Committee
Infection Control Committee
Risk Management
Institutional Ethics Committee
Chief of Staff

Policies Superseded by This Policy:

- *7-45-17 – Lookback Program*

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Review/Revision Date:
6/9/99
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