Name of Policy: Lookback Protocol Policy Number: 3364-108-503 Approving Officer: Senior Hospital Administrator Director, Blood Transfusion Service Responsible Agent: Blood Transfusion Service Supervisor Administrative Director, Lab Scope: University of Toledo Medical Center Pathology/Laboratory – Blood Bank	UTOLEDO HEALTH Effective date: ~~03/01/2025~~ Original effective date: 10/1986
Key words: Lookback, transfusion, HIV, HTLV, HCV, Blood	

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

(A) ~~(A)~~ Policy Statement

The Blood Transfusion Service participates in Look-back programs according to the Association for the Advancement of Blood & Biotherapies (AABB) and blood supplier~~ARC~~ standards.

(B) ~~(B)~~ Purpose of Policy

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

(C) ~~(C)~~ Procedure

(1) The blood supplier ~~American Red Cross~~ has a policy to notify Blood Transfusion Services of blood units from previous donations when donors' current donation tests positive for anti-HIV-1/HIV-2, anti-HTLV I, anti-HCV, HCV NAT, HIV NAT, HBV DNA NAT or WNV NAT. Recipients of past donations from these donors are considered "at risk" and must be identified and offered testing. If confirmed positive, the recipient is offered counseling for clinical management and to reduce the possibility of spreading infection. Testing and counseling services are also provided by American Red Cross Blood Services, Donor and Client Support Center (ARCDCSC).

~~1.~~(a) The Lookback procedure is initiated by the ~~ARCDCSC~~ blood supplier following confirmation of donor's positive tests.

~~2.~~(b) ~~ARCDCSC~~ The blood supplier will notify the UTMC Blood Transfusion Service (BTS) Medical Director by letter, identifying the implicated blood component units.

~~3.~~(c) The UTMC BTS Medical 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 ~~ARCDCSC~~ blood supplier form. The completed ~~ARCDCSC~~ blood supplier notification form is returned to the ~~ARCDCSC~~ blood supplier Medical Director.

~~4.~~(d) The UTMC BTS Medical Director notifies the attending physician in writing and provides the physician with a copy of the completed ~~ARCDCSC~~ blood supplier notification form. Information concerning resources for testing and counseling services is provided to the physician. The resources include but are not limited to the following:

~~a)~~(i) HIV Clinical Nurse Specialist (AIDS Resource Team – ART)
~~b)~~(ii) HIV Psych Clinical Nurse Specialist
~~c)~~(iii) Infection Control Practitioner
~~d)~~(iv) ARCDCSC

~~5.~~(e) The UTMC BTS Medical Director notifies the Risk Management department. If the recipient's physician is unwilling or unavailable to contact the ~~recipient, Risk~~recipient, Risk Management (in collaboration with the AIDS Resource Team or the Infection Control Practitioner in the case of HCV and other viral tests) will contact the recipient on the attending physician's behalf. Required written documentation and notification requirements will be processed according to the Department of Health and Human Services 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~~ blood supplier guidelines will be followed for other viral tests.

(f) The physician must contact Risk Management to clarify legal issues related to disclosure to any individuals other than the recipient.

(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 (HCV) infections and HCV-related Chronic Disease. MMWR 1998;47(No. RR-19)
(3) Current Good Manufacturing Practice for Blood And Blood Components. Supplemental testing, and Donors Notification of Consignees and Blood Recipients of Recipients of Donor Test Results for anti-HCV. Docket number 98D-0143 USDHSS, FDA CBER September 1998.
(4) 21 CFR 610.46-48 and 42 CFR 482.27(c)
(5) FDA Guidance for Industry, August 24, 2007, "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".

Approved by:	Policies Superseded by This Policy:
	• *None*
_____	Initial effective date: 10/1986
Lauren Stanoszek, M.D. Assistant Professor Director, Blood Transfusion Service	All Review/Revision Dates: 6/96 3/20/2023 1/98 ~~2/28/2025~~ 3/99 1/05 12/07 6/9/2008 3/25/2011 3/01/2013 3/02/2015 3/1/2017 3/1/2019 3/1/2021
_____	
Date	
_____	
Russell Smith Pharm D, MBA, BCPS, CPEL, FACHE Senior Hospital Administrator	
_____	
Date	Next review date: ~~03/01/2027~~
Review/Revision Completed by: Danielle Weilnau MLS(ASCP)^{CM}	

~~6.~~

~~Approved by:~~	~~Review/Revision Date:~~
_____ _____	~~6/96~~ ~~3/20/2023~~
~~Lauren Stanoszek, M.D.~~ ~~Date~~	~~1/98~~
~~Assistant Professor~~	~~3/99~~
~~Director, Blood Transfusion Service~~	~~1/05~~
	~~12/07~~
	~~6/9/2008~~
	~~3/25/2011~~
	~~3/01/2013~~
	~~3/02/2015~~

~~Christine Stesney-Ridenour~~ ~~Chief Operating Officer – UTMC~~ ~~Review/Revision Completed By:~~ ~~Danielle Weilnau, MLS(ASCP)CM~~	~~Date~~	~~3/1/2017~~ ~~3/1/2019~~ ~~3/1/2021~~ ~~Next Review Date: 3/1/2025~~
~~Policies Superseded by This Policy:~~		

~~It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.~~

~~Reference:~~

~~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 (HCV) infections and HCV-related Chronic Disease. MMWR 1998;47(No. RR-19)~~
~~3. Current Good Manufacturing Practice for Blood And Blood Components. Supplemental testing, and Donors Notification of Consignees and Blood Recipients of Recipients of Donor Test Results for anti-HCV. Docket number 98D-0143 USDHSS, FDA CBER September 1998.~~
~~4. 21 CFR 610.46-48 and 42 CFR 482.27(c)~~
~~5. FDA Guidance for Industry, August 24, 2007, "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".~~