



University of Colorado **Anschutz Medical Campus**

OMOP CDM ETL

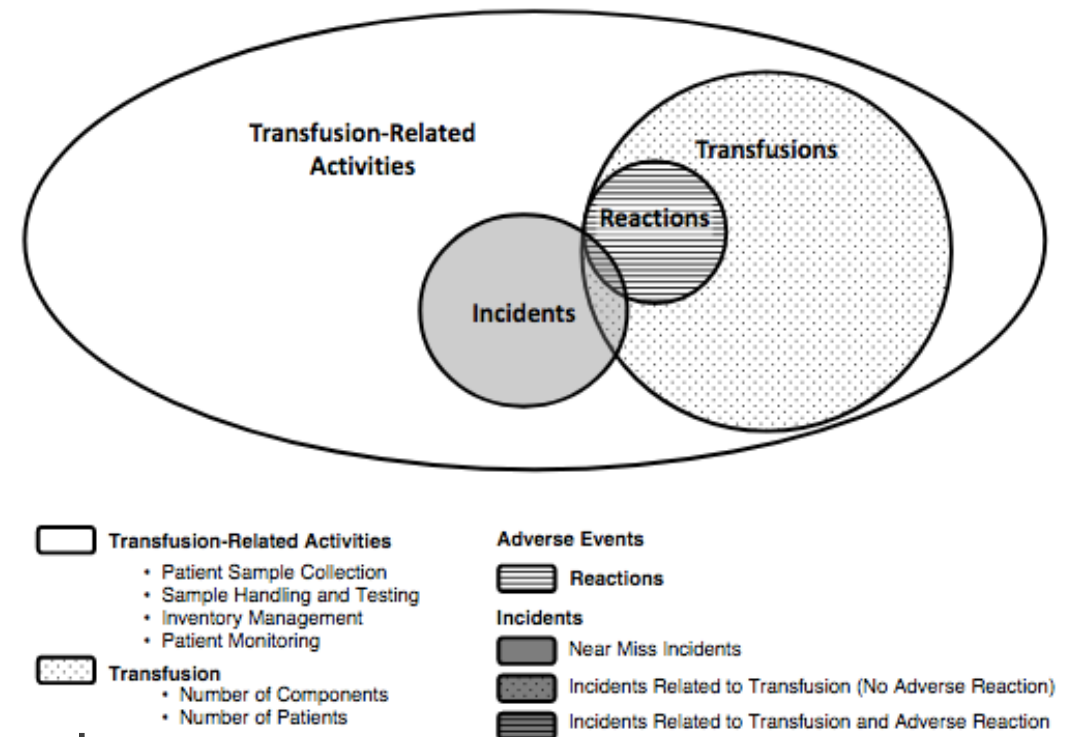
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FDA Center for Biologic Evaluation and Research (CBER) Biologics Effectiveness and Safety (BEST) [2018-2020]

- Task 1 – Data Network
- Task 2 – OMOP CDM and Data Quality
- Task 3 – Surveillance queries and analytics
- Transfusion-related lung injury (TRALI)
- Transfusion associated circulatory overload (TACO)

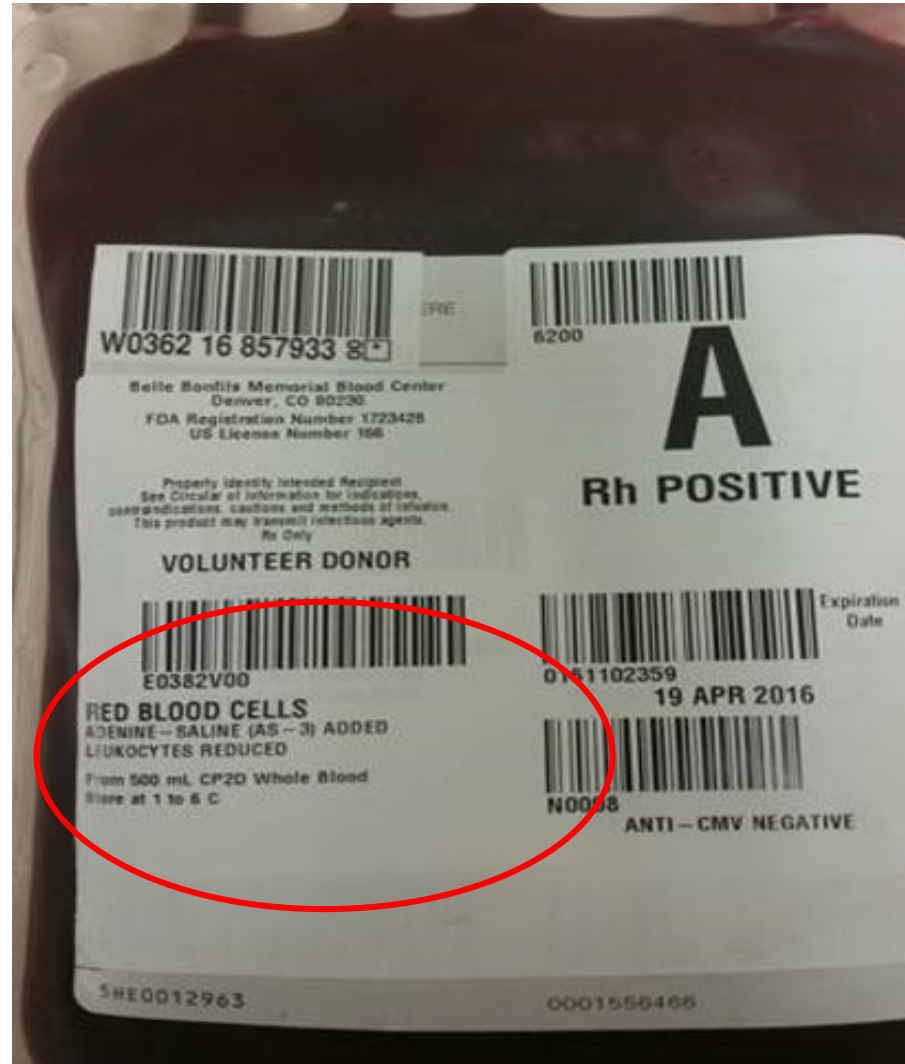
Figure 1. Venn diagram of NHSN Hemovigilance Module surveillance terms.



Where's the Data?

Complexities:

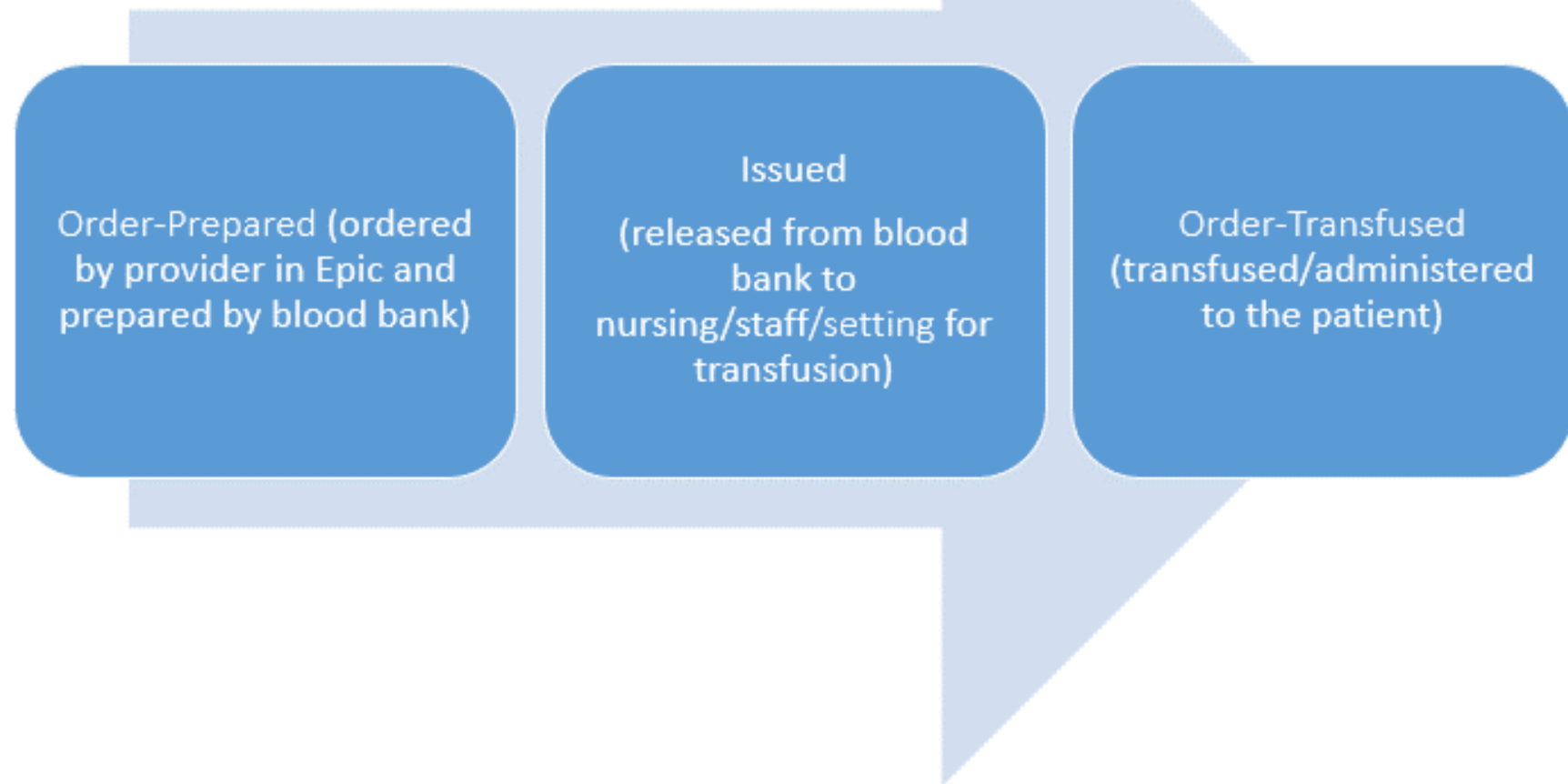
- 1) Prepared > transfused,
- 2) Order-Prepare and Order Transfusion,
- 3) Documentation varies
- 4) EHR and Blood Bank data integration



Products, Product Codes and ISBT Codes

PRODUCT CODE	PRODUCT NAME	ISBT CODE	ISBT PRODUCT DEFINITION	PRODUCT TYPE
LRC	AS-3 RED BLOOD CELLS LEUKOCYTES REDUCED	E0382	RED BLOOD CELLSICP2D>AS3/500mL/refglResLe u:<SE6	RBC
ILR	AS-3 RED BLOOD CELLS LEUKOCYTES REDUCED IRRADIATED	E0379	RED BLOOD CELLSICP2D>AS3/500mL/refglIrradiat edlResLeu:<SE6	RBC
ILRA-H	AS-3 RED BLOOD CELLS LEUKOCYTES REDUCED IRRADIATED DIVIDED ("Octopeds" 8 Aliquots)	E0379 A0-H0	RED BLOOD CELLSICP2D>AS3/500mL/refglIrradiat edlResLeu:<SE6 Divided	RBC
ILRCSA-H	CPDA-1 RED BLOOD CELLS DIVIDED IRRADIATED LEUKOCYTES REDUCED ("Octopeds" 8 Aliquots)	E0224 A0-H0	RED BLOOD CELLSICPDA- 1/500mL/refglIrradiatedlResLeu:<SE6 PART 1-8	RBC
LRC5-A-H	CPDA-1 RED BLOOD CELLS DIVIDED LEUKOCYTES REDUCED ("Octopeds" 8 Aliquots)	E0226 A0-H0	RED BLOOD CELLSICPDA- 1/500mL/refglResLeu:<SE6 DIVIDED PART 1-8	RBC
LRC-A-H	CP2D RED BLOOD CELLS DIVIDED LEUKOCYTES REDUCED ("Octopeds" 8 Aliquots)	E0382 A0-H0	RED BLOOD CELLSICP2D>AS3/500mL/refglResLe u:<SE6 PART A-H	RBC
LRCX	Apheresis RED BLOOD CELLS ACD-A>AS1	E4531	Apheresis RED BLOOD CELLSIACD- A>AS1/XX/refglResLeu:<SE6	RBC
LRCX1	Apheresis RED BLOOD CELLS ACD-A>AS1 (1 st container)	E4532	Apheresis RED BLOOD CELLSIACD- A>AS1/XX/refglResLeu:<SE61st container	RBC
LRCX2	Apheresis RED BLOOD CELLS ACD-A>AS1 (2 nd container)	E4533	Apheresis RED BLOOD CELLSIACD- A>AS1/XX/refglResLeu:<SE62nd container	RBC
LRCA	Apheresis AS3 RED BLOOD CELLS LEUKOCYTE REDUCED- ACDA	E4543	Apheresis RED BLOOD CELLSIACD- A>AS3/XX/refglResLeu:<SE6	RBC
RA4544	Apheresis AS3 RED BLOOD CELLS LEUKOCYTE REDUCED- ACDA (1 st container)	E4544	Apheresis RED BLOOD CELLSIACD- A>AS3/XX/refglResLeu:<SE61st container	RBC
LRCA2	Apheresis AS3 RED BLOOD CELLS LEUKOCYTE REDUCED- ACDA (2 nd container)	E4545	Apheresis RED BLOOD CELLSIACD- A>AS3/XX/refglResLeu:<SE62nd container	RBC
ILRCA	Apheresis AS3 RED BLOOD CELLS LEUKOCYTE REDUCED IRRADIATED- ACDA	E4538	Apheresis RED BLOOD CELLSIACD- A>AS3/XX/refglIrradiatedlResLeu:<SE 6	RBC
RA4539	Apheresis AS3 RED BLOOD CELLS LEUKOCYTE REDUCED IRRADIATED- ACDA (1 st container)	E4539	Apheresis RED BLOOD CELLSIACD- A>AS3/XX/refglIrradiatedlResLeu:<SE 61st container	RBC

EHR Process & Terminology



An Order in Epic

- Blood transfusion orders in Epic combine both a 'prepare' blood product and a 'transfuse' product order.
- The order-prepare request data is sent from Epic to SafeTrace, where the blood bank staff monitor a work queue to 'prepare' and 'issue' blood products back to the patient's setting of care (floor, ED, OR, OIC).
- The order-transfuse the order is 'released', patient id wristband is scanned, product bar code is scanned, and Blood Product Adm Flowsheet is available for further data entry
- The data (including ISBT codes) from SafeTrace regarding the specifics of the 'prepared and issued' blood products are stored in Epic Clarity Beaker Lab tables and in Epic Caboodle.

Use of different documentation processes for various scenarios!

- Massive Emergent Transfusion Protocols and ED- Use Order-Prepare, units transfused not recorded
- OR and Anesthesia Records- don't use Order-Transfuse, just give it.
- Plasma exchanges

Example: This data is from Epic Lab data- has ISBT, unit #, issue data and status- is displayed in Hyperspace Transfusion Summary

Bank Products Dispensed in This Admission - INCLUDES MTP, EMERGENT AND CODE WHITE (RETURNED = NOT GIVEN)						
Issue Date	Current Status	Blood Product	Blood Product	Unit Number	NICU/Subunit ID	Current !
08/2019 19:13	Ready	E8333V00	Platelets	W036219007133		
	Transfused	E3087V00	Platelets	W036219019421		
08/2019 13:56	Transfused	E3591V00	Cryoprecipitate	W036219053156		
08/2019 13:56	Transfused	E3591V00	Cryoprecipitate	W036219052819		
08/2019 08:30	Transfused	E2720V00	FFP	W432819000506		
08/2019 08:30	Transfused	E7731V00	FFP	W036219018343		
08/2019 08:30	Transfused	E2720V00	FFP	W036219047524		
08/2019 08:30	Transfused	E7731VB0	FFP	W036219026541		

counter Long term

Sort by: Product Time

Transfusions Started	Transfused	Flowsheet Time	BP	Tem
1 unit	215 mL			

The Flowsheet Time column corresponds to: transfusion start, 15 minutes after transfusion start, transfusion end

Transfuse platelets: 1 Units Transfusion (1 of 1 released) Comments: NOTE: This order will print d...

Prepare platelets for transfusion: 1 Units Blood - Once Comments: 2 Units for OR Use Only. NOTE...

Prepare cryo for transfusion: 2 Units Blood - Once

Prepare plasma for transfusion: 4 Units Blood - Once

Example Flowsheet OR and ICU (W0362) – missing ISBT in OR

	UCHealth Surgical Care - Anschutz Inpatient Pavilion					UCHealth Cardio...		
	04/08							
Time:	1209	1226	1252	1315	1320	1401	1915	2030
▼ OR FFP								
FFP Units	2			1	1			FFP Units
FFP Volume	500mL			250mL	250mL			FFP Volume
▼ OR PLT								
Platelet Units		1						Platelet Units
Platelet Volu...		200mL						Platelet Volume
▼ OR Cryo								
Cryo Volume						2mL		Cryo Volume
▼ OR Cell Saver								
Cell Saver In...			279mL					Cell Saver Input
▼ Transfuse platelets								
Status: Completed 04/08/19 2036 -- Unit: W0362 19 019421 C-E3087V00								
Action						New...	Stopped	Action
Rate						350 m...	0 mL/hr	Rate
Volume							215	Volume

OR

ICU

Example Flowsheet ED – missing ISBT

	UCHea...	
	04/09	
Time:	1315	
▼ ED RBC		
RBC Units	1	RBC Units
RBC Volume	300mL	RBC Volume
▼ ED FFP		
FFP Units	1	FFP Units
FFP Volume	250mL	FFP Volume

Caboodle Table by Data

Table	ISBT Code	Issue Time	Start Time	End Time	Status	Transfusion Rate
LabComponentResultFact	X	X			X	
BloodProductAdministrationFact	X		X			
FlowsheetValueFact			X			X
ProcedureEventFact	?	Records order start and end time				

Verification Using SafeTrace Data from 2017

	RBC	PLT	FFP	Cryo
Blood Bank Report (gold standard)	21,008 (100%)	7,373 (100%)	9,327 (100%)	4,034 (100%)
LabComponentResultFact	20,449 (97.3%)	7,233 (98.1%)	9,052 (97.1%)	3,942 (97.7%)
BloodProductAdministrati onFact	14,661 (70.0%)	5,934 (80.5%)	2,775 (30.0%)	2,795 (69.3%)
FlowsheetValueFact	0 (0%)	1,156 (15.7%)	3,536 (37.9%)	880 (21.8%)

Summary

- Subject matter expertise
- EHR frontend and backend investigation
- Validation against source (Blood Bank database)





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THANK YOU-QUESTIONS