

# **Expansion of the US FDA Sentinel System to inpatient blood transfusion data from Hospital Corporation of America: new surveillance options**

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# Disclosure

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- The views expressed in this paper are those of the authors and are not intended to convey official U.S. Food and Drug Administration (FDA) policy or guidance

# Background

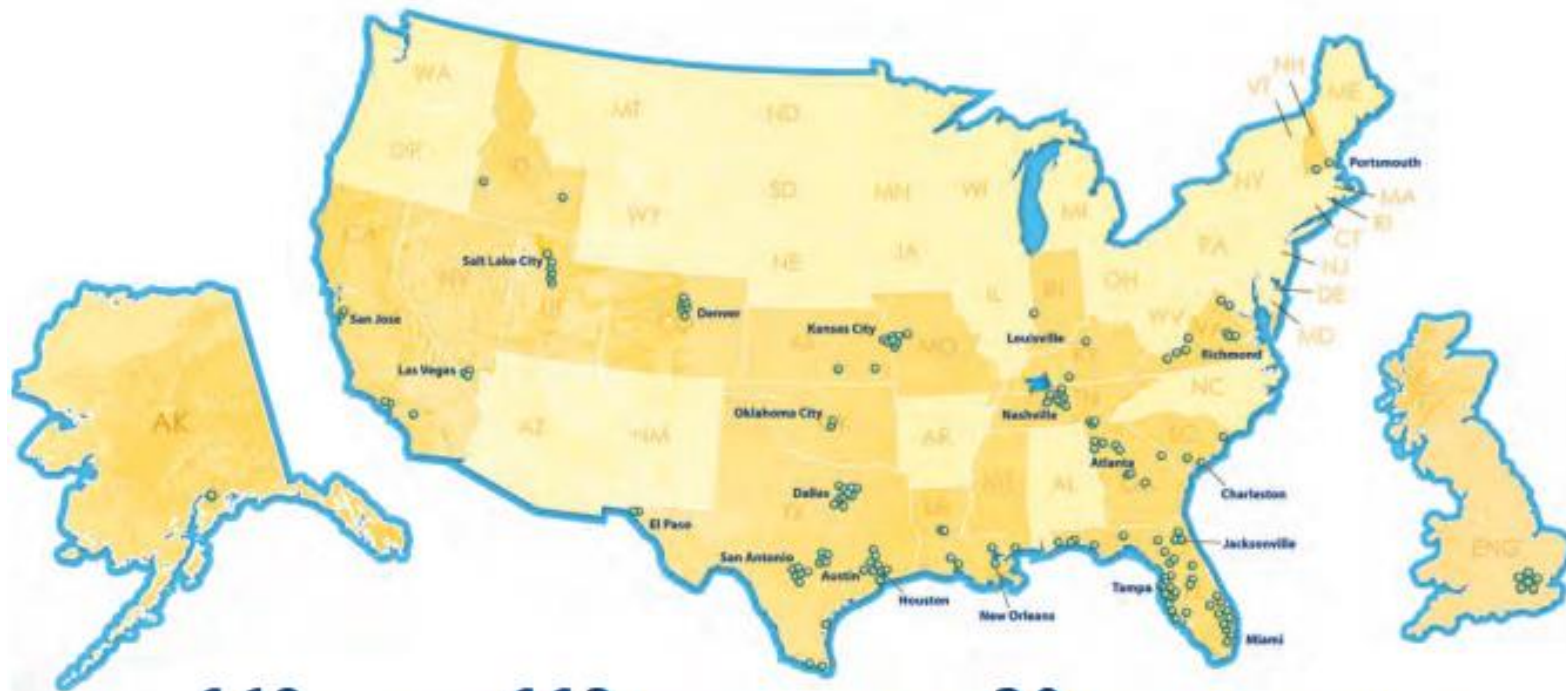


- **Sentinel System is the US Food and Drug Administration (FDA)'s active safety surveillance system to monitor medical products**
- **US FDA's Center for Biologics Evaluation and Research (CBER) responsible for ensuring safety of blood & blood products/ components**
- **Blood Safety Surveillance Continuous Active Network (BloodSCAN)**
  - A subcomponent of the Sentinel System sponsored by CBER to monitor recipient safety of FDA-regulated blood components and blood-derived products

# Background

- **Hospital Corporation of America (HCA) became a full Sentinel data partner in 2016**
  - Many blood transfusions occur in inpatient settings
  - Claims data often do not contain important transfusion details
  - Full-text electronic health records
    - Facilitate chart review and health outcomes of interest validation
  - Provides new safety surveillance potential for BloodSCAN

# Hospital Corporation of America



**168** hospitals and **113** surgery centers located in **20** states and The United Kingdom.

**~5% of all inpatient care delivered in USA**

<http://hcahealthcare.com/util/documents/HCA-presskit-fact-sheet.pdf>

# Objective

- To describe Sentinel's HCA transfusion data expansion and characterize data elements with potential for conducting surveillance for adverse events after exposure to blood components and blood-derived products

# Methods

- Sentinel and HCA created an inpatient transfusion table and added it to the Sentinel Common Data Model (SCDM)
- As HCA worked to populate the SCDM with quality checked data from more than 165 facilities
  - A test database was provided for blood component characterization
- Using analytic programs we:
  - Explored transfusion test data (March 2013-January 2015) & HCA's first Sentinel approved database (July 2011-May 2015)
  - Described data elements relevant to BloodSCAN.
  - Mapped Codabar and ISBT-128 product codes in the HCA Sentinel database to blood components

# Sentinel Common Data Model: HCA

## Existing SCDM Tables

| Demographic      | Encounter                 | Diagnosis                     | Procedure                 | Vital Signs               |
|------------------|---------------------------|-------------------------------|---------------------------|---------------------------|
| <b>Person ID</b> | <b>Person ID</b>          | <b>Person ID</b>              | <b>Person ID</b>          | <b>Person ID</b>          |
| Birth date       | Service date(s)           | Service date(s)               | Service date(s)           | Measurement date and time |
| Sex              | Encounter ID              | Encounter ID                  | Encounter ID              | Height and weight         |
| ZIP code         | Encounter type & provider | Encounter type & provider     | Encounter type & provider | Diastolic & systolic BP   |
| Etc.             | Facility                  | Diagnosis code & type         | Procedure code & type     | Procedure code & type     |
|                  | Etc.                      | Principal discharge diagnosis | Etc.                      | Tobacco use & type        |

## New SCDM Tables

| Inpatient Pharmacy Dispensing | Inpatient Transfusion         |
|-------------------------------|-------------------------------|
| <b>Person ID</b>              | <b>Person ID</b>              |
| Encounter ID                  | Encounter ID                  |
| NDC                           | Unique transfusion identifier |
| Rx Administration date        | Product code and codetype     |
| Rx Administration time        | Blood type                    |
| Actual/administered route     | Transfusion date/time start   |
| Actual/administered dose      | Transfusion date/time end     |
| Etc.                          | Etc.                          |



# National Healthcare Safety Network (NHSN): Variable Prod\_CDC

| Broad Categorization   | Description                                                              |
|------------------------|--------------------------------------------------------------------------|
| <b>Plasma</b>          | APHPLASMA - Apheresis plasma                                             |
|                        | WBDPLASMA - Whole blood derived plasma                                   |
| <b>Platelets</b>       | APHPLAT - Apheresis platelets                                            |
|                        | IRAPHPLAT - Irradiated apheresis platelets                               |
|                        | IRRAPHPLAT - Irradiated leukocyte reduced apheresis platelets            |
|                        | IRLRWBDPLAT - Irradiated leukocyte reduced whole blood derived platelets |
|                        | IRWBDPLAT - Irradiated whole blood derived platelets                     |
|                        | LRSPHPLAT - Leukocyte reduced apheresis platelets                        |
|                        | LRWBDPLAT - Leukocyte reduced whole blood derived platelets              |
|                        | WBDPLAT - Whole blood derived platelets                                  |
| <b>Red Blood Cells</b> | APHRBC - Apheresis red blood cells                                       |
|                        | IRAPHRBC - Irradiated apheresis red blood cells                          |
|                        | IRLRAPHRBC - Irradiated leukocyte reduced apheresis red blood cells      |
|                        | IRLRWBDRBC - Irradiated leukocyte reduced whole blood derived RBC        |
|                        | IRWBDRBC - Irradiated whole blood derived red blood cells                |
|                        | LRAPHRBC - Leukocyte reduced apheresis red blood cells                   |
|                        | LRWBDRBC - Leukocyte reduced whole blood derived red blood cells         |
|                        | WBDRBC - Whole blood derived red blood cells                             |
| <b>Whole Blood</b>     | WB - Whole blood                                                         |
| <b>Other</b>           | CRYO – Cryoprecipitate                                                   |
|                        | GRAN – Granulocytes                                                      |
|                        | LEUK – Leukocytes                                                        |
|                        | LYMPH – Lymphocytes                                                      |
|                        | MNC - Mononuclear cells                                                  |
|                        | SERUM - Serum                                                            |

# Results

- HCA's inpatient transfusion table captures administered transfusions including start and end times, product blood type, Rh factor
  - Number of units can also be derived
- ISBT-128 or Codabar codes assigned to each unit allow for identification of blood component and blood processing (eg, leukocyte reduction) methods

# Results: HCA's Sentinel database: Inpatient transfusions



- Provides information often not available in claims data
- Actual administered **start/end transfusion dates AND times**
- Blood type [A, B, O, AB, RH factor (+, -)]
- Information about transfused unit (can be used to identify blood component)
- # units, potentially large volume transfusion



# Results: HCA's Sentinel database:

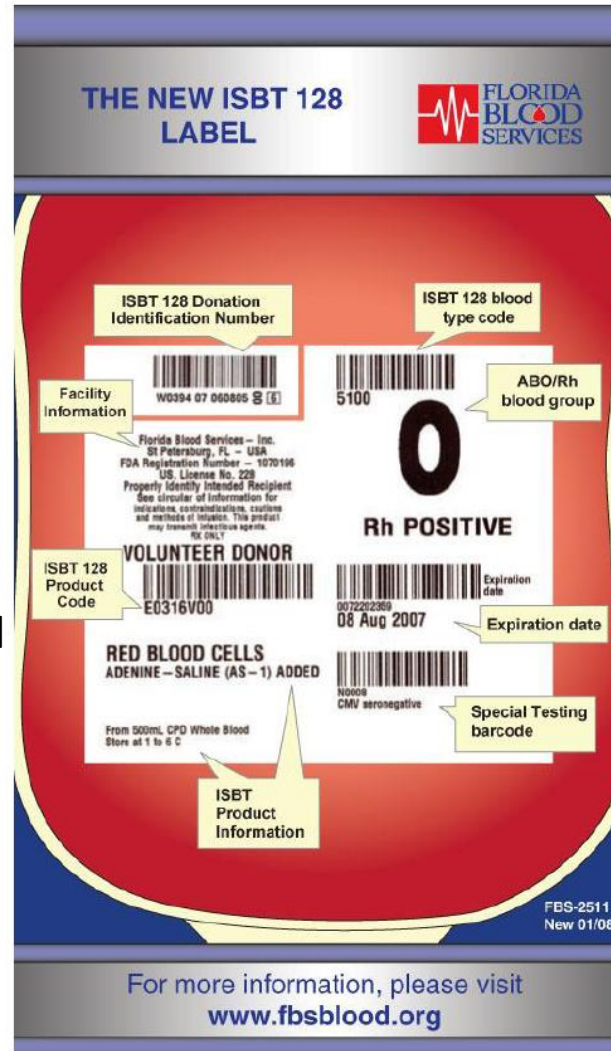
## Inpatient transfusions

- Captures transfused units, each labeled with code
- Two transfusion coding systems in use
  - >4,500 ISBT-128 codes
  - >1,500 Codabar codes
- Granular codes= new potential
  - Identification of blood components
  - Potential for identification of processing method (e.g., leukocyte-reduced, irradiated)

# Results: HCA's Sentinel database: Inpatient transfusions

- Although both Codabar and ISBT-128 systems are still in use at HCA, there has been an increased uptake in use of ISBT codes and a decrease in use of Codabar codes over time
  - By mid-2015 less than 1% of HCA transfusions were coded with a Codabar code

ISBT-128 product code, 5 digits in Sentinel Common Data Model



Source: ISBT-128 website, <https://www.iccbba.org/>

# Results: Sample Transfusion Codes at HCA

## CODABAR

| <u>Code</u> | <u>Description</u>                                                                                  |
|-------------|-----------------------------------------------------------------------------------------------------|
| 18831       | PLASMA IRRADIATED (from 250ml Whole Blood)(Storage -18 C or colder)                                 |
| 18901       | LIQUID PLASMA IRRADIATED                                                                            |
| 31458       | CPD WHOLE BLOOD LEUKOCYTES REDUCED^1 DIVIDED (Part H or 8)                                          |
| 31461       | CPDA-1 WHOLE BLOOD LEUKOCYTES REDUCED^1 DIVIDED (Part A or 1)                                       |
| 35772       | AS-3 Red Blood Cells leukocyteS reduced^1 DIVIDED IRRADIATED (ACDA anticoagulant)(by pheresis)(P... |
| 35773       | AS-3 Red Blood Cells leukocyteS reduced^1 DIVIDED IRRADIATED (ACDA anticoagulant)(by pheresis)(P... |

## ISBT

| <u>Code</u> | <u>Description</u>                                                                              |
|-------------|-------------------------------------------------------------------------------------------------|
| E0135       | WHOLE BLOOD Heparin/450mL/refg                                                                  |
| E0154       | RED BLOOD CELLS CPD/450mL/refg Open                                                             |
| E1146       | Apheresis FRESH FROZEN PLASMA NaCitrate/XX/<-65C Aphr not automated                             |
| E1149       | Thawed Apheresis FRESH FROZEN PLASMA ACD-B/XX/refg                                              |
| E5326       | Apheresis PLATELETS ACD-A/XX/20-24C Irradiated ResLeu:<5log6 2nd container Approx 300 log9 plts |
| E5329       | PLASMA CP2D/450mL/<=-18C ResLeu:NS Frozen <=24h                                                 |

# National Healthcare Safety Network (NHSN): Variable Prod\_CDC

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|                        | GRAN – Granulocytes                                                      |
|                        | LEUK – Leukocytes                                                        |
|                        | LYMPH – Lymphocytes                                                      |
|                        | MNC - Mononuclear cells                                                  |
|                        | SERUM - Serum                                                            |



# Results: Sample Transfusion Codes: With Prod\_CDC

| <b>CODABAR</b> |                                                                                                     |                                                                     |
|----------------|-----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| <u>Code</u>    | <u>Description</u>                                                                                  | <u>Prod_CDC</u>                                                     |
| 18831          | PLASMA IRRADIATED (from 250ml Whole Blood)(Storage - 18 C or colder)                                | WBDPLASMA - Whole blood derived plasma                              |
| 35772          | AS-3 Red Blood Cells leukocyteS reduced^1 DIVIDED IRRADIATED (ACDA anticoagulant)(by pheresis)(P... | IRLRAPHRBC - Irradiated leukocyte reduced apheresis red blood cells |
| 35773          | AS-3 Red Blood Cells leukocyteS reduced^1 DIVIDED IRRADIATED (ACDA anticoagulant)(by pheresis)(P... | IRLRAPHRBC - Irradiated leukocyte reduced apheresis red blood cells |
| <b>ISBT</b>    |                                                                                                     |                                                                     |
| <u>Code</u>    | <u>Description</u>                                                                                  |                                                                     |
| E0135          | WHOLE BLOOD Heparin/450mL/refg                                                                      | WB - Whole blood                                                    |
| E1149          | Thawed Apheresis FRESH FROZEN PLASMA ACD-B/XX/refg                                                  | APHPLASMA - Apheresis plasma                                        |

## Results: Proportion of units attributed to each blood component (March 2013-January 2015)\*

| Blood product/component, units administered | Percent |
|---------------------------------------------|---------|
| Red Blood Cells                             | 62.8%   |
| Plasma                                      | 13.4%   |
| Platelets                                   | 9.2%    |
| Whole Blood                                 | 0.0%    |
| Other or unknown**                          | 14.7%   |
| <b>Grand Total</b>                          |         |

### Learned:

- National Blood Collection and Utilization Survey 2011 Report: RBC, 63%, Plasma, 18%, Platelets, 15% Other or unknown\*\*\*
- Underestimating plasma/platelets

\*Analysis conducted on HCA Sentinel test database

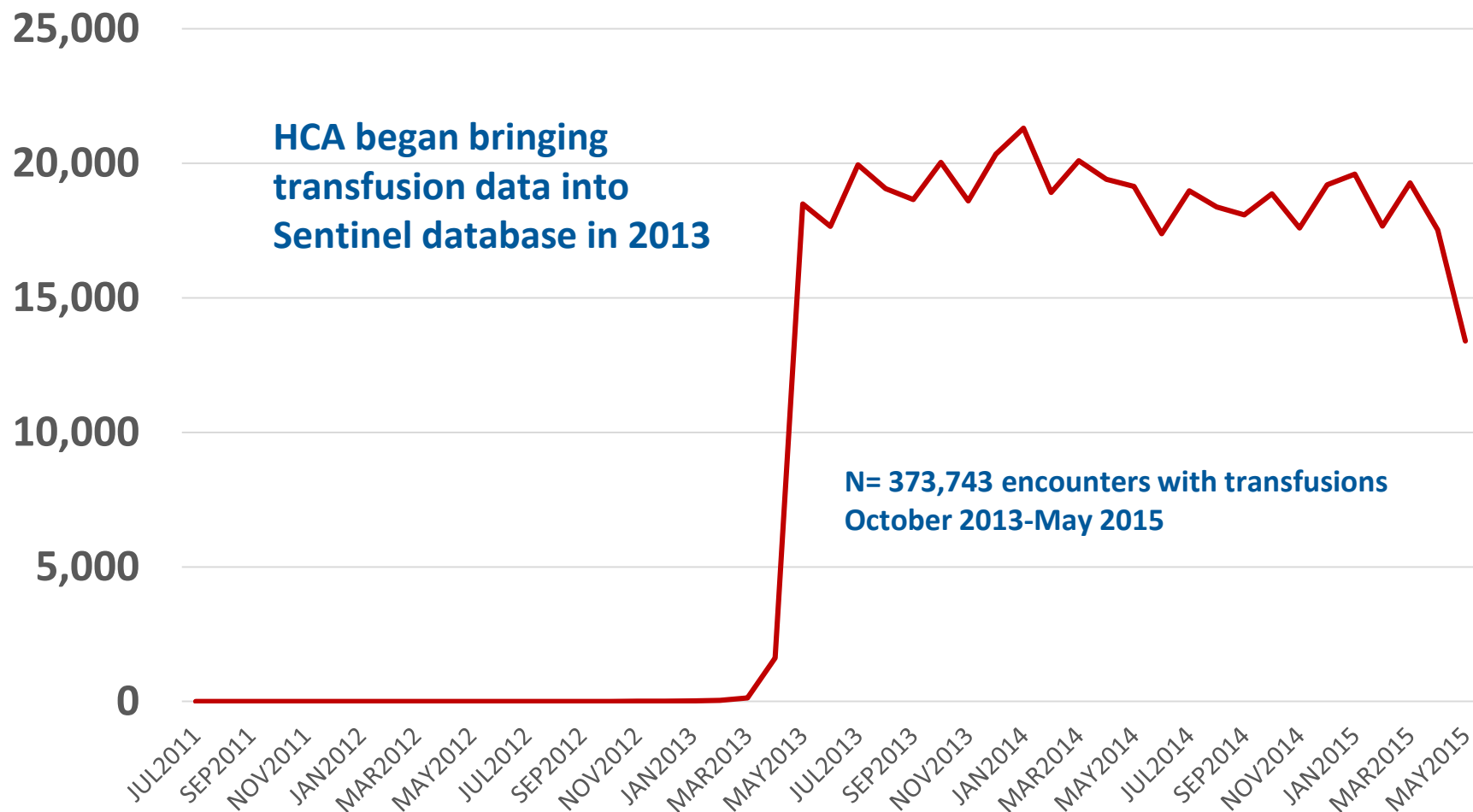
\*\*Other includes codes which could not be identified, along with other valid codes

\*\*\* <https://www.aabb.org/research/hemovigilance/bloodsurvey/Documents/11-nbcus-report.pdf>

# Results

- HCA's Sentinel database included consistently populated transfusion data starting in late 2013

## Results: # Encounters in HCA Sentinel database with a recorded transfusion (June 2011-May 2015, *HCA Sentinel database 1*)



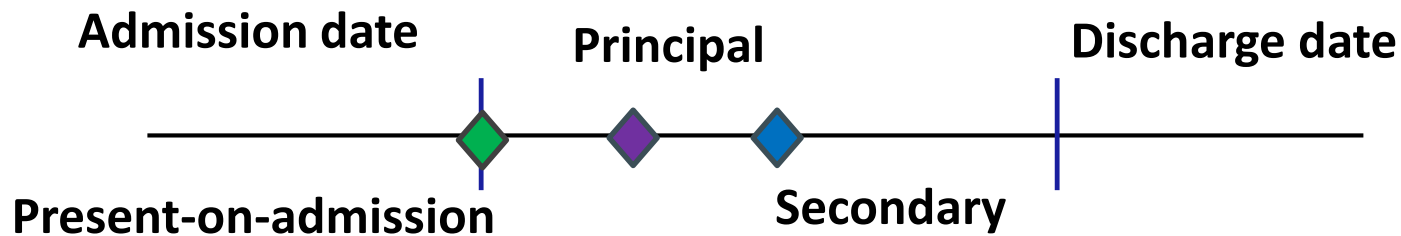
## Results: Variables for outcomes of interest

- Diagnosis and procedure codes could be used to define adverse events.
- Present-on-admission and principal discharge diagnosis flags
  - Provide further refinement potential
- Also available:
  - Admission and discharge dates
  - Discharge disposition (eg, expired)
  - Admitting source (eg, hospital transfer)

# Results: What do we know about diagnoses?

**ICD-9**

**ICD-10**



# Results: What do we know about procedures?

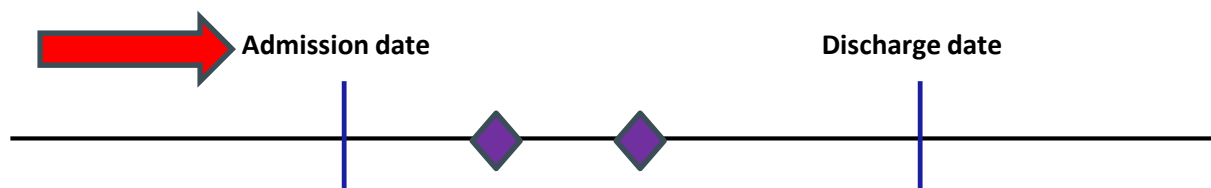
**ICD-9**

*cpt*

**HCPCS**

**ICD-10**

- 642 million observed procedures codes
  - 21 million ICD-9 procedure codes (typically describe surgical procedures)
  - Over 3 million drug administrations (injections)



# Results: CBER test cases underway

- Evaluation of development of Transfusion–Related Acute Lung Injury (TRALI) after exposure to blood and blood products
  - Publically posted protocol, assessment underway, includes chart validation component



# Limitations

- Current SCDM includes admission and discharge dates, no procedure or diagnosis dates or times
  - Transfusion administration dates and time are available, but temporality of exposures/outcomes may be difficult to capture
  - Data model expansion currently being evaluated
- Unit of analysis is a hospitalization
  - Limitations for tracking patients within HCA Sentinel data
- More evaluation of blood coding systems needed, including validation of blood product/component

# Conclusions

- HCA's inpatient transfusion data hold potential for BloodSCAN expansion, but need validation
  - Potential for identification of blood processing method
  - Dates/times of blood transfusions available
  - # units available
  - Full-text electronic health records, facilitate chart review/validation
- Identified red blood cell proportions were similar to those reported in national surveys, but those of plasma and platelets maybe under-identified
  - Examination of local hospital coding and additional blood component mapping systems needed
  - Test cases underway, 1 includes chart validation of transfusion exposure

# Acknowledgements

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