



# Utilization of a Clinical Data Warehouse as a Primary Data Source for Clinical Studies

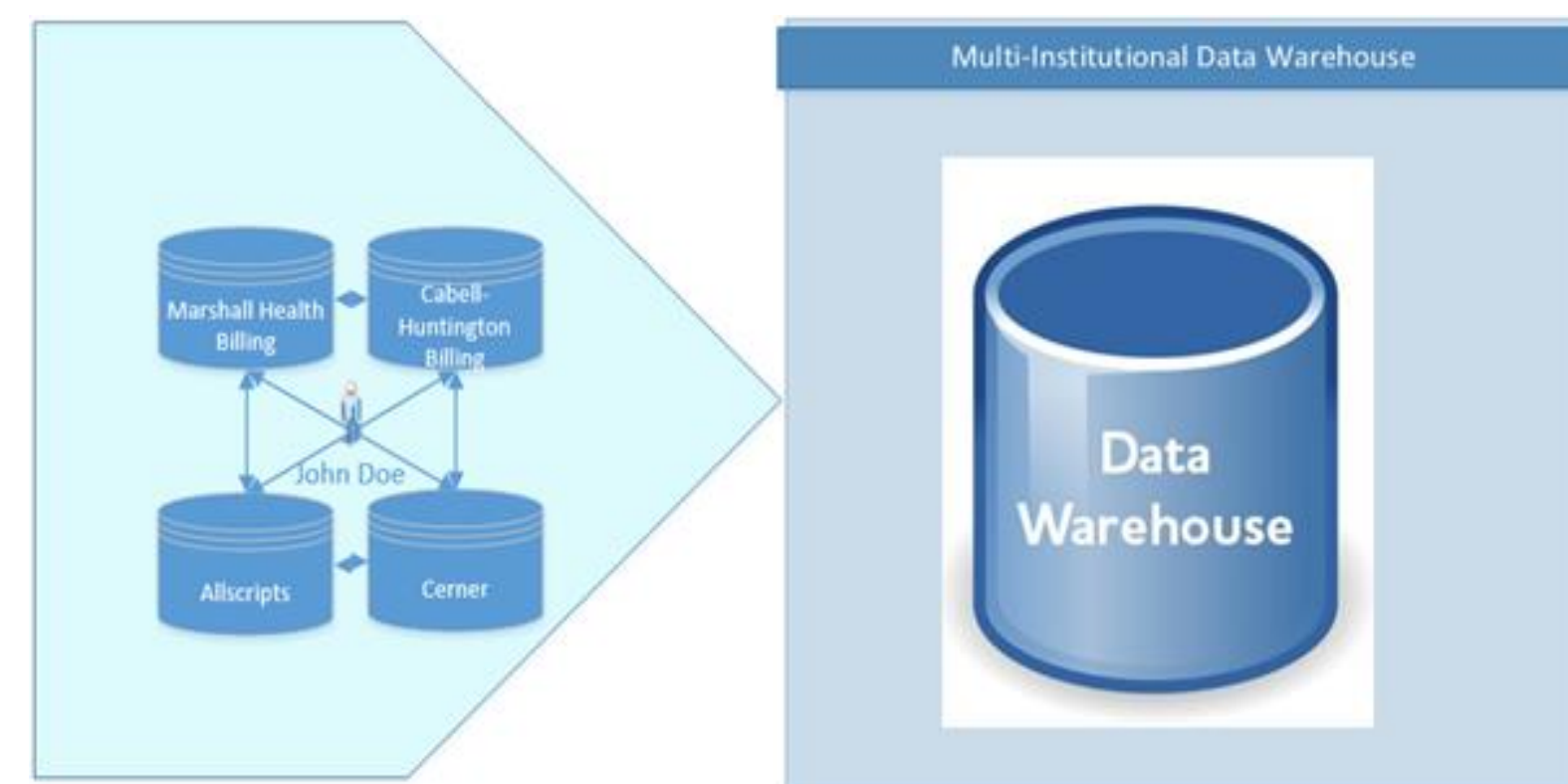


Shanmuga Sundaram, Chris Schafer, Debra Stinson, and Alfred Cecchetti  
Department of Clinical and Translational Sciences. Joan C Edwards School of Medicine

## Background:

- Institutional data warehouse of all medical information is valuable to improve patient care, facilitate quality assurance and cost/benefit analysis.
- Data warehouse is essential for clinical outcomes research within and between health science centers.
- An i2b2-based clinical data warehouse is a key component every funded CTSA institution in this country (e.g. Marshall/Univ. Kentucky CTSA) to become a Clinical Hub.
- Recently an i2b2 Marshall Data Warehouse (MDW) of all clinical and billing information at Cabell Huntington Hospital and Marshall Health was created (Figure 1).
- It is currently not clear whether this MDW may be exclusively used as source data for clinical studies.

Figure 1.



## Hypothesis:

- Retrospective clinical study to validate MDW.

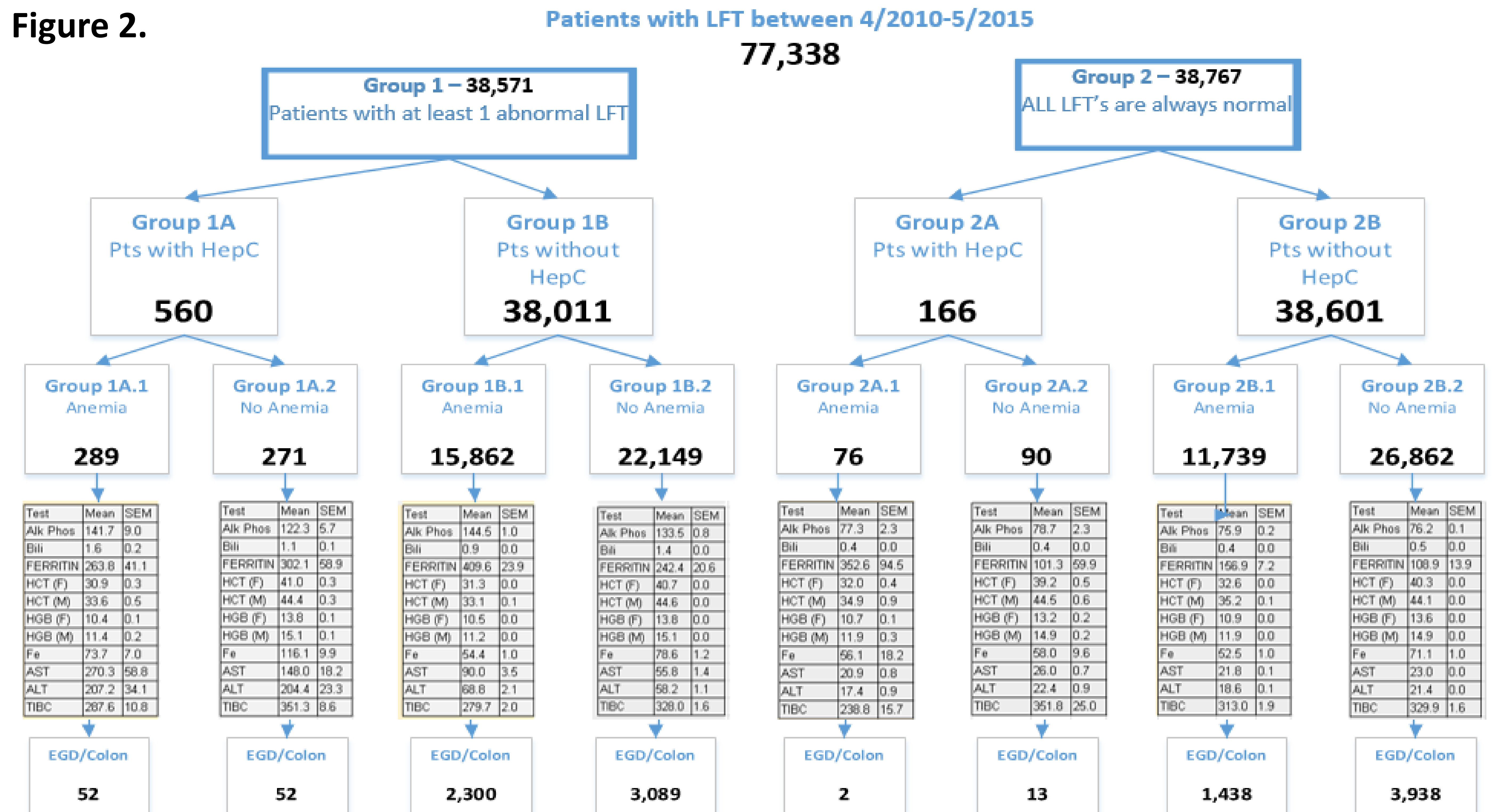
## Aim:

- Primarily utilize MDW for a clinical study to validate the warehouse.

## Methods:

- Clinical observation - Anemia frequently leads to suboptimal treatment and outcome of hepatitis C.
- Clinical question - In the Appalachian population with abnormal LFTs (AST, ALT, Billi, Alk phos), what is the incidence of hepatitis C and anemia?
- MDW Query: Figure 2. All patients who had normal or abnormal LFTs in the last 5 years (Groups 1&2), all with or without hepatitis C in either group (Groups 1A,1B, 2A&2B) and all with or without anemia.
- Validation - examine 10, 20, or 30 randomly selected medical records for each condition to determine whether MDW is accurate.

Figure 2.



## Results:

- Validation: Randomly selected charts 10, 20 or 30 in each of the 8 subgroups demonstrated 100% concordance between medical records and the data in the warehouse for LFTs, Hb, Hct, Fe, TIBC and Ferritin.
- Between 2010 and 2015 of 77,338 patients seen 49.9% had abnormal LFTs
- Hepatitis-C was more likely present in patients with abnormal LFTs (1.45 vs 0.42%).
- Anemia is found in almost half the patients (47.9%) with hepatitis C.
- In non hepatitis C patients, anemia was present more in those with abnormal LFTs (41.7% vs 30.4%).

## Conclusions:

- For this specific retrospective clinical study at least the MDW appears to be validated.
- Anemia is a common occurrence in patient with hepatitis C and may need to be fully evaluated and treated before initiation of hepatitis C treatment to optimize anti-viral treatment
- The panoramic view of this large data set raises possibility of using it for optimizing patient care. For example, should all patients with anemia have a more rigorous GI evaluation?
- A warehouse data set may be a hypothesis generating tool. For example, does abnormal LFT predispose patients to anemia?
- The results of this study demonstrate that the Marshall Data Warehouse may be used as primary source for clinical retrospective studies with only a small sampling validation of source data.