

The Usual Suspects? An Assessment of Biospecimen Collection Deviations

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ABSTRACT

Biospecimen collection deviations are detrimental to clinical trial outcomes and operations; they may result in spurious data and are costly, time-consuming, and may be inconvenient to patients. As a result, it is necessary to systematically track these deviations in order to identify when, and to what extent, they are occurring. We worked with the Vanderbilt-Ingram Cancer Center (VICC) Clinical Trials Processing Core (CTPC) and Strategy and Analytics teams to create a more efficient and streamlined method for recording these collection deviations. Using the REDCap reporting tool, we built and launched a deviations database covering 18 cancer groups and their respective studies across 22 different VUMC clinic locations. Data from currently >1,000 records are being collected (since February 1, 2016), exported, and automated for analysis and dashboarding in Tableau. These data indicate < 4% deviated biospecimens overall. Common reasons for biospecimen collection deviations recorded were: (1) missed sample collections within clinics, (2) untimely sample processing, and (3) patient/sample specific issues. **For the first time, the VICC has a comprehensive overview of total biospecimen collections and deviations within the CTPC.** These data will inform process improvements to optimize biospecimen collections, resulting in greater utility of precious patient samples and resources.

BACKGROUND & OBJECTIVES

The clinical trials management system used by the VICC is the Online Collaborative Research Environment (OnCore) system. The majority of VICC clinical trial biospecimens are collected and processed by the CTPC. Biospecimen deviations are uploaded by CTPC into OnCore as scanned hardcopy paper forms and email missives. As a result, extraction of these data for comprehensive analyses was not easily accessible across all cancer groups at the VICC. The objective of our project was to create a better system for tracking, extracting, and reviewing deviated biospecimens data and then, using this information, answer the following questions: 1) Were deviations occurring? 2) How prevalent were they? 3) What kind of deviations were they? 4) At what level did they occur? 5) and, Is further action needed to reduce deviations?

METHODS

Deviations entered into both the REDCap and OnCore reporting systems by CTPC team members, dating from February 1, 2016, are being exported and analyzed. Currently, 220 records (through March 2017) have been updated and transferred into Tableau dashboard figures.

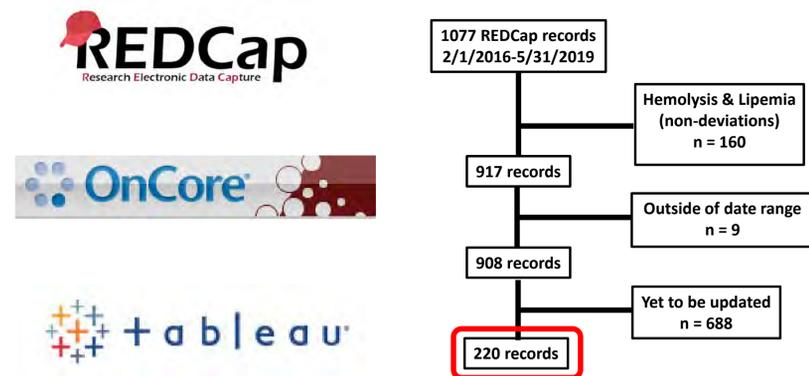


Figure 1. 220 REDCap records were analyzed. Out of 1,077 records reported in REDCap, 220 records were selected for analysis and were cross-referenced with data collected in the OnCore database. The resulting 220 records were used to calculate the deviation frequencies and interrogate the reason(s) for biospecimen collection deviations.

RESULTS

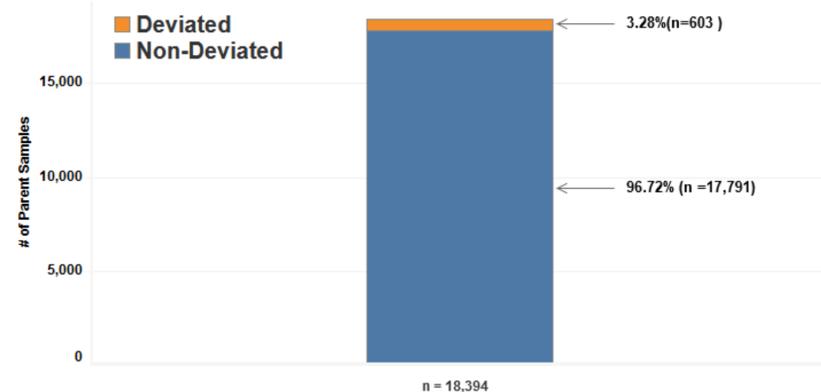


Figure 2. 3.3% of parent samples were deviated. Analysis of data from both REDCap and OnCore reporting systems indicated that 603 parent samples were deviated or missed out of 18,394 total samples slated for collection by the CTPC.

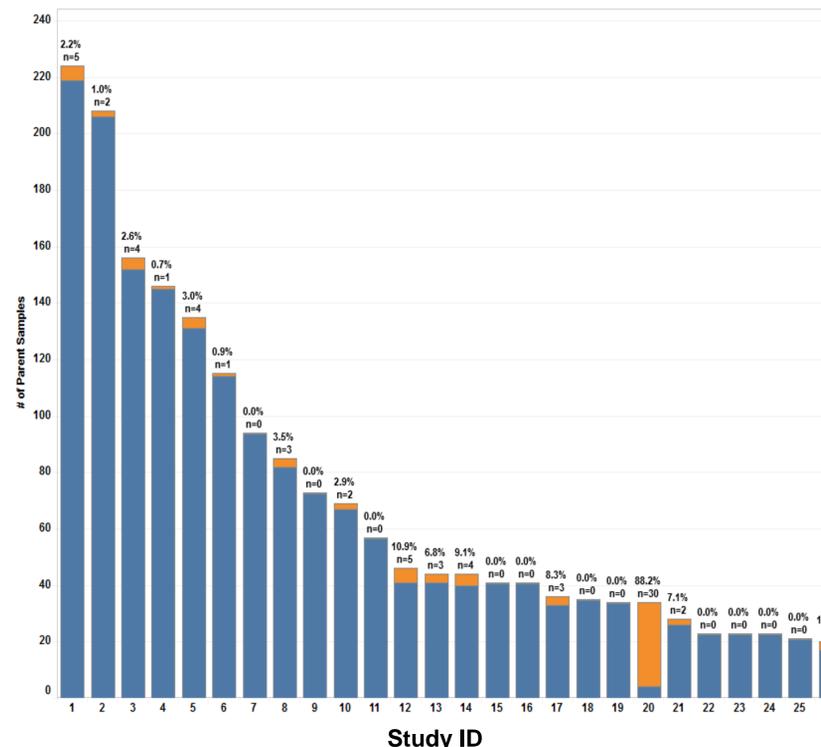


Figure 4. High accrual AND high deviation frequency may point to areas for intervention. Analysis of data from both REDCap and OnCore reporting systems indicated that some studies which had high accrual and incurred a high deviation frequency required closer investigation. Study ID indicates de-identified clinical trial studies from one of the de-identified cancer groups from Figure 3.

CONCLUSIONS & FUTURE DIRECTIONS

For the first time, the VICC has a comprehensive overview of the total biospecimen collections and deviations within the CTPC. Less than 4% of all parent samples were deviated or missed and deviation frequency varied among cancer groups, studies within those groups, and clinic locations. Missed collections and timely sample processing were the most common reasons for biospecimen deviations. Future directions include an analysis of institutional costs of deviations for future quality assurance and educational opportunities.

RESULTS

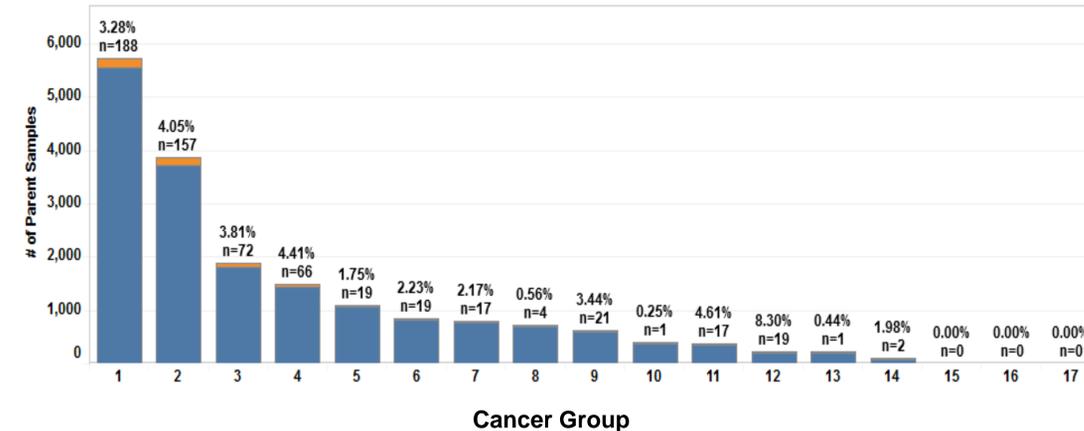
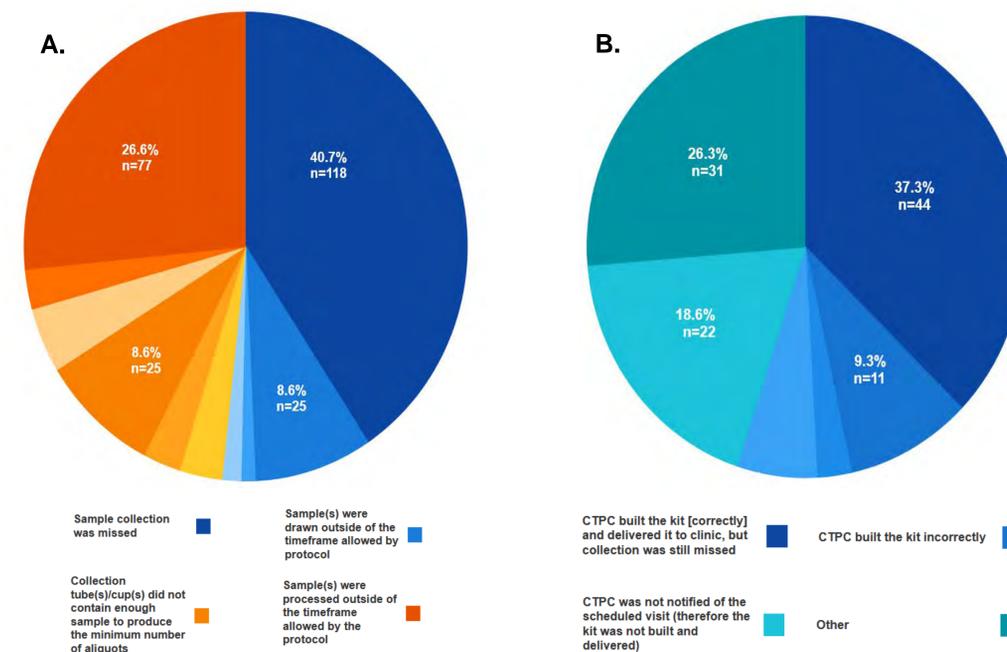


Figure 3. Deviation frequency varies among cancer groups. Analysis of data from both REDCap and OnCore reporting systems indicated variability in number of deviations among cancer groups. All cancer groups are de-identified.



Figures 5 A and B. Reasons for biospecimen collection deviations. A. Analysis of data from the REDCap reporting system indicated that missed sample collections was the highest reported deviation. B. Follow-up reporting indicated that errors in the clinic were the largest contributor to missed sample collections.

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