

ABSTRACT

Introduction: The Division of Infectious Diseases is performing a *Streptococcus pneumoniae* serotype incidence study in all hospitals in Jefferson County. Urine samples are obtained from all hospitalized patients seven days a week. Since a large number of hospitalized patients will be enrolled in this study, a large number of samples will need to be managed.

Objective: To describe the strategy developed to track study samples.

Methods: A pneumonia study sample flow chart was developed to identify all possible challenges during the study implementation. Several brainstorming meetings were conducted to develop strategies and interventions aimed at possible challenges.

Results: More than 6,000 urine samples were collected during the first year of the pneumonia study. Interventions were developed to resolve challenges in: 1) the consent process, 2) urine collection, 3) urine transport, 4) data tracking, 5) specimen banking, and 6) specimen shipment. The rate of missing urine samples after the first year of the study was less than 1%.

Conclusions: Our data indicate that creation of a study sample flowchart and targeted interventions can optimize the management of a large number of clinical research samples.

INTRODUCTION

The Division of Infectious Diseases is performing several studies in the area of Community acquired pneumonia (CAP). They include the Community Acquired Pneumonia Organization (CAPO) study, The hospitalized adults with pneumococcal pneumonia incidence (HAPPI) study, and the urinary antigen detection (UAD) for *Streptococcus pneumoniae* serotypes. The UAD is a prospective study enrolling hospitalized patients with CAP from the following adult hospitals in Jefferson County: Baptist Hospital East, Jewish Hospital, Norton Hospital, Norton Audubon, Norton Brownsboro Hospital, Norton Suburban Hospital, University of Louisville Hospital, Robley Rex VA Medical Center, Sts. Mary & Elizabeth Hospital

Urine samples are obtained from all adult hospitalized patients seven days a week. Since a large number of hospitalized patients will be enrolled in this study, a large number of samples are being managed.

A total of 50 Research Associates in the Division of Infectious Diseases are participating in the UAD study. They screen patients and approach eligible patients in all nine adult hospitals in Jefferson County. The large number of urine samples obtained combined with the large number of Research Associates in charge of study operations creates the possibility for suboptimal management of study samples.

The objective of this study was to describe the methodology developed to track study samples and optimize study procedures.

MATERIALS AND METHODS

The objective to optimize study procedures several meetings were organized among investigators and research associates. First, was decided that research associates would be structured in four research teams. Each team will consist of a team leader, sub-leader, an assistant, research scholars and at least six research associates. Each team was in charge of three hospitals. One of the teams is dedicated to performing study procedures during the weekend days.

As part of the methodology it was decided first to develop a study flowchart, second to perform several brainstorming meetings to develop strategies to resolve possible challenges.

RESULTS

The study flowchart developed during the brainstorming sessions is depicted in Figure 1

- The following challenges and strategies to resolve them were recognized:
 - Pending enrollment-Sign out sheet (Figure 2)
 - Sample storage-Biorespository REDCap sample tracking (Figure 3)
 - Increased frequency of scanning of urine sample barcodes-hired additional lab personnel
 - Developed standard operating procedures for biorepository and sample management
 - Back to basic trainings with refreshment of urine sample procedures every 6 months
 - Increased communication with hospital nurses and hospital lab personnel

A total number of urine samples collected during the first year from the nine adult hospitals is depicted in Table 1

From the total number of urine samples, the percentage of withdrawals, percentage of no urine available, percentage urine collected and percentage of samples processed and shipped are depicted in Figure 4

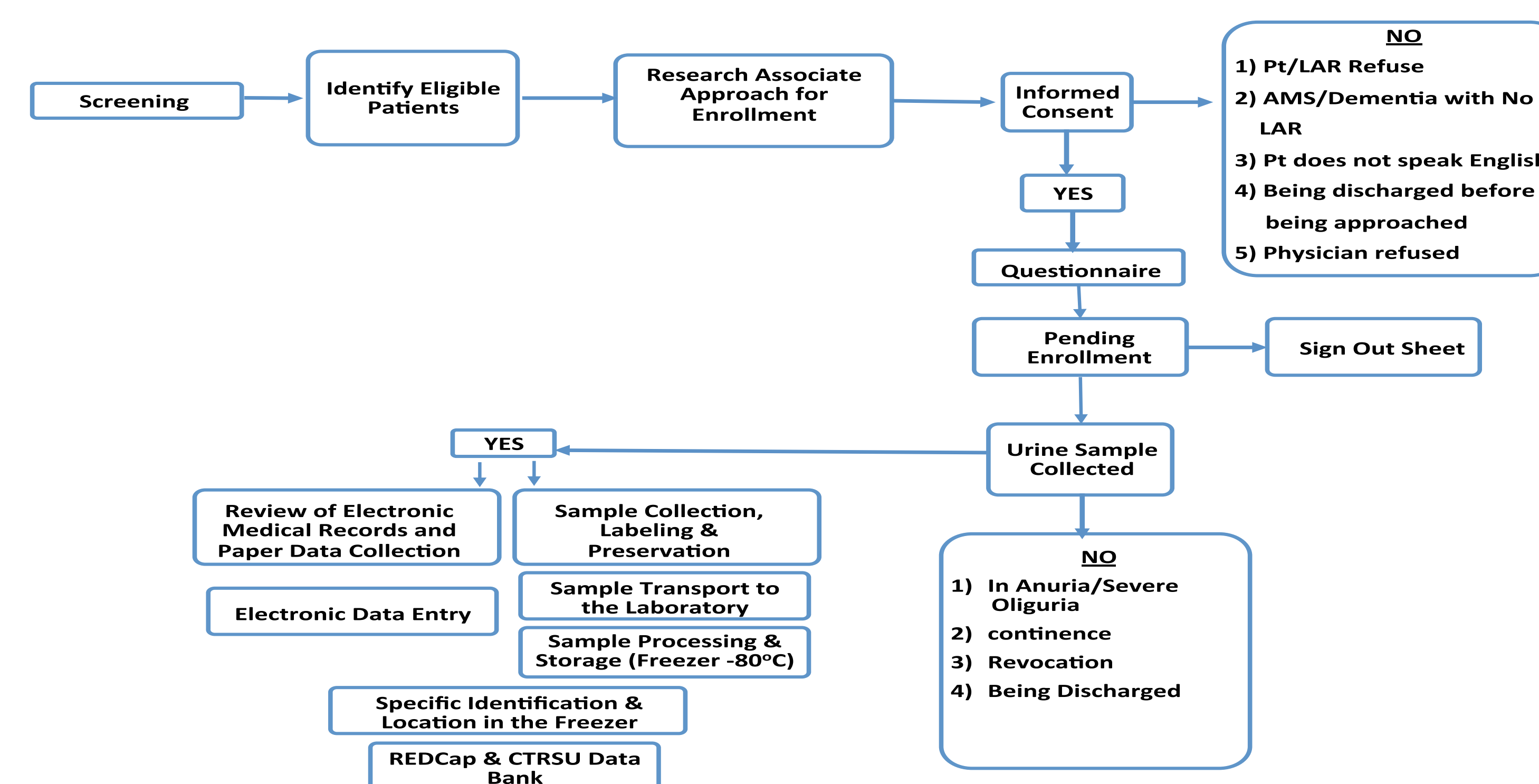


Figure 1 Study flowchart developed during the brainstorming sessions

Figure 2 Pending enrollment-Sign out sheet

Figure 3 Biorespository REDCap sample tracking

RESULTS

Table 1 Total number of urine samples collected during the first year from the nine adult hospitals

2014-2015	NA	ST	VA	BE	NS	NB	JH	ND	UofL	Total	% Total
Enrolled	1,622	753	236	1,371	742	520	1,110	715	319	7,388	100%
Withdrawn	244	139	30	249	106	107	132	141	90	1,238	16.7%
No Urine Collected & Processed	112	76	16	103	50	43	54	75	23	521	7.1%
	1,266	538	190	1,019	586	370	924	499	206	5,629	76.2%

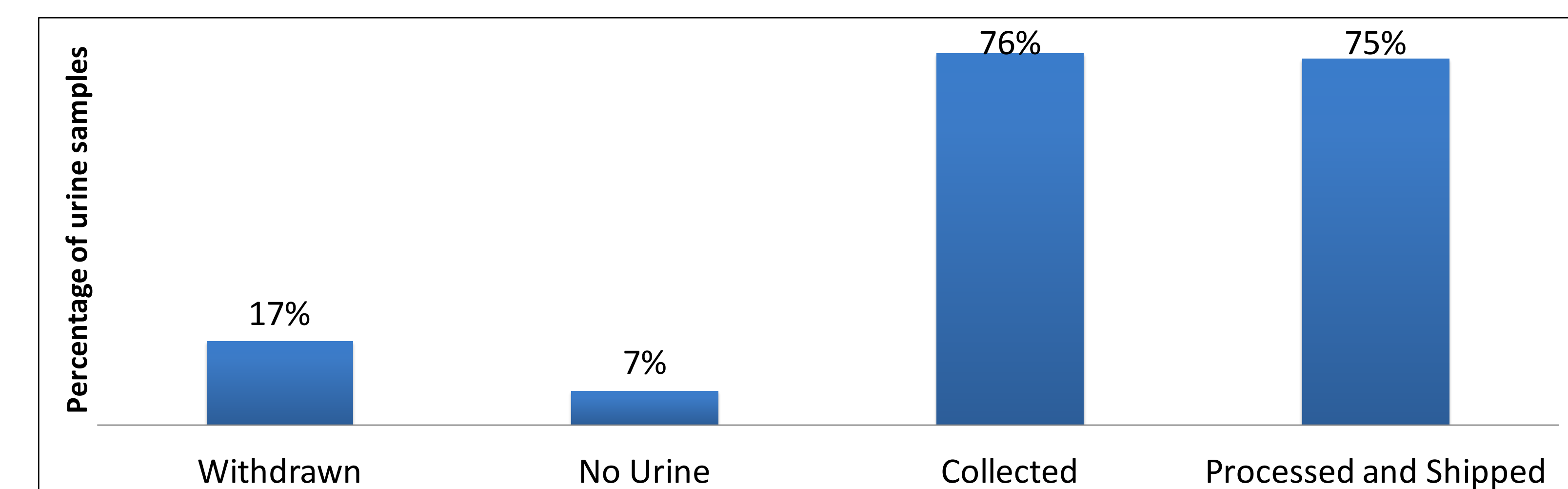


Figure 4 Percentage of total number of urine samples collected during the first year from the nine adult hospitals

CONCLUSIONS

- The creation of a study sample flowchart and targeted interventions can optimize the management of a large number of clinical research samples.
- Recording and reviewing lessons learned is key to identify & implement performance improvement strategies.
- Out of the 7,388 patients enrolled in the study, we collected and processed 5,629 samples after removing the withdrawn and no urine cases.
- Samples shipped to the testing facility of those enrolled, resulted in a 99% success rate of sample tracking, storage and shipments.
- In conclusion, several brainstorming sessions by investigators and members of the research team were successful in overcoming the multiple challenges associated with a clinical study with more than 5,000 study samples.

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