Specimen Focused Study

INTRODUCTORY PACKET

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Goal

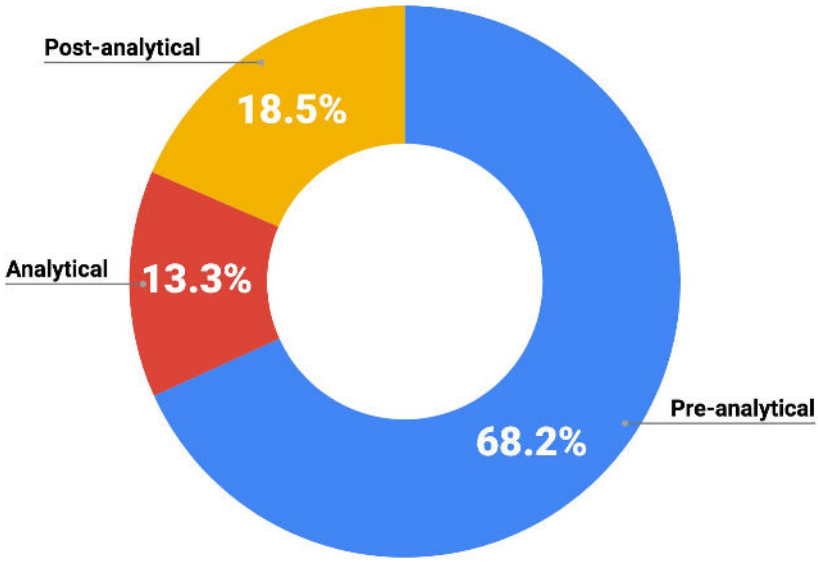
Join Arkansas' Movement to Reduce Specimen Errors!

Collect and analyze specimen events in a collaborative environment and enhance patient safety through data-driven improvement strategies.

Overview & Purpose

Laboratory testing provides essential information used by providers in medical decision making with an estimated 60–70% of these decisions based on laboratory test results (Green 2013). Patient safety events involving specimens can be precursors to serious mistakes, including diagnostic errors and inappropriate treatments. While mix-ups and mishaps do happen in laboratories, literature suggests that the majority of specimen events actually occur outside the lab. In fact, errors occurring in the Pre-analytical Phase of testing, like mislabeling and inaccurate patient identification, account for 68.2% of all specimen events, as seen in Figure 1. Studies also find that events occurring in the Post-analytical Phase are more likely to result in patient harm, like when critical results are not reported in a timely manner.

Fig 1: % of Errors By Testing Phase



Specimen errors can be expensive, too. Researchers at Loyola University Health System calculated the average cost of a labeling error to be $712 per redraw, not including inestimable damages of patient anxiety, discomfort and delays in diagnosis or treatments. Consider a hospital with an annual specimen labeling defect rate of 0.02% per million tests. This would result in 2,000 patients requiring redraws and cost the hospital over $1.4 million.

The good news is that specimen errors are believed to be highly preventable, and effective interventions based on strong policies, clear feedback, and relevant education do not need to be

resource intensive. After analyzing nearly 3,000 specimen events collected over four years, ADNPSO noted that 77% of specimen incidents either almost certainly or likely could have been prevented.

Thus, ADNPSO is launching its Specimen Focused Study in order to positively impact Patient Care, Satisfaction, Quality/Safety and Finance. The study is designed to help healthcare professionals, both inside and outside the laboratory, better understand why specimen events happen and how they can collaborate to decrease errors across the testing process.

Participation Criteria

1. **Hospitals Only:** The specimen study is limited to acute care facilities in Arkansas.
2. **Protected Health Information Submission:** Hospitals will be required to submit specimen event details to ADNPSO, including PHI, for data analysis purposes.
3. **ADNPSO Member:** As hospitals are required to submit PHI, participants in the study must be a member of the American Data Network Patient Safety Organization for the duration of the study. All data submitted to ADNPSO will be considered Patient Safety Work Product (PSWP), to which federal protections of privilege and confidentiality are applied.

Data Collection Process

Laboratory errors have been defined as “any defect that occurs during the entire testing process, from ordering tests to reporting results, and in any way influences the quality/safety of laboratory services” (Goldschmidt 1995).

ADN collaborated with other Patient Safety and Laboratory experts to design it’s Specimen Reporting Form. Standardizing the specimen form allows for collection of the same discrete data elements across participants, maximizing the analytic potential and providing clearer insight into root causes. ADN’s specimen form addresses Incidents, Near Misses and Unsafe Conditions. Data elements to be gathered include Specimen Source, Collection Technique, Collector Details, Error Categorizations, Patient Outcomes and more.

Participants in the Specimen Focused Study must submit events through ADN's proprietary event reporting application, Quality Assurance Communication (QAC). This ensures secure data entry using the standardized Specimen Reporting Form and seamless data transmission to

ADNPSO for use in analytics. Since QAC is a web-based application, minimal involvement from hospital IT is required, and ADN will guide each organization's Primary Contact through the onboarding steps outlined in Appendix A. ADNPSO will provide QAC training via webinar and video tutorials, as well as offer ongoing support for users.

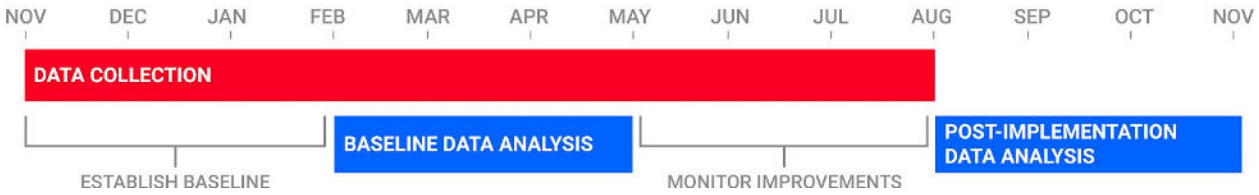
Participants may already be capturing specimen events via paper tools, self-developed electronic applications and/or third-party vendor products. However, participants in the study must consider one of the following QAC implementation options:

- **Option 1 (Preferred): Staff will begin reporting specimen events concurrently into QAC for duration of study.**
    - QAC link to be added to hospital intranet or desktops for easy access
    - Video training available to quickly onboard staff to QAC specimen reporting
    - No QAC login required by staff for specimen reporting
    - Assures data capture using ADN's standardized form to inform data analytics
- **Option 2: Staff continues reporting specimen events via existing system and Primary Contact (or designee) performs monthly data entry in QAC.**
    - Less training required if general staff not using QAC for specimen reporting
    - Imposes burden of data entry and redundant systems as QAC is necessary for PSO transmission
    - Risks data capture since current system unlikely to include all elements within ADN's standardized form

Specimen events collected in QAC must be finalized by the Primary Contact and approved for submission to ADNPSO. Preparation steps include (1) assigning Final Harm; (2) designating as Patient Safety Work Product; and (3) closing the event. All events meeting this criteria will be transmitted seamlessly to ADNPSO per the schedule in Appendix B. Per the Patient Safety Act, all events submitted to ADNPSO have federal protections of privilege and confidentiality applied.

Timeline

The duration of the Specimen Focused Study is 12 months and includes two data analysis phases. Data collection is expected to be continuous for 9 months, from November 2018 to July 2019.



- **November 1, 2018.** Data collection to begin using ADN's standard Specimen form.
- **November 2018 to January 2019.** First 90 days of data collection will establish the baseline.
- **February 2019 to April 2019.** Serves as the first data analysis phase, where ADNPSO and clients will meet to review baseline data. Analytic phases will include PSO transmission, aggregate analysis to identify improvement strategies and implementation of corrective actions..
- **May 2019 to July 2019.** Data collected will be used to monitor specimen events post-implementation of improvement strategies.
- **August 2019 to October 2019.** Serves as the final data analysis phase, where ADNPSO and clients will meet and evaluate the effectiveness of the corrective actions, as well as examine overall trends in reporting.

ADNPSO/Provider Obligations

ADN Obligations

- Provide access to Quality Assurance Communication (QAC) application
- Set up QAC for specimen reporting, PSO Transmission, and User Access
- Provide ongoing QAC support
- Transmit reported specimen events to ADNPSO

ADNPSO Obligations

- Host a kick-off webinar
- Provide materials for introducing and promoting specimen reporting
- Send email reminders of approaching data transmission deadlines
- Conduct aggregate analysis of specimen event data
- Host analytic learning sessions

Provider Obligations

- Engage senior leadership for participation approval
- Provide signed originals of required documents: Letter of Participation, Business Associate Agreement, and Patient Safety Organization Participating Provider Agreement
- Participate in the entire study, November 1, 2018 - October 31, 2019
- Attend the kick-off webinar
- Appoint representative(s) to attend analytic learning sessions
- Disseminate lessons learned and implement corrective actions

Appendix A: QAC Onboarding Steps

Onboarding Steps	ADN Responsibilities	Hospital Responsibilities
SET UP	Subscribe hospital to QAC application for Specimen reporting and PSO transmission	Provide required information for QAC set up, including User and Department Lists
ACCESS	Establish hospital-specific QAC link to share with hospital	Include QAC link on hospital intranet or desktops for easy access by staff for specimen reporting
TRAINING (Primary Contact)	Host webinar to train Primary Contact(s), addressing QAC usage and preparation steps for PSO transmission	Attend virtual kick-off webinar Review video tutorials
TRAINING (Staff)	Provide hospital with 5-minute training video “Reporting an Event using QAC” for frontline staff	Disseminate QAC training video to responsible staff Example: Consider adding and requiring QAC training video through hospital’s Learning Management System
DEADLINES	Provide PSO Transmission Schedule (See Appendix B)	Establish internal schedule to finalize events for PSO transmission, including Final Harm, PSWP Designation, and Event Closure

Appendix B: PSO Transmission Deadlines

Quarter	Event Report Date	Client Review Deadline	Auto-Lock and ADNPSO Transmission
Q1	January	February 28	March 1
	February	March 31	April 1
	March	April 30	May 1
Q2	April	May 31	June 1
	May	June 30	July 1
	June	July 31	August 1
Q3	July	August 31	September 1
	August	September 30	October 1
	September	October 31	November 1
Q4	October	November 30	December 1
	November	December 31	January 1
	December	January 31	February 1

Appendix C: References

Goldschmidt HMJ, Lent RW. Gross errors and work flow analysis in the clinical laboratory. Klin Biochem Metab 1995;3:131–40.

Green, S. F. (2013). The cost of poor blood specimen quality and errors in preanalytical processes. *Chemical Biochemistry, 46*, 1175-1179.

Kahn S, Jarosz C, Webster K, et al. Improving process quality and reducing total expense associated with specimen mislabeling in an academic medical center. Poster. 2005 Institute for Quality in Laboratory Medicine Conference: Recognizing Excellence in Practice. April 28, 2005. Accessed September 21, 2009.

Plebani M, Carraro P: Mistakes in a stat laboratory: Types and frequency. Clin Chem 1997;43:1348-1351.