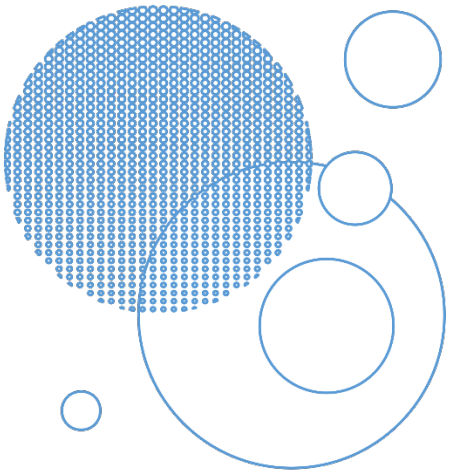

A Six Sigma Lean Green Belt Analysis of Electronic Pathology Reporting in Central Cancer Registries

January 2021

Acknowledgment

This publication was supported by the Cooperative Agreement Number 6-NU38OT000286-01 funded by the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the author and do not necessarily represent the official views of CDC or the U.S. Department of Health and Human Services.

Overview

Although hospitals have long been the primary source of cancer reporting to central registries, reporting by pathology laboratories helps to ensure that cancers diagnosed outside of the traditional hospital setting are captured by the central registry. Compared to hospital reporting, electronic pathology laboratory reporting to central registries is a relatively recent development, and each state has developed its own unique process for its management. As a result, a great deal of variability exists in the format and content of pathology reports submitted to central registries, as well as in the way reports are processed by each registry. A team composed of NAACCR staff, cancer registry subject-matter experts, and Lean Six Sigma Greenbelt students from Rutgers University undertook a study to identify the challenges and variations in the electronic pathology reporting processes used by four population-based state cancer registries and propose possible solutions to make these reporting process more efficient across states. Unfortunately, significant variability among registries in electronic pathology reporting processes makes it is difficult to identify measures necessary to make comparisons across registries. However, despite the unavailability of comparison data, the team was able to identify common themes across registries regarding the benefits and challenges of electronic pathology reporting. The key findings of the study are outlined below. The full report that follows includes detailed reporting of the Lean Six Sigma methodology used, benefits and challenges identified, and recommendations for process improvement.

Key Findings

- Electronic reporting by independent pathology laboratories is necessary to ensure complete ascertainment of cancer cases.
- Electronic reporting by independent pathology laboratories is an essential element of a population-based cancer surveillance system.
- Despite the availability of no-cost software, the current state of electronic pathology reporting involves significant manual processes requiring substantial staff time.
- Currently available no-cost software programs neither reduce processing time nor improve data quality and may, in fact, increase manual workload.
- Some central registries may not be receiving the full benefits of electronic pathology reporting because of insufficient capacity to handle the manual work necessary to fully utilize all reports.
- Large-volume registries experience greater challenges to electronic pathology reporting due to the manual workload, which is directly proportional to caseload.
- The current electronic pathology processes used by most central registries are not sustainable and will not support either the expansion of reporting by additional facilities or the increased caseload posed by a growing and aging population.

Introduction

Central cancer registries (CCRs) collect, analyze, and store cancer-related data for surveillance, research, and public health. Although specific requirements vary, all U.S. states and territories mandate the reporting of cancer to the central registry by hospitals and other health care facilities and providers, including laboratories. Pathology laboratories have long reported on paper or in non-machine-readable formats like PDF, but electronic pathology reporting in a standardized, machine-readable format is increasingly preferred and is thought to reduce the burden on cancer registries.

In general, electronic pathology reporting requires (1) identifying reportable cases from among all laboratory specimens, (2) ensuring secure transmission of the reports from the laboratory to the CCR, and (3) coding of key data elements, such as patient and tumor identifiers, using cancer registry standards. Most registries accomplish this using a tool provided by either the Centers for Disease Control and Prevention (CDC) or the National Cancer Institute (NCI). The CDC provides registries with access to its Public Health Information Network Messaging Service (PHIN-MS) for identification and transmission of cases and with eMaRC+ software for coding. The NCI-supported software E-Path, managed by Inspirata, Inc., accomplishes all three steps. Registries have incorporated these systems into their general operations in different ways based on their infrastructure, caseload, available resources, and overall experience. Variations within the reporting process can lead to barriers that may negatively impact the timely collection of cancer data.

Lean and Six Sigma are process improvement tools that have been widely used to increase efficiencies in production by various top-level businesses, including Motorola and Toyota. More recently, many in the health care industry have adopted a combined Lean Six Sigma (LSS) approach for enhancing the quality and efficiency of health care. A team of LSS Green Belt students and the faculty at Rutgers University Master of Health Administration program (RMHA) collaborated with the North American Association of Central Cancer Registries (NAACCR), the National Association of Chronic Disease Directors (NACDD), and the CDC to perform a Lean analysis of the electronic pathology reporting structure. The project aimed to apply the LSS framework to identify the challenges and variations in the electronic pathology reporting processes used by four states and propose possible solutions to make these reporting process more efficient across states. A secondary aim was to determine the utility of LSS in improving registry operations.

DMAIC is a key tool in the LSS model. The DMAIC methodology relies heavily on data to **D**efine, **M**easure, **A**nalyze, **I**mplement and **C**ontrol processes. Often applied to complex problems with an unknown cause, it is a cornerstone of the LSS paradigm. Unlike the familiar Plan, Do, Study, Act (PDSA), DMAIC places greater emphasis on pre-intervention planning and data collection with three distinct steps—Define, Measure and Analyze—before any improvement is implemented. A key advantage of DMAIC is its applicability to complex processes, making it an ideal tool for use in cancer registries.

The Rutgers LSS students conducted in-depth interviews with central registries in four states. The states were selected to represent the diversity of registries in the United States with regard to size, structure, and operations. The characteristics of the participating registries are summarized in Table 1.

Table 1. Participating Registry Characteristics

	Registry A	Registry B	Registry C	Registry D
Population	8.8 million	11.6 million	5.1 million	1.05 million
Registry software system	SEER DMS	Registry Plus	Registry Plus	Registry Plus
Pathology transmission system	Inspirata E-path* & PHIN-MS	PHIN-MS	PHIN-MS	PHIN-MS
Pathology screening/ coding system	Inspirata E-path* & SEER DMS	eMaRC+	eMaRC+	eMaRC+
2016 cancer incidence (invasive)	52,065	66,927	27,921	6,090

*Registry A receives reports from hospital-based laboratories and some independent laboratories through Inspirata E-path; only independent laboratory pathology reporting was included in this analysis.

*D*MAIC: Define

The Define phase of DMAIC identifies the project goals and deliverables. In this case, it also required the LSS team to develop a general understanding of central registry operations. The tools used in this phase of the Lean Process were the Project Charter, Stakeholder Analysis, and Process Maps.

Project Charter

A project charter introduces the project and defines the project scope, problem statement, and objectives, as well as the roles and responsibilities of the team members. After thorough consideration and consultation with NAACCR staff and registry subject-matter experts, the LSS team generated the project charter shown in Figure 1.

Lean Project Charter

Start Date: 12/05/2019
Planned End Date: 6/15/2020

Problem Statement: There is uncertainty around the best process for using electronic pathology reports so as to maximize their value in improving completeness and timeliness while reducing the extra manual labor that surrounds their use.

Objectives: (1) To define how four diverse model states process electronic pathology reports; (2) To assess the differences in efficiencies and outcomes associated with various electronic pathology reporting processes; and (3) To identify defects and opportunities for improvement within the current processes.

Project Scope Information:
- In scope: Pathology reports received in machine-readable structured electronic format from independent lab by the four model cancer registries and the methods used to process them.
- Out of scope: Pathology report structures, state laws & regulations, hospital-based lab reports

Executive Sponsor(s): Stephanie Hill & Ann Marie Hill

Project Owner: Betsy Kohler

Process Improvement Facilitators: Jill Anderson & Green Belt Students

Ad Hoc Member(s): NAACCR Consultants

Figure 1. Project charter.

Stakeholder Analysis: ARMI

ARMI is a project management tool that scrutinizes the stakeholder (team) involvement in any project. It represents the different levels of support required, and the acronym stands for **A**pproval of team decisions; **R**esource to the team, who will provide expertise and skills on an ad hoc basis; **M**embers of the team whose expertise is needed regularly; and an **I**nterested party who will be continuously informed on direction and findings. The ARMI worksheet in Figure 2 indicates various levels of support and involvement for the team.

Key Stakeholders	Define	Measure	Analyze	Improve	Control
Stephanie Hill	A, R, I	A, R, I	A, R, I	A, R, I	A, R, I
Betsy Kohler	A, R, I	A, R, I	A, R, I	A, R, I	A, R, I
Jill Anderson	A, R, M, I	A, R, M, I	A, R, M, I	A, R, M, I	A, R, M, I
Ashli Clarke	A, M, I	A, M, I	A, M, I	A, M, I	A, M, I
Sabrina Caramant	A, M, I	A, M, I	A, M, I	A, M, I	A, M, I
Nida Rahman	A, M, I	A, M, I	A, M, I	A, M, I	A, M, I
Melissa Beatty	A, M, I	A, M, I	A, M, I	A, M, I	A, M, I
Aakanksha Deoli	A, M, I	A, M, I	A, M, I	A, M, I	A, M, I
Lori Havener	A, I	A, I	A, I	A, I	A, I
Ann Marie Hill	A, R, I	A, R, I	A, R, I	A, R, I	A, R, I
NAACCR Consultants	A, R, I	A, R, I	A, R, I	A, R, I	A, R, I

Communication Plan			
Information or Activity	**Information Channel**	**Who**	**When**

Project Status	Email	PI Facilitators, GB students, consultants	Weekly
Tollgate Review	Email, in-class review	PI Facilitators	Weekly
Project Deliverables	Emails, Group Me, Phone	GB Students	Weekly
A – Approval of team decisions R – Resource to the team; one whose expertise and skills may be needed on an ad hoc basis M – Member of the team, one whose expertise will be needed on a regular basis I – Interested party; one who will need to be kept informed on direction and findings			

Figure 2. ARMI worksheet.

Process Maps

A process map illustrates the set of activities carried out to complete a process. Process mapping helps to visualize the problems and errors within the process and to identify opportunities for improvement. In this case, the process maps also demonstrate the variability in how different states implement electronic pathology reporting. The process maps for electronic pathology reporting were developed based on in-depth discussion with each of the four model states (Figures 3–6).

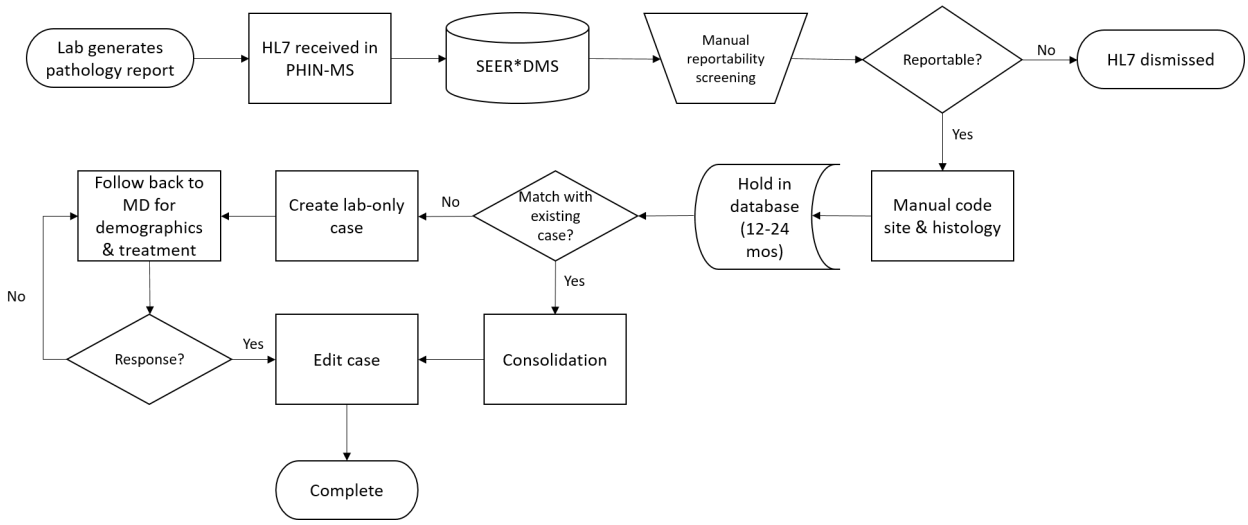

Figure 3. Registry A electronic pathology process map.

Key points

- Registry A receives electronic-pathology reports from independent laboratories through both PHIN-MS and Inspirata E-Path.
- All electronic pathology reports are imported into the main registry database (SEER*DMS) as they are received.
- Registry A manually screens and codes all electronic pathology reports from independent laboratories within the SEER*DMS system (40–50 reports per hour).
- eMaRC+ is not used by Registry A because of the quality of auto-coding and because it would convert all electronic pathology reports to NAACCR Abstract (NA) format. The registry workflow within SEER*DMS requires that electronic pathology reports remain in HL7 format.
- Pathology reports are used to create cases only after cases from all other sources have been processed.

Registry A uses a combination of Inspirata E-Path and PHIN-MS to receive electronic pathology reports from both independent and hospital-based laboratories. This project focused on independent laboratory reporting, but it should be noted that hospital-based laboratory reporting can be used to validate hospital reporting completeness, and the registry credits these reports with identifying thousands of otherwise unreported hospital cancer cases each year with minimal effort on the part of the central registry. Registry A receives and processes nearly 129,000 electronic pathology reports per year from hospital-based and independent laboratories but manually screens and codes only reports of hematopoietic cancers from hospital laboratories and all reports from independent laboratories, totaling more than 40,000 such reports annually. All automated and manual screening and coding are performed within the main cancer registry system, SEER*DMS.

Registry A tested the use of eMaRC+ software but identified several of the following drawbacks that made its use counter-productive:

- The need to create a full NA in eMaRC+ requires manual work that is unnecessary in the majority of cases. Most NA data items are not available in a pathology report but already exist in an NA in the registry database. Therefore, coding and reviewing them in eMaRC+ is redundant and represents a non-value-added step.

- The workflow in the registry database, SEER*DMS, requires electronic pathology reports to be in HL7 format, which cannot be produced by eMaRC+.

- Auto-coding and screening performed by eMaRC+ is unreliable and does not reduce or eliminate the need for manual review.

During the consolidation process, electronic pathology reports are used to validate clinical information, such as date of diagnosis, primary site, histology, prognostic factors, and treatment. Data from hospital cancer registries often are found to be incorrect or less specific when compared to information in the pathology report. These errors are used as an opportunity to identify hospital registrar training needs.

Registry A identified rapid case reporting, identification of missed cases, and validation of clinical information as some important benefits of electronic pathology reporting. A major challenge to pathology reporting for Registry A is the volume of manual work involved in screening and coding electronic-pathology reports from independent laboratories and in following back to physicians for demographic and other information for laboratory-only cases.

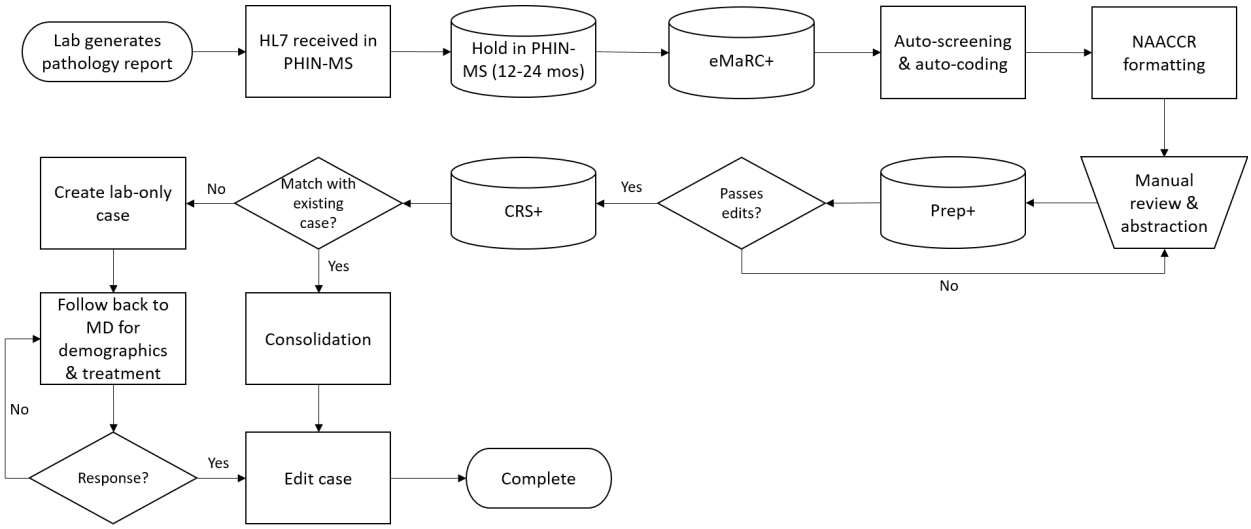

Figure 4. Registry B electronic pathology process map.

Key Points

- Registry B receives electronic pathology reports from independent laboratories through PHIN-MS.

- All electronic pathology reports are screened and auto-coded by eMaRC+ as a batch once per year.
- All electronic pathology reports are manually reviewed and edited after auto-coding in eMaRC+ because of the inaccuracy of eMaRC+ auto-coding and the need to complete additional fields in the NA to ensure it passes edits (2–6 reports per hour).
- All reportable electronic pathology reports are imported into the Registry B cancer registry database, CRS Plus.
- Pathology reports are used to create cases only after cases from all other sources have been processed.

Registry B receives electronic pathology reports from independent laboratories through PHIN-MS and processes them in eMaRC+. The advantage of the electronic pathology reporting that Registry B cited is receiving the pathology reports electronically to identify unreported cases and missing information.

However, Registry B experiences a few challenges with the process. The Registry B caseload is too large to manually look up each electronic pathology report in the cancer registry database. Without a way to electronically match the reports in eMaRC+ with the registry database in CRS Plus to identify otherwise unreported cases, Registry B must process all electronic pathology reports, which includes coding and editing an NA in eMaRC+ and Prep+. This contributes significantly to the manual workload involved in the process, which includes entering the data into eMaRC+ to complete the NA; running edits in Prep+ and correcting them in eMaRC+; finding the matches and deduplication; and following back with the physicians for missing information. Because all this work is manual, Registry B finds it very time-consuming. Registry B also noted that eMaRC+ auto screening for reportability is unreliable, and cases marked non-reportable often are reportable; 100 percent manual review is required to ensure that no cases are missed.

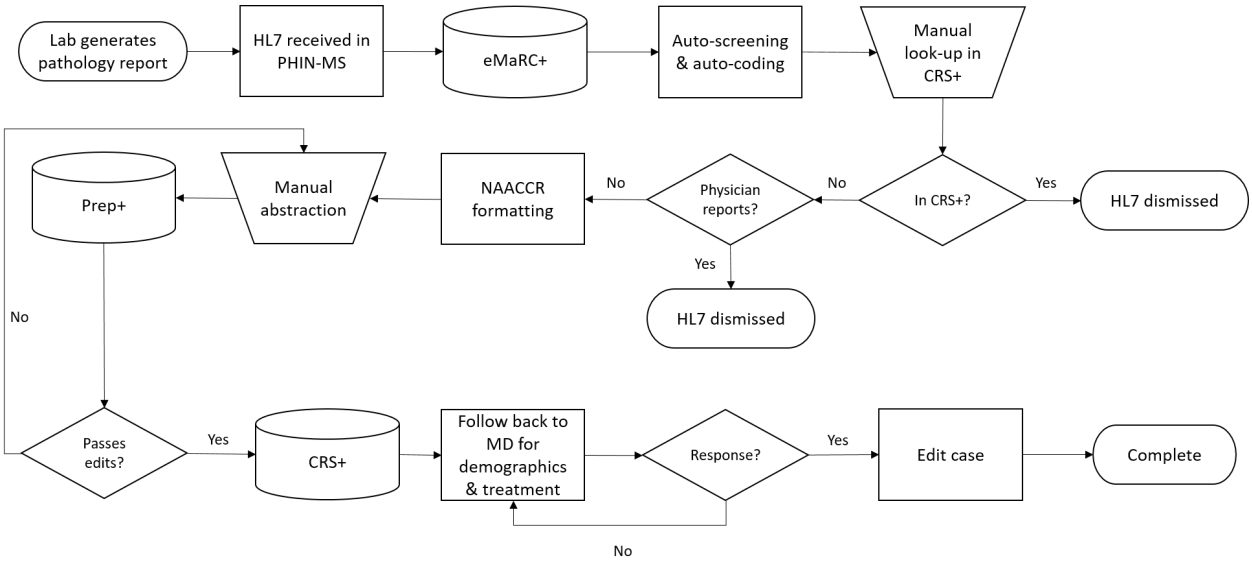

Figure 5. Registry C electronic pathology process map.

Key Points

- Registry C receives electronic pathology reports from independent laboratories through PHIN-MS.
- All electronic pathology reports are screened and auto-coded by eMaRC+ as they are received (within 5 days).
- Electronic pathology reports are manually looked up in the main registry database, CRS Plus.
- The Registry processes electronic pathology reports only for cases not already in CRS Plus or when the ordering physician reports to the CCR. The decision to process an electronic pathology report into the registry database is subjective, based on the reviewer's expectation of the probability of receiving the case from another source.
- NA are completed manually in eMaRC+ for all reportable electronic pathology reports.

Registry C receives electronic pathology reports from independent laboratories through PHIN-MS and processes them in eMaRC+ and Prep Plus. Staff manually review all electronic pathology reports to determine which to process into the registry database based on whether they expect to receive the case from the ordering physician. The reports are processed as they are received. Registry C identified the major advantage of the electronic pathology reporting process as its being a tool to find missing cases that otherwise were not reported.

The challenges that Registry C faces are similar to what other states face and include the need for extensive manual labor, lack of interoperability with other registry systems, and lack of integrated edit checks in eMaRC+.

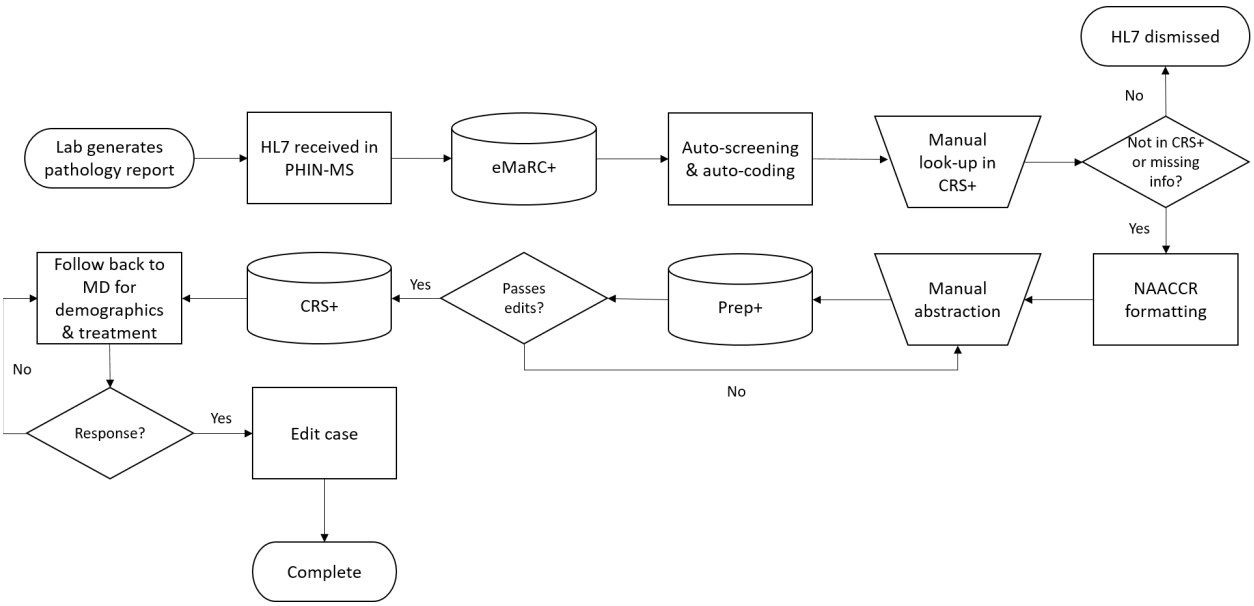

Figure 6. Registry D electronic pathology process map.

Key Points

- Registry D receives electronic pathology reports from independent laboratories through PHIN-MS.
- All electronic pathology reports are screened and auto-coded by eMaRC+ as they are received.
- NA are completed manually in eMaRC+ for all reportable reports.
- Cases are manually looked up in the registry database.
- Only electronic pathology reports for unreported cases or for cases with missing information are processed.

Registry D receives electronic pathology reports from four independent laboratories through PHIN-MS and processes them in eMaRC+ and Prep Plus. Registry D reported that the benefits of the electronic pathology reporting process were keeping records, identifying missing cases, and receiving information directly from pathologists.

In contrast, the biggest challenge for Registry D is receiving all the electronic pathology reports. Currently, only four laboratories send electronic pathology reports to Registry D; it is unknown how many laboratories are not reporting and how many cases may be missing from those laboratories. Registry D also reported the lack of automated screening and matching within the eMaRC+ as a challenge.

Threats and Opportunities

Based on the process maps and considering the cancer surveillance reporting structure and the importance of cancer reporting, the team identified potential threats and opportunities in the timely availability of quality cancer data (Figure 7). The most significant threats to cancer registries involve the expanding workload due to the rising number of cancer cases and the expansion of data items required for collecting, manually consolidating, and editing, combined with increasingly constrained financial resources. Central registries will continue to be expected to “do more with less.” Compounding this is the threat of a growing number of patients’ receiving cancer care outside the traditional hospital setting, requiring central registries to rely on reporting by nonhospital sources, such as independent laboratories.

Although cancer surveillance faces a number of threats, opportunities are open to the registry community. Technological advances in computational science have made artificial intelligence and advanced natural language processing more available than ever before. These tools have the potential to significantly improve the automated abstraction of data from unstructured text. Likewise, the availability of big data provides opportunities for linkages to supplement and enhance manual data collection processes. And last, the cancer surveillance community has vast collective expertise that can and should be leveraged in the development of new methods and best practices.

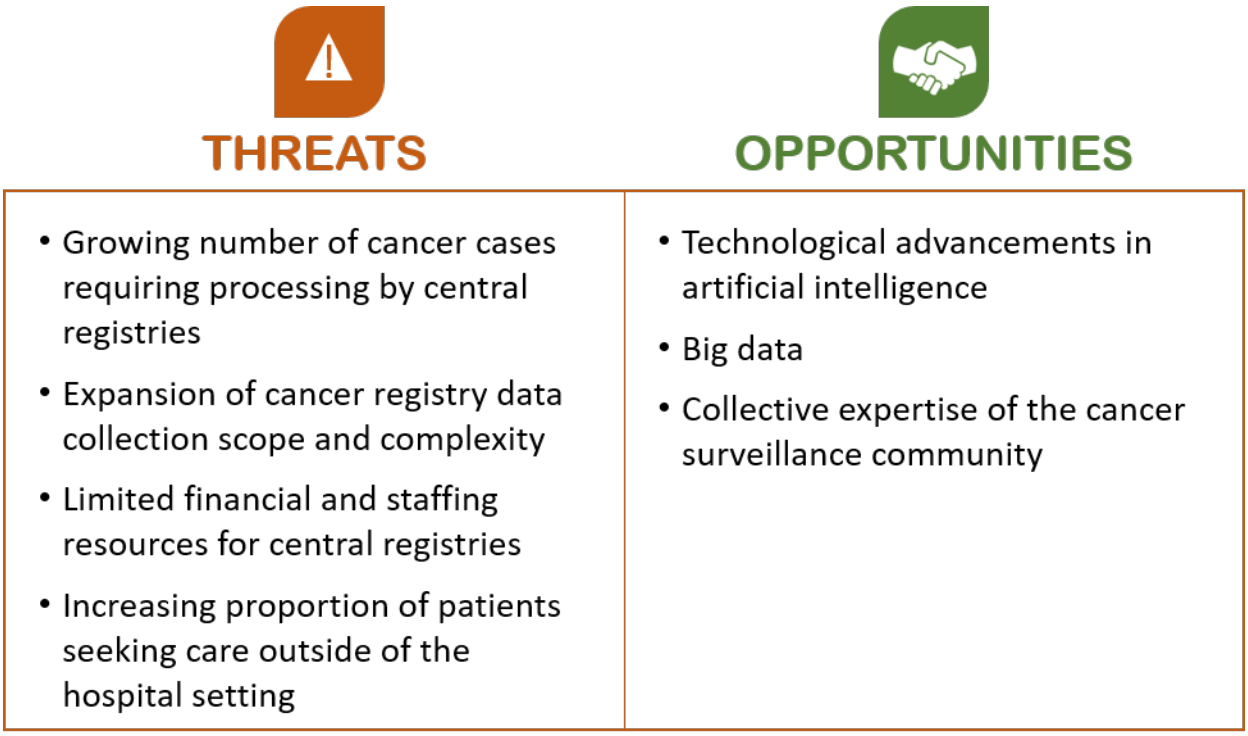

Figure 7. Threats and opportunities.

D*M*AIC: Measure

The Measure phase of DMAIC is fundamental to evaluating the assumptions made regarding the problems and errors within a process during the Define phase of a process improvement project. It further delves into the process and relies heavily on information collected from the subject-matter experts.

Because registries use different terminology to describe their processes, developing clear operational definitions was an important element in the Measure phase. For this project, the following operational definitions are used:

- **Consolidation:** Unification of all pertinent documents pertaining to a single cancer diagnosis
- **Screening task:** Reviewing reports to determine reportability and completeness of data
- **Abstract:** Summary of all information pertaining to a single cancer diagnosis
- **Gold Standard:** Meets reporting deadlines and internal best practices
- **Reportable:** Cases that meet criteria to be included in incidence calculations
- **Deduplication:** Process of eliminating duplicate copies

Data Collection Plan

Data were collected primarily through telephone interviews with key staff at each participating registry. NAACCR consultant subject-matter experts and executive sponsor were present for all interviews to assist the team in interpreting and summarizing information. Registries provided general process documentation for the LSS team to review ahead of the interview, and questions were designed to investigate the variations within the electronic pathology reporting process across the model states. The interviews focused on the advantages of the current electronic pathology reporting process, challenges faced, and state-specific recommendations to improve the process.

Although defining the process used by each registry was relatively straightforward, identifying a consistent set of metrics that could be easily collected across all four registries was more challenging. During a typical LSS project, team members would collect data through on-site observation. However, due to geographic distance, the short time frame of the project, and the nature of cancer registry work spanning many months, direct observation was not possible. The LSS team had to rely on data previously collected by each registry or on retrospective collection of data on processes already performed. The advantages and disadvantages of each method are discussed in Table 2.

Table 2. Data Collection Methods

Method	Advantages	Disadvantages
Data previously collected	• No additional data collection work	• Not available for all registries • Inconsistently collected across registries
Retrospective data collection	• Ability to apply consistent definitions across all registries	• Software-dependent • Limited availability of canned reports • Reliant on registry resources and knowledge of generating reports. • Not available for tasks performed outside of a software program

Significant time and effort were devoted to identifying metrics that could be provided by all four model registries. Several challenges were observed in one or more registries, impeding the team's ability to collect comparable data across all four registries:

- Registries do not regularly track process metrics.
- Registries lack the necessary experience in writing complex queries to extract process data from software applications.
- No-cost software applications lack easy access to metrics for monitoring processes.
- Different software applications are required to process electronic pathology reports, creating the need for manual labor.
- Metrics are not available for tasks performed manually (i.e., manual look-up)
- Differences in processes across registries make comparison of associated metrics challenging.

Data collected from each registry using a combination of methods are included in Table 3 and discussed below.

Table 3 Data Metrics Compared Across Model States

Measure	Registry A	Registry B	Registry C	Registry D
Population	8.8 million	11.6 million	5.1 million	1.05 million
Registry software system used	SEER*DMS	CRS Plus	CRS Plus	CRS Plus
Pathology transmission system	PHIN-MS & Inspirata E-Path	PHIN-MS	PHIN-MS	PHIN-MS
Pathology processing system	Inspirata E-Path & SEER*DMS	eMaRC+ & Prep Plus	eMaRC+ & Prep Plus	eMaRC+ & Prep Plus
Annual incident cases	60,000	75,000	30,000	6,000
Total cancer records received annually	300,000+	130,000	31,000	7,000
Number of electronic pathology reports received annually	130,000	2,900	Thousands	N/A¥
Number of electronic pathology reports processed annually into registry database	130,000	2,900	600–700	N/A¥
Number (%) of incident cases received from laboratories only (no other reporting source)	2,800 (4.7%)	N/A¥	600–700 (2-2.3%)	N/A¥
Number of consolidations performed annually	~45,000	~55,000	N/A¥	~7,500
Electronic-path reports imported into registry data	All	All reportable	Only unique	Only unique
Number of non-reportable cases	8,385 (2017)	450 (2017)	10%	Varies by facility, 1–100%
Number of manual screening tasks	40,675 (2017)	2,900	Thousands	N/A¥
Screening time	40–50 reports per hour	10–30 minutes per report (screening + data entry into eMaRC to complete NA)	20 minutes per report	1 week for all reports
Consolidation time (minutes per case)	~12	~10–30	N/A¥	~15–20
Consistently meets CDC 12-month completeness standard	Yes	No	No	N/A¥

¥Registry did not provide this information.

Registry A

With a population of 8.8 million, Registry A has approximately 60,000 incident cancer cases per year. Each year Registry A receives more than 300,000 individual records of cancer, including 130,000 electronic pathology reports. Registry A performs more than 40,000 manual electronic path screening tasks and 45,000 manual consolidation tasks each year. Pathology screening tasks, which include assigning reportability and coding primary site, histology, behavior, and grade, are performed at a rate of 40–50 tasks per hour. Consolidation tasks, which include visual editing of key data items and resolution of all edits, are performed at a rate of five tasks per hour. Registry A consistently meets the 12-month completeness standard.

Registry B

With a population of 11.6 million, Registry B has approximately 75,000 incident cancer cases each year. Registry B receives approximately 130,000 individual records of cancer annually, including 2,900 electronic path reports. All 2,900 electronic pathology reports are manually reviewed to validate eMaRC+ auto-coding and reportability and to complete the NA. These tasks are performed at a rate of 2–6 per hour. Registry B performs approximately 55,000 manual consolidation tasks each year, at a rate of 2–6 per hour. Registry B met the 12-month completeness standard for the first time in 2018.

Registry C

With a population of 5.1 million, Registry C has an annual cancer incidence of approximately 30,000 cases. Registry C receives approximately 31,000 individual reports of cancer each year, not including the thousands of electronic pathology reports received. Because Registry C manually screens electronic path reports and does not process reports for diagnoses already in the registry, it could not provide data on the total number of electronic pathology reports received each year beyond describing it as in the “thousands.” Registry C imports into its registry database approximately 600–700 electronic pathology reports annually for cases not reported by another source (mostly dermatology and urology cases). Registry C estimates that screening tasks are performed at a rate of 20 per hour. Registry C reported that it has never met the 12-month completeness standard.

Registry D

With a population of 1.05 million, Registry D is the state with the smallest population among the model states, with an annual cancer incidence of approximately 6,000 cases. Registry D performs approximately 7,500 consolidation tasks annually at a rate of 3–4 per hour. Registry D was able neither to provide data on the number of records received nor to report on its record of meeting the 12-month completeness standard.

Problem Areas in the Process Maps: Storm Clouds

Considering all the data collected, problem areas were identified for electronic pathology reporting for each state. These problem areas are identified as storm clouds in the process maps below.

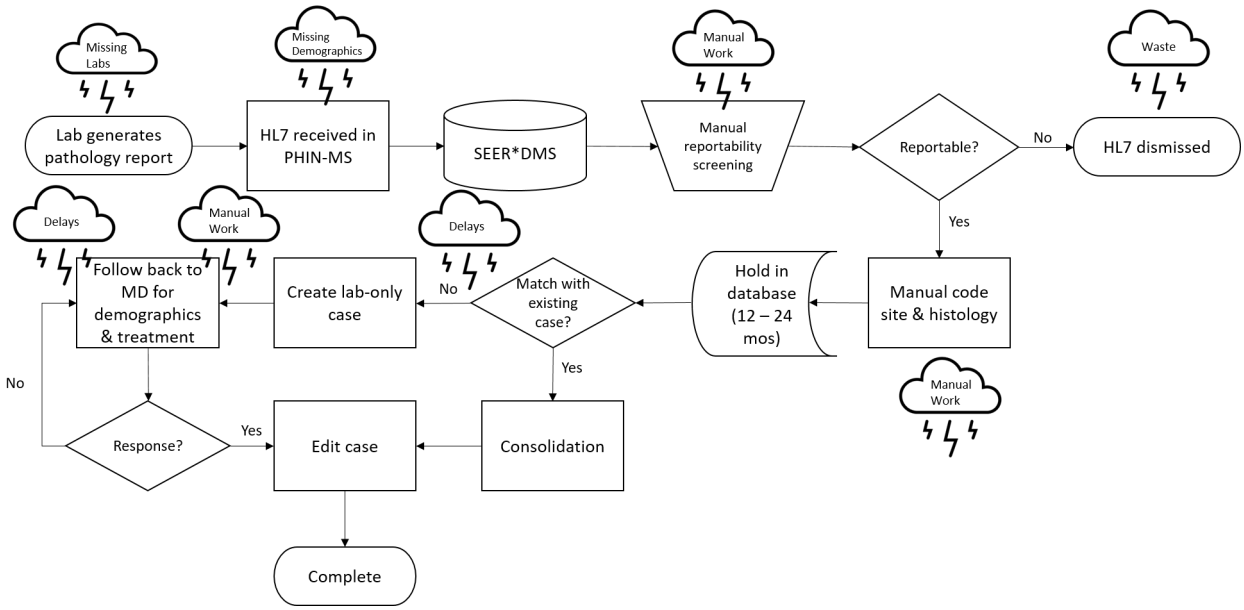

Figure 8. Registry A storm clouds

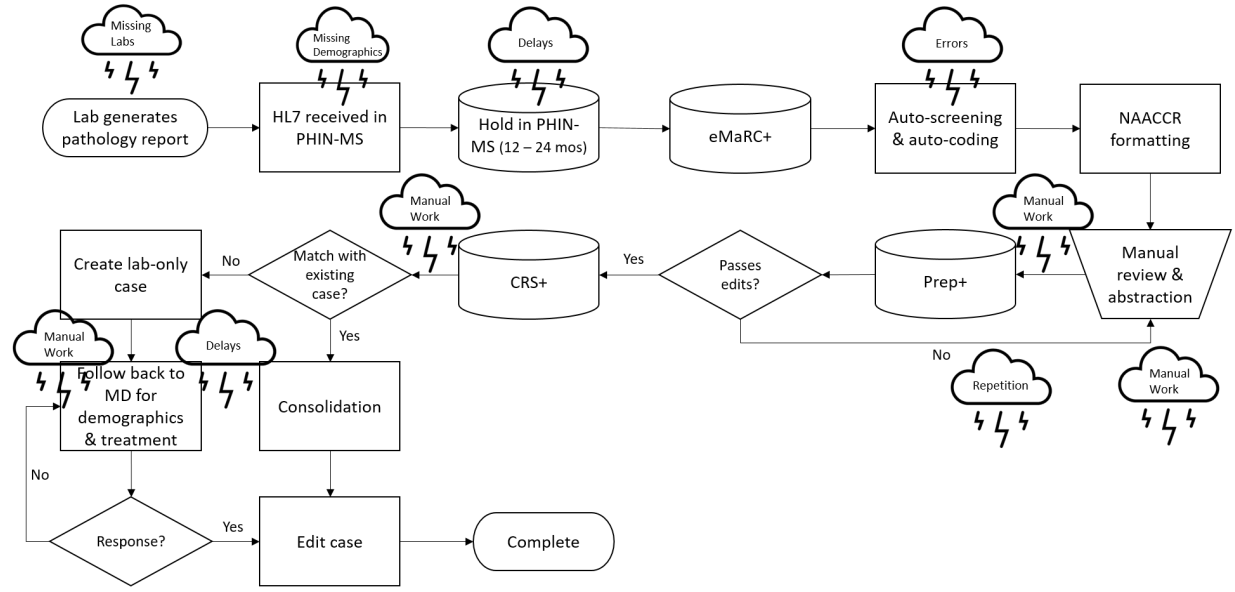

Figure 9. Registry B storm clouds.

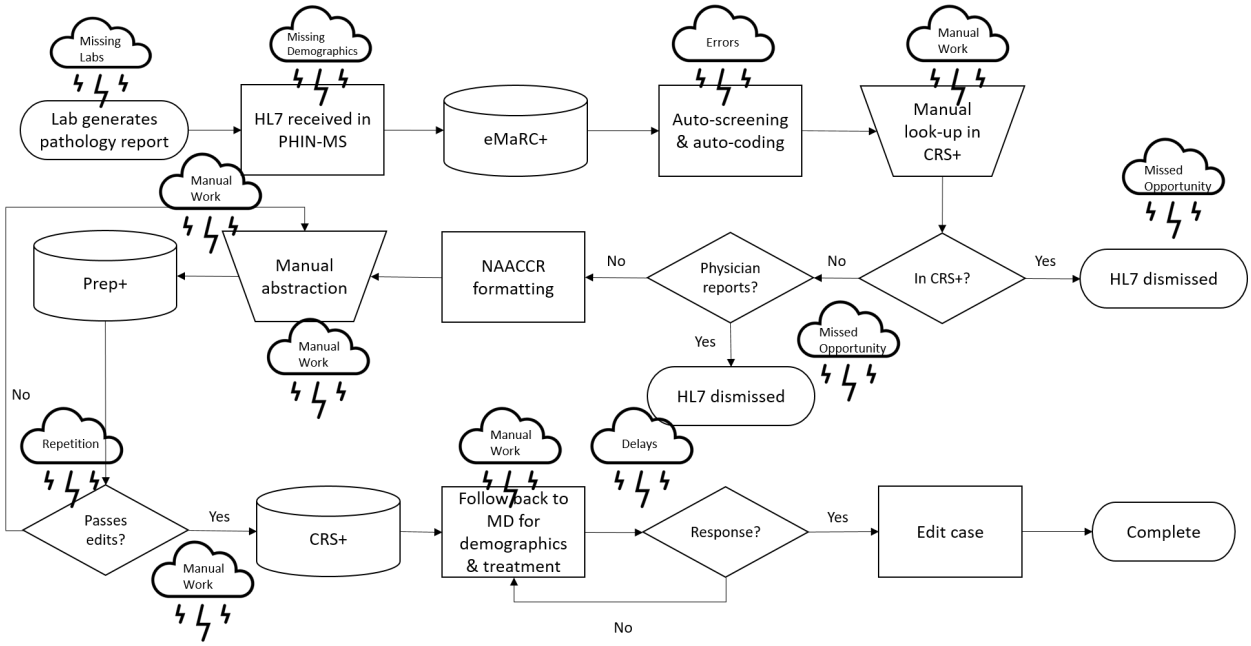

Figure 10. Registry C storm clouds.

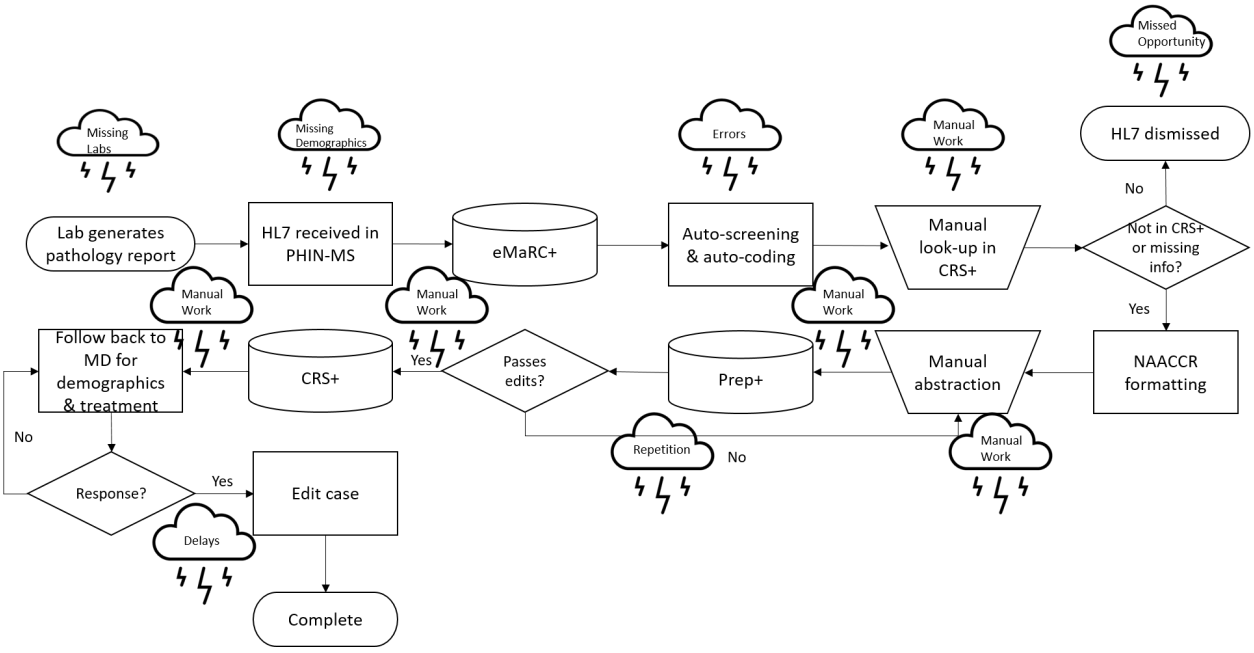

Figure 11. Registry D storm clouds.

Common Challenges Faced by Registries with E-Path Reporting Process

It is now well established that each state has a different electronic pathology reporting process and, therefore, each state's process has unique benefits and challenges that make it difficult to suggest common solutions. Furthermore, registries use electronic pathology reports to different degrees. However, some challenges are common to all four registries' processes. For example, a lack of interoperability between software systems is a common problem. Moreover, all four states require some degree of manual labor for processing electronic pathology reports and following back for additional information. Common challenges identified across all states are listed in Figure 12.

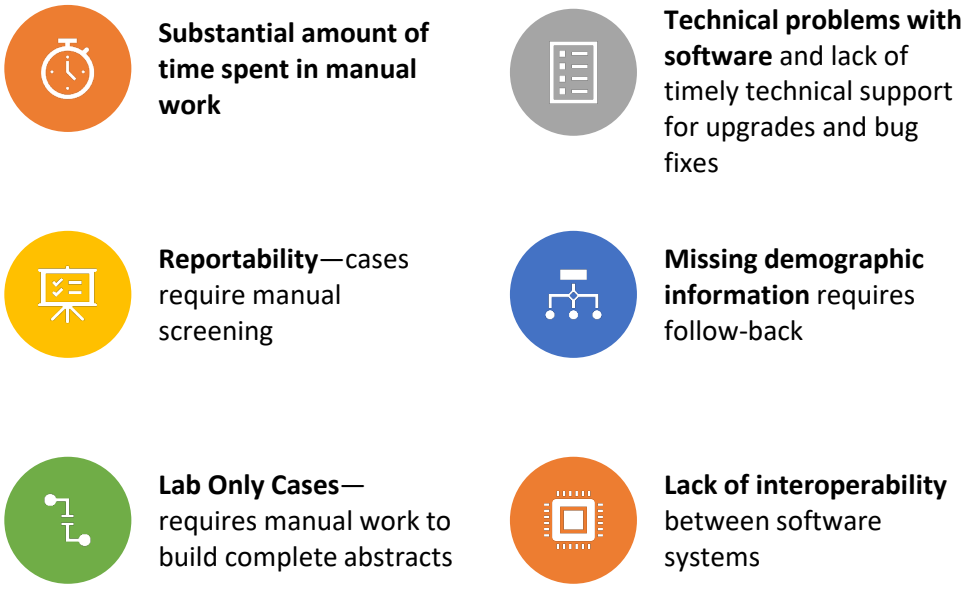

Figure 12. Common Challenges.

The key observations across multiple registries are summarized in Table 4.

Table 4. Electronic Pathology Benefits and Challenges Reported by Registries

Benefits				
	REGISTRY A	**REGISTRY B**	**REGISTRY C**	**REGISTRY D**
Identification of missed cases	Y	Y	Y	Y
Quality control	Y	Y	N	N
Collection of information missing from reports received from other sources.	Y	Y	N	Y
Education and training	Y	Y	N	N
Hospital case finding audits	Y	N	N	N
Challenges				
	REGISTRY A	**REGISTRY B**	**REGISTRY C**	**REGISTRY D**
Electronic-pathology reports missing key demographics	Y	Y	Y	N
Time-consuming manual follow-back	Y	Y	Y	N
Accuracy of eMaRC+ auto-coding and reportability	Y	Y	N	N
Duplicate electronic pathology reports	Y	Y	N	N
Creating NAs in eMaRC+	Y	Y	N	N
Managing edits in Prep Plus	N/A	Y	Y	N
Non-reportable cases submitted	Y	Y	Y	N
Technical problems with eMaRC+ and timely availability of upgrades	Y	Y	N	Y
Lack of interoperability/ integration of software	Y	Y	Y	Y
Lack of standardized process metrics	Y	Y	Y	Y
Lack of jurisdiction over national laboratories/reliance on CDC to onboard laboratories and address issues	N	Y	Y	Y

Benefits

The registries cited varying degrees of benefit from electronic pathology reporting, with all four registries reporting the identification of missing or otherwise unreported cases as the primary benefit. Between 2.3 percent and 4.7 percent of the registries' cancer cases were reported by laboratories as the sole source ("lab only"). This supports the role of electronic pathology reporting in ensuring complete ascertainment of cases. In fact, the one registry that consistently met the 12-month reporting standard also had the highest proportion of cases from laboratories only. Most of the registries also benefited from using electronic pathology reports to supplement missing or non-specific information pertaining to cases from other sources. Registries that process all electronic path reports (regardless of reporting by other sources) indicated an additional benefit of validating and correcting case information from other sources (e.g., date of diagnosis, histology, site-specific data items, treatment dates). The results of these quality control activities also were used for education and training. One registry also used hospital-based electronic pathology laboratory reports path reports to conduct case-finding audits of hospitals.

Challenges

Lack of interoperability—or communication—between software systems was a challenge cited by all four registries. Examples include the following:

- *Inability of CRS Plus to import and process HL7-formatted records.*

  Electronic pathology reports are received in HL7 format. Because the CRS Plus software cannot accept records in this format, they must first be converted to NA formal using eMaRC+.

- *Inability to filter electronic pathology reports in eMaRC+ based on cases already in CRS Plus.*

  Doing so would allow the registry to prioritize those electronic path reports that would create new cases and improve overall completeness while reducing manual workload. Smaller registries are currently manually comparing cases between the two systems, but this approach is not feasible for registries with large caseloads. One registry tested the use of LinkPlus as a possible solution but concluded that it did not ultimately reduce manual work.

- *Lack of edits built into eMaRC+.*

  Under the current system, electronic pathology reports in eMaRC+ are converted to NA format, which requires the manual coding of data items that do not exist in the electronic pathology record. Because eMaRC+ does not include edits, the cases must then be exported and processed through a separate edits software. Errors identified by the edits software must then be corrected in eMaRC+, the cases re-exported and run through the edits software again. This cycle continues until all edits are resolved. Registries reported this redundancy as a source of delay and frustration.

DMAIC: Analyze

The Analyze phase of DMAIC considers the data collected and dissects the problem further to explore the possible causes. As indicated in the previous section, the model states use methods to store and process information making this phase challenging to execute. After identifying two main problems in the electronic pathology reporting process, a root cause analysis was performed for each. Processes also were compared and contrasted across model registries.

Root Cause Analysis

As the name suggests, a root cause analysis is conducted to identify the root cause of the problems in the process under consideration. The “5 Whys” method was used to perform the root cause analysis on the main problem identified in the Project Charter: that uncertainties surround the best method of usage for electronic pathology reports (Figure 13).

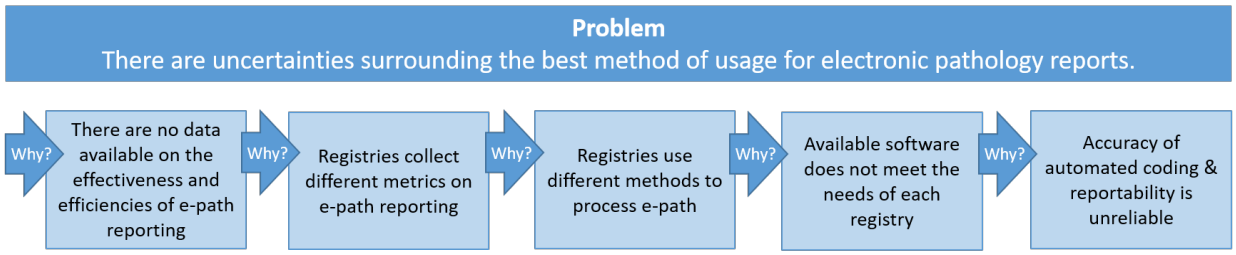

Figure 13. Root cause analysis—5 Whys

The root cause analysis identified deficiencies in the existing software as the root cause of the problem. Because of these deficiencies, each registry has each developed its own work-around processes that are primarily manual.

A second problem was identified during the Measure phase of the study: Electronic pathology reporting places a substantial manual burden on cancer registries. A second root cause analysis was used to examine the factors contributing to manual workload (Figure 14).

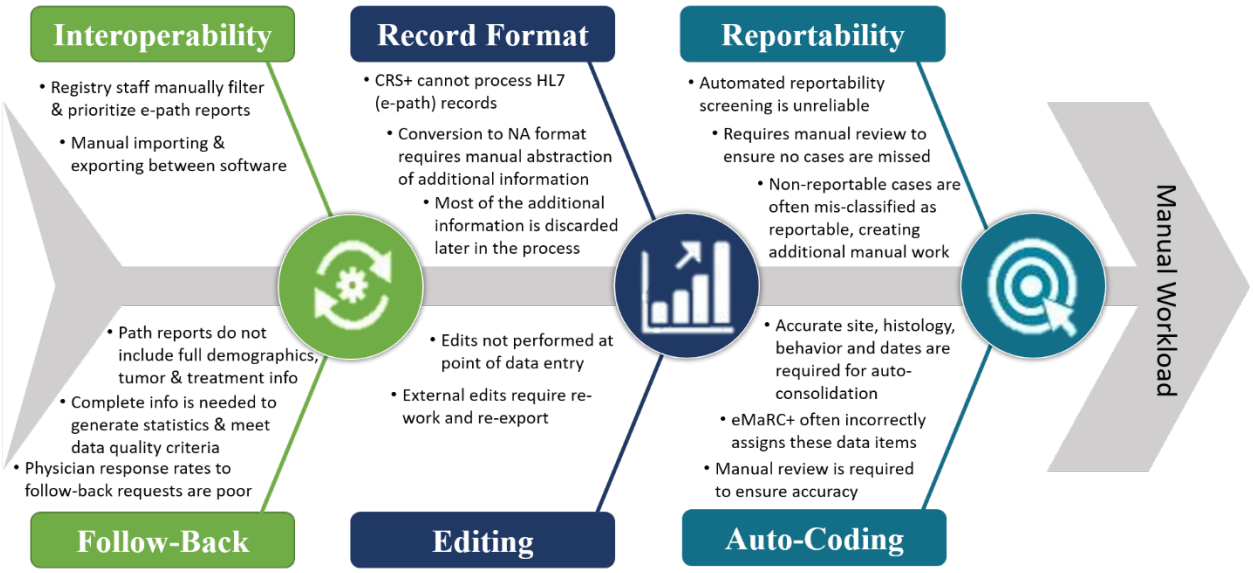

Figure 14. Root cause analysis—Ishikawa Diagram

Process Comparison

Because caseload and registry size influence processes, efficiencies, and—particularly—challenges, the states with similar caseloads were compared in an attempt to adjust for this effect. The two large registries (A and B) were compared, as were the two smaller registries (C and D).

States with Large Caseloads

The two model states with larger caseloads had similarities and differences in their processes. Notable similarities included the following:

- Receiving electronic pathology reports from independent laboratories.
- Manually reviewing all electronic pathology reports from independent laboratories.
- Using electronic pathology reports for case-finding only after all other reporting sources are complete.
- Following back to physicians for missing information.

Despite Registry A's manually screening a significantly greater number of electronic pathology reports than Registry B, Registry A consistently meets the 12-month submission standard and Registry B does not. Therefore, it is important to analyze where the registries differ in their processes. Some notable differences identified were the following:

- Software systems used to screen, code, and process electronic pathology reports.
- Registry A manually assigns reportability, primary site, and histology, whereas Registry B relies on eMaRC+ to assign these values and conducts 100 percent manual review. By eliminating the use of eMaRC+ and instead performing manual screening and

coding of all electronic path reports, Registry A achieves 10 times greater efficiency than Registry B (Table 5).

Table 5: Comparison of Registries with Larger Populations

	Registry A	Registry B
Process	Manual coding of HL7	eMaRC+
Average tasks per hour	45	4
Total tasks	41,000	2,900
Total FTE (electronic pathology)	0.5	0.4
Annualized tasks per FTE	87,750	7,800

States with Smaller Caseloads

Likewise, the two registries with smaller caseloads had similarities and differences in their processes; however, due to the magnitude of the difference in caseload between the two smaller states, the strength of the comparison is not as significant. Some similarities between Registries C and D included the following:

- Use of eMaRC+, Prep+ and CRS Plus.
- Electronic pathology reporting by independent laboratories only.
- Manual look-up of electronic pathology cases in CRS Plus.
- Not processing all electronic pathology reports.

In addition to the difference in caseload, Registries C and D also differed in these ways:

- Number of laboratories reporting.
- Timing of electronic pathology report processing.
- Method used to determine whether an electronic pathology report is processed into the registry database.

Table 6: Comparison of Registries with Smaller Populations

	Registry C	Registry D
Process	Manually filter e-path for new cases	Manually filter e-path for new cases
Tasks per hour	20	3–4
Total FTE[1] (electronic pathology)	1	1
Follow back	Does not perform follow back	~200 cases

DMA/C: Improve

The Improve phase of the DMAIC process focuses on finding solutions to the problems and their causes identified in the previous sections.

Potential Solutions

Based on interviews with the model registries, the project team conceived several potential solutions to the challenges identified in the Measure and Analyze phases (Figure 15).

[1] Full-time equivalent employee

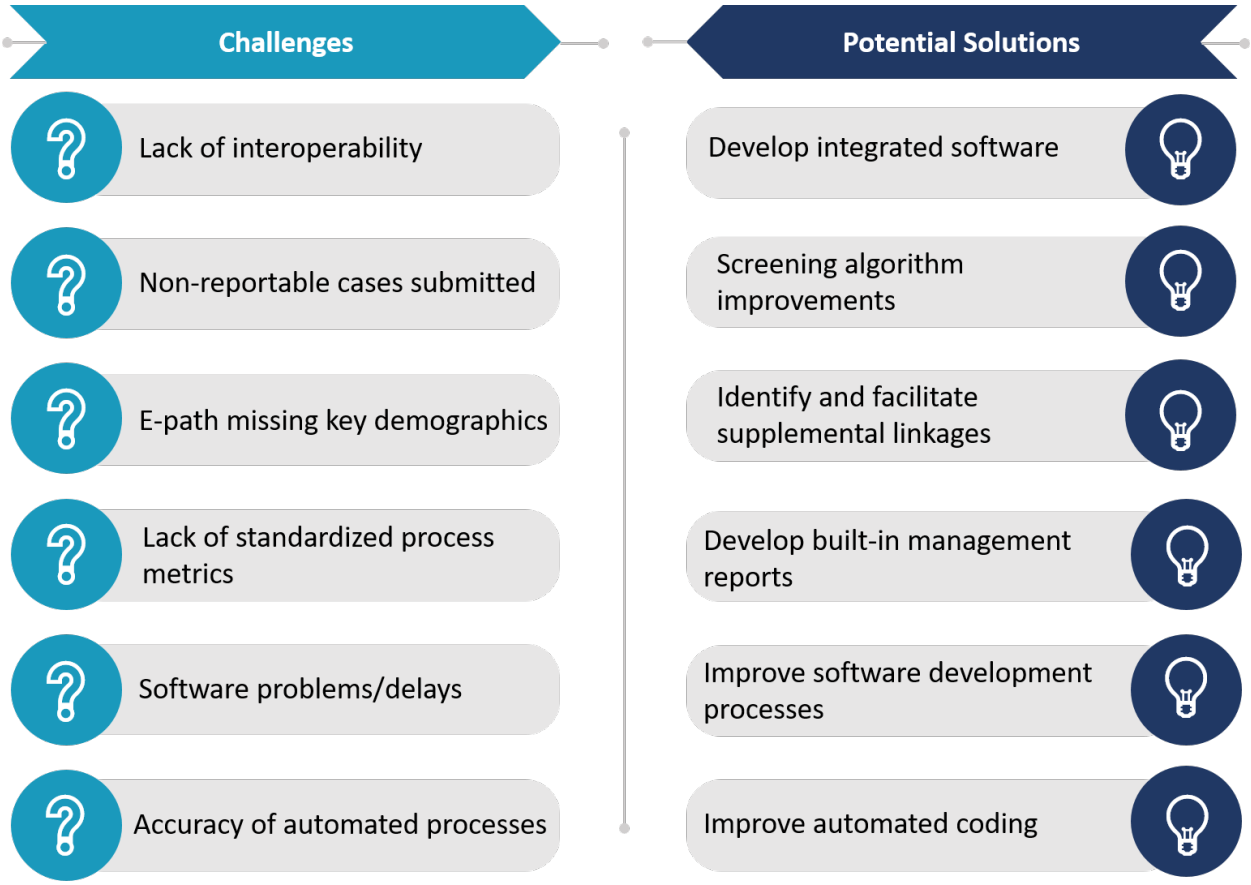

Figure 15. Challenges and Potential Solutions.

Develop Integrated Software

The development of a software platform that integrates all steps in the electronic path process—from screening and coding of electronic path records to consolidation and editing of the final case—would reduce the burden of manual work and redundant work on registries. The software should have the capability to process electronic pathology records directly, eliminating the need to complete a full abstract for each pathology report.

Screening Algorithm Improvements

Algorithms and rules that determine the reportability of electronic path reports should be improved to increase their sensitivity and specificity. This may be accomplished by reviewing samples of misclassified reports and adjusting automated rules accordingly. It may be beneficial to assign a probabilistic score or uncertainty quotient to the reportability classification of each report, allowing registry staff to prioritize screening cases with the highest uncertainty and reduce the need to manually screen 100 percent of electronic pathology reports.

Identify and Facilitate Supplemental Linkages

To reduce the burden of manual follow-back to obtain complete case information, the program should identify and facilitate linkages with data sets that contain patient demographic and tumor information. A reduced data standard for laboratory-only cases also should be considered,

although the need for some data items (i.e., race, state at diagnosis) cannot be eliminated without affecting stratified incidence rates.

Develop Built-in Management Reports

Management reports for monitoring process metrics should be built into an integrated data management software platform; however, it is necessary to eliminate the need for external processes (processes performed outside the software) for the management reports to capture accurate process metrics.

Improve Software Development Processes

Registries reported experiencing delays in the availability of software upgrades and in the responsiveness of technical support staff to software bugs and other issues. The software development process should be examined for delays and other issues, and improvements made. In addition, if one is not already in place, a ticketing system in which users can view support request status and turnaround time should be implemented.

Improve Automated Coding

A similar approach is recommended to addressing automated coding as was suggested for improving screening algorithms. Improvements should include a combination of improved accuracy of coding and an uncertainty quotient to allow users to prioritize cases requiring manual review.

DMAIC: Control

The Control phase of DMAIC describes the systems that are put in place to measure and monitor the new process and ensures the sustainability of the changes/improvements made to the process.

In the Improve phase, the LSS team put forth recommendations for improvements to enhance the use of electronic path reporting in cancer surveillance. In the Control phase, the team suggests ways that the effectiveness of these improvements can be monitored, including the ongoing collection of metrics through a dashboard built into registry software. Recommended metrics for the dashboard include the following:

- Number of electronic pathology reports received.
- Percent of reportable/non-reportable electronic pathology reports received.
- Number of laboratory-only cases (by primary site)
- Number/percent of electronic pathology reports matching with a record from a hospital or physician office.

Conclusion

The primary aim of this project was to identify strategies that might reduce the manual labor involved in processing electronic pathology reports and thereby improve the timeliness and completeness of cancer surveillance reporting. Under the ideal state, electronic pathology reporting would be used to collect cancer incidence data in near-real time, allowing central registries to generate preliminary incidence data within 12 months of the end of the diagnosis year, or sooner. However, achieving the ideal state requires several conditions that have not been met:

- Electronic pathology reporting coverage must include the majority of all pathologically confirmed cancer diagnoses. This would require the expansion of current electronic pathology reporting to additional independent laboratories as well as hospital-based laboratories.

- Automated reportability screening and coding of—at a minimum—primary site, histology, behavior and date of diagnosis must be improved to eliminate the need for manual review of the majority of reports.

- Elimination of requirements that laboratory-only cases pass validation and edits for data not included in the pathology report (e.g., stage, treatment).

- Auto-consolidation routines must be developed or improved to reduce or eliminate the need for manual consolidation of more complete cancer reports received after the electronic pathology report for a particular case.

None of the four model registries assessed was found to be using what could be described as a "best practice" for electronic pathology reporting, although some processes were more effective and efficient than others.

Electronic reporting by pathology laboratories is an essential element of a population-based cancer surveillance system. The following key benefits were identified in this assessment:

- *Identification of cases not reported by other sources.*

  States reported that up to 5 percent of incident cases are reported by laboratories only. This represents a significant proportion of cases and may account for underreporting by registries with less-than-optimal electronic pathology reporting processes.

- *Validation and correction of abstracted data reported by other reporting sources.*

  Most central registries do not access clinical documentation directly; rather, they rely on cancer registrars and physician office staff to abstract pertinent information and submit it to the central registry. Electronic pathology reports contain information documented by the clinician and can therefore be used to verify abstracted information, such as primary site, histology, stage, and other site-specific factors. Abstraction errors identified in this manner are an important opportunity to educate hospital cancer registrars.

- *Collection of information missing from reports received from other sources.*

Hospital registrars often do not have access to information from procedures performed outside the hospital setting. The abstract submitted to the central registry is therefore based on the information available to the hospital registrar at that time. For example, a biopsy of a skin lesion in a physician's office reveals invasive melanoma. Wide excision performed at the hospital shows melanoma in situ with no evidence of invasion. The hospital reports this to the central registry as a melanoma in situ, based on the information available in the hospital record. If the central registry has received the electronic pathology report of the outpatient biopsy, however, the case can be correctly documented as an invasive melanoma. Some registries, however, may not be realizing the full benefits of electronic pathology reporting because of a number of challenges they encounter:

- *Current electronic pathology processes require manual work.*

  Manual work includes transferring files among multiple software programs; screening for reportability; coding or verifying automated coding of key data elements; completing the full NA for each pathology report; resolving edits; matching to existing cases; consolidating with existing cases; and performing follow-back to physician offices for laboratory-only cases.

- *Manual workload is directly proportional to the number of electronic pathology reports received.*

  Larger registries are disproportionately burdened by manual workload. Smaller registries that receive only a few hundred electronic pathology reports annually can absorb manual work into their regular operations, but larger registries that receive tens or hundreds of thousands of electronic pathology reports are not able to do so.

- *Currently available no-cost software programs do not reduce processing time.*

  A comparison of two similarly sized registries revealed that efficiencies could be increased by 10 times with improved, seamless software.

Ultimately, the current electronic pathology reporting model used by most central registries is not sustainable and will not support the expansion of reporting. The conclusions drawn from this study assume that the experiences of the four model states are representative of registries of comparable size throughout the United States. Although this may not be true in all cases, based on information collected from focus groups and interviews conducted previously, most central registries experience similar challenges and barriers in electronic pathology reporting.

Recommendations

Based on the analysis described in this report, we recommend the following steps be taken by CDC and by central registries to improve electronic pathology reporting:

CDC

As demonstrated by the root cause analysis, many of the challenges faced by states in electronic pathology reporting are related to software. Therefore, we recommend that CDC—

- Invest in the development of an integrated cancer registry software platform that—
    - Has the ability to process electronic pathology reports as HL7 messages without the need to convert them to NA format and allow the HL7 messages to be uploaded directly to the database.
    - Performs automated reportability screening and coding of primary site, histology, behavior, and event date with a high degree of accuracy and flags for manual review cases for which there is uncertainty.
    - Links incoming HL7 electronic pathology reports with existing patients and tumors with a high degree of accuracy and flags for manual review cases for which there is uncertainty.
    - Uses auto-consolidation rules when an incoming record has known values and the existing case has unknown values.
    - Has built-in edits.
    - Auto-fills values (i.e., “9”) for cases created from HL7 records.
    - Incorporates a follow-back manager module.
    - Provides on-demand reports of electronic pathology processing statistics.
- Provide registries with technical support and software upgrades in a timely manner.
- Develop a reduced edit set for cases with a laboratory as the only reporting source (laboratory only)

Central Registries

Although many of the challenges faced by states in electronic pathology reporting are related to limitations in the available software, states may consider implementing some strategies to make the best use of electronic pathology reports. It is important to note that registries may gain varying degrees of benefit from these strategies, depending on their caseload and other factors.

- Pathology Screening
    - Screen for reportability and code electronic pathology reports as they are received.
    - Analyze the accuracy of automated screening and coding by cancer site; prioritize manual review of sites with the highest error rate from automated processes.
- Processing
    - Wait to import pathology reports into the registry database until most hospital cases have been processed.
    - Work with vendor staff to make use of available auto-consolidation routines in the registry software.

    - If electronic pathology reports cannot be imported directly into the registry, use an external linking software to identify new cases.

- Follow-Back
    - Review electronic pathology reports to identify referring physicians; contact these physicians to enroll them in electronic reporting using Web Plus or Abstract Plus. Make use of linkages with hospital discharge data, health information exchanges, and other sources to supplement demographic data.

Tips to Improve Electronic Pathology Reporting

Although software programs for processing electronic pathology reports differ, registries can implement some strategies to make the most efficient use of this important resource. Registries have reported that as much as 5 percent of the annual caseload may come from laboratories as the only reporting source.

Screening

- Screen for reportability and code electronic pathology reports as they are received
- Analyze the accuracy of automated screening and coding by cancer site; prioritize manual review of sites with the highest error rate from automated processes

Processing

- Wait to import pathology reports into the registry database until most hospital cases have been processed
- Work with vendor staff to make use of available auto-consolidation routines in the registry software
- If electronic pathology reports cannot be imported directly into the registry, use an external linking software, such as Link Plus or Match Pro to identify new cases

Follow-Back

- Review electronic pathology reports to identify referring physicians; contact these physicians to enroll them in electronic reporting using Web Plus or Abstract Plus
- Make use of linkages with hospital discharge data, health information exchanges, and other sources to supplement demographic data

These tip sheets are not meant to lay out a specific methodology, but rather, are meant to serve as a starting point for more in-depth discussions, development of tools, and the establishment of new processes or practices within individual registries as appropriate.