Producing Accurate Clinical Quality Reports for Population Health: A Delivery System-Oriented Approach to Report Validation

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About Qualis Health

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Executive Summary

Over the past decade, there have been robust national efforts to improve the quality of patient care and increase the value of healthcare through better population health management. Two elements that are essential for improved population health management are:

- 1. Optimizing the use of the electronic health records (EHR) to capture clinical quality data and generate ongoing data reports to summarize patient outcomes, and
- 2. Understanding the internal processes that are necessary to produce accurate and valid data reports.

Generating accurate and valid reports is particularly important as healthcare delivery systems see an increase in requirements for reporting data to the Centers for Medicare & Medicaid Services (CMS) and other payers for value-based reimbursement tied to quality.

This white paper addresses the need to develop accurate and valid data reports for internal clinical quality improvement purposes, as well as external public data reporting purposes. We first describe the foundational aspects of data reporting, including the different methodologies for generating reports and the purposes for which the data can be used, such as through point-prevalence (e.g., population health management) or incidence-interval (e.g., fee for service event) reporting. Following this, we lay out a step by step process for identifying inclusion and exclusion errors that contribute to data report inaccuracy. Additionally, we provide tools that can be useful to delivery systems to guide them through the process of validating their own clinical quality reports.



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Introduction

Modern healthcare has come to rely heavily on electronic data systems to generate clinical information for purposes of managing population health, improving quality of care, and reporting clinical outcomes for value-based reimbursement. 1 This usage of electronic data systems to manage healthcare information is due in no small part to the national investment in the "meaningful use" of electronic health record (EHR) systems, stimulated by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.2 The initial focus of meaningful use was to implement an EHR system, use specific features of the system, and document patient care using structured data.3,4 The early challenges of using the EHR were related to implementation of multiple interrelated software features, adaptation of clinical workflow to the technology, minimizing disruptions to patient-clinician interactions, and stabilization of the delivery system following implementation in the new electronic environment.5,6

Over time, the meaningful use program has shifted away from simply using specific EHR features and toward exchanging information between healthcare entities, using the EHR for clinical decision support, reporting clinical quality measures, and submitting data to national registries for cancer, chronic renal failure and syndromic surveillance.^{7,8}The Affordable Care Act of 2010 further increased the need for EHRs to be optimized for population health management by accelerating the transition to a reimbursement system based on clinical quality outcomes.9 In January 2015, Secretary of Health and Human Services (HHS) Sylvia Burwell announced that HHS intends to aggressively transition its traditional fee-for-service payment models to one that would tie 85 percent of Medicare payments to quality or value by the end of 2016, and 90 percent by the end of 2018. Additionally, HHS plans to tie 30 percent of payments to quality or value through alternative payment models, including bundled payment arrangements, by the end of 2016, and tie 50 percent of reimbursement to these types of models by the end of 2018.10

Delivery system viability is increasingly dependent on the ability of providers to identify gaps and quickly close them in order to remain competitive.

With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA),¹¹ the nation begins its transition from a singular focus on health IT through the meaningful use program to a world where meaningful use would become part of a structured reimbursement approach that combines clinical quality, cost, and practice improvement. Evidenced by the MACRA legislation, there is the expectation on a national policy level that healthcare delivery systems of all sizes will use EHR data to manage the patient experience of care, drive clinical quality improvement, monitor and reduce costs,¹² and subsequently report those data for reimbursement and transparency purposes.¹³

From the provider's perspective, the emphasis on changes in delivery system workflow and new ways of managing information resulting from EHR adoption are giving way to increasing accountability for quality outcome metrics derived from the data themselves, and this involves risk. ¹⁴ In addition to the financial risks of value-based reimbursement, provider-specific clinical quality data have become transparent to patients through web-based services such as the Medicare. Gov Physician Compare website. ¹⁵ Delivery system viability is increasingly dependent on the ability of providers to identify important gaps in an ever-expanding list of clinical quality metrics, and quickly close them in order to remain competitive. ^{16,17}

This paper addresses tactical approaches to generating and validating reports from an EHR for measuring clinical quality, which is necessary but insufficient for improving quality. In order to achieve the full potential of quality reporting for clinical quality improvement purposes, a practice should be prepared to integrate clinical reports as a standard process into its quality improvement strategy, and use the reports consistently over time to modify its care delivery processes as an integral part of continuous quality improvement.

The Three Methods of Generating Clinical Quality Reports

Healthcare systems must be able to generate EHR data and reports to be successful in the new value-based healthcare environment, yet many EHR products have weak reporting functionality that is inadequate to meet the growing demand for flexible and accurate quality reports. Some EHRs limit the variables that can be pulled into a patient list, thereby reducing the utility of this method for generating useful reports. Likewise, many products limit the data fields present in the reporting database, and have little capacity to create custom fields to capture new information as structured data that can be added to the reporting database.

There are three general methods for producing clinical reports from EHR data: two methods that can be conducted internally but may require multiple steps including exporting data to a spreadsheet for further manual manipulation, and one method requiring an external yendor.

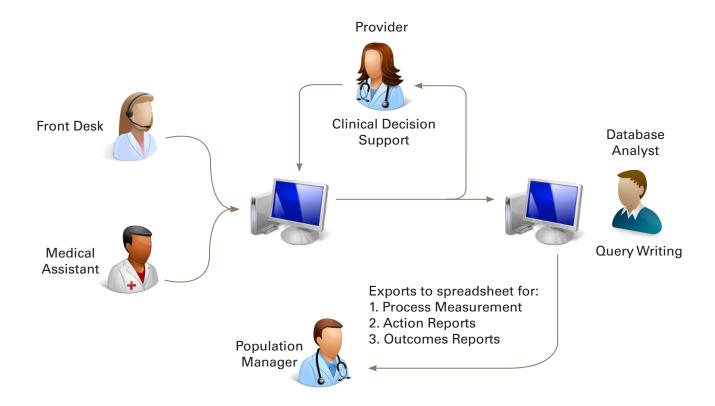
Queries Run Locally from a Reporting Database

Healthcare delivery systems can run their own queries if they have access to their data in a relational database maintained locally or hosted by their technology service provider. As shown in Figure 1, to generate reports using an internal process, the delivery system must have query writing software and someone who knows how to use it. These queries are often relatively simple in structure, and can be layered, or stacked, into multiple steps. For example:

- Query 1 may list the patient identifiers for all patients with a given chronic disease such as diabetes.
- Query 2 then uses the output from Query 1
 to generate data about the most recent date
 and value for a test, such as blood pressure or
 glycosylated hemoglobin, for each patient
 on the list.
- Query 3 would then match patients from Query 2 with HbA1c > 9, for example, with patients in the database who have not been referred for case management.

The results of these stacked queries can be exported to a spreadsheet where the data are manipulated to generate numerators and denominators for graphic display in a run chart or to create other needed reports.

Figure 1. Internal Query Writing



There is always a tension between the number of reports that one could create to monitor different aspects of a care process, and the cost of writing and validating reports. In addition to creating queries to monitor care gaps, the delivery system may wish to develop reports to monitor how well care processes are performing, action reports to identify patients in a target population who are overdue for key actions, as well as clinical outcomes. The critical questions to ask when trying to decide whether to create and validate a new report are:

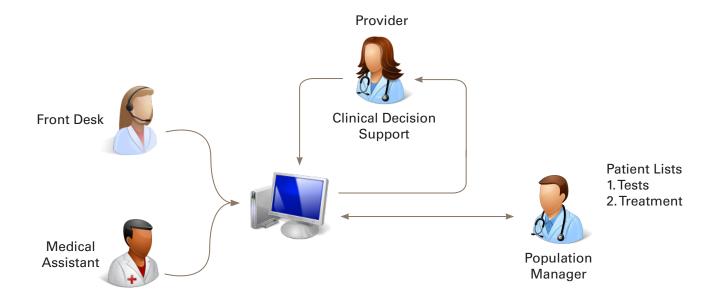
- 1. Is the report essential for internally managing a key indicator of strategic importance to the enterprise?
- 2. Will the information in the report be used to make decisions on which the success or failure of an important initiative will depend?

In general, priority should be given to reports that help care teams measure and close care gaps, an example of which would be action reports that highlight patients in the target population who are due for interventions that are used for reporting clinical quality to a payer.

Developing Patient Lists Directly out of the EHR

Most EHRs have features that allow users to create lists of patients based on clinical characteristics such as a problem list diagnosis along with most recent date and value of vital signs, laboratory tests results and medication class, etc. These features are designed to identify patients due for evidence-based monitoring and other interventions as part of a population health program, as shown in Figure 2. If the output can be exported to a spreadsheet, many EHRs have patient list features that are sufficiently robust for generating numerators and denominators to use in ad hoc clinical quality reports for purposes of population management.

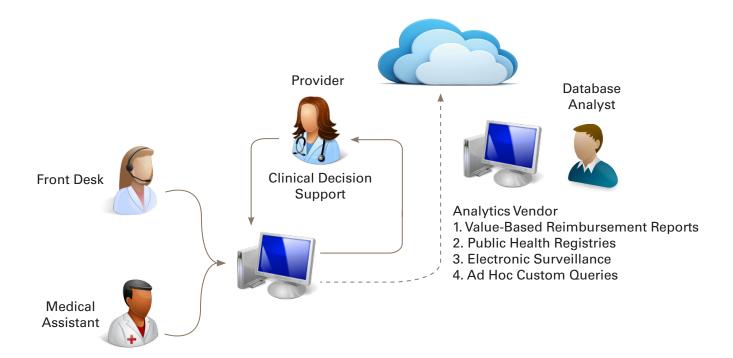
Figure 2. Patient Lists



Export to a Data Layer Hosted by an Analytics Service

Analytics services are sometimes called "registries." These analytic reporting services are generally provided by third party vendors to delivery systems on a cost structure, usually based on the number of providers. Data are exported from the EHR to a "data layer" operated by the vendor, as shown in Figure 3. The data are then "normalized," meaning that data from different sources representing the same clinical concept, such as influenza vaccination, are standardized for reporting. The analytic queries built by the vendors are capable of complex logic that may not be transparent to the report customer. The reports are then sent to the delivery system and also potentially other appropriate agencies, which may include payers, the state immunization registry, or other disease registries in addition to the clinic of origin, formatted appropriately for the recipient.

Figure 3. Exporting Data to an Analytics Service



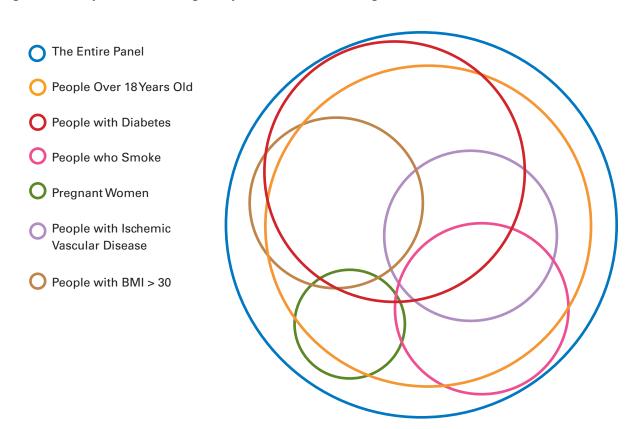
Reporting for Population Health

Regardless of the method used to generate clinical quality reports from EHR data, the purpose of the reports is to create accurate numerators and denominators in order to determine the percent of patients in a target population meeting an agreed upon standard of care for that population. This, in turn, serves as a quality metric that the care team, the clinic, or delivery system can use to guide quality improvement activity for that target population.

Defining and Reporting on Target Populations

A target population is defined, either entirely or in part, by demographic variables such as age, gender, or ethnicity. Examples of target populations defined by demographic variables alone would be children from 6 months to 6 years of age, or women over age 50. Frequently a target population is defined by a clinical condition in addition to demographic variables. If the clinical condition is a chronic illness, such as diabetes, the presence of an ICD code on the problem list serves as the data definition for inclusion in the target population. Other clinical conditions that define a target population (such as pregnancy, smoking status, or being followed for anticoagulation therapy) may require more complex logic. Figure 4 portrays graphically the presence and overlap of multiple potential target populations within a single care team's panel, or the population of patients for a single clinic.

Figure 4. Multiple Potential Target Populations within a Single Panel



In population management reporting, it is essential that the target population be defined, and not merely described. "Defined" means not only having a precise data definition for inclusion, but also making the target population visible by having a list of everyone in the population, knowing how many people are on the list, and being able to see who they are. The care teams need to be able to easily identify members of the target population on their schedule for the coming clinic day so plans can be made to close care gaps during the office visit.

Different Types of Reports to Support Organizational Objectives

A well-designed clinical report creates a picture of the quality that patients are receiving. Just as a series of single pictures can be shown in rapid sequence to create a moving picture that tells a story, a series of clinical reports displayed in sequence is used to tell a story in quality improvement. When designing a clinical quality report, it is essential that the unit of analysis chosen for the report is appropriate to the story the report is designed to tell. "Point prevalence reports," which are most appropriate for population health management, place patients who are members of the target population as the unit of analysis. In contrast, "interval incidence reports," more typical of traditional clinical reporting, uses an event, or activity, as the unit of analysis.

A point prevalence report places patients who are members of the target population as the unit of analysis. In contrast, an interval incidence report uses an event, or activity, as the unit of analysis.

Interval Incidence Reports

Incidence is defined as the number times an event occurs during a specified time interval. In the world of fee-for-service medicine, interval incidence reports are commonly used to measure productivity (e.g., how many procedures were performed, or office visits completed, in a given period of time). A quality report using an interval incidence approach might have a denominator defined as the number of office visits performed during the month, and a numerator defined as the number of office visits in which the patient was given an after-visit summary. It doesn't matter if a patient was seen multiple times in the same month. Interval incidence reports are most appropriately used in quality improvement efforts to evaluate the effectiveness of a workflow in achieving a desired outcome. However, interval incidence reports are usually inappropriate for population reporting because the unit of analysis is an event, rather than the patient.

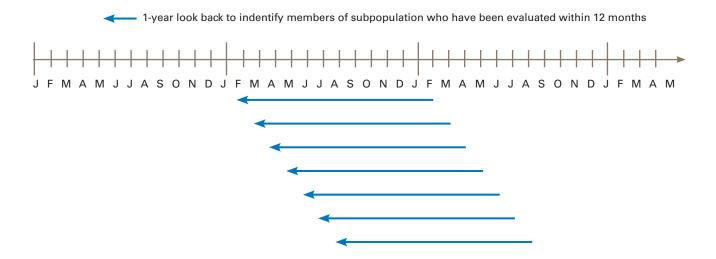
Point Prevalence Reports

Prevalence is defined as the frequency of a specific finding in a population at a single point in time. Point prevalence reports are essentially a snapshot view of the population. They are used to define a population (denominator) and the number of patients in that population whose care meets a designated quality standard (numerator) at the point in time in which the report was run. These reports often entail a "look-back period." For example, a point prevalence report might show the percentage of patients over age 18 with hypertension, who have had their blood pressure measured within the prior 12 months from the date of the report. The look-back period, in this case 12 months, should not be confused with the number of times an event occurs during a time period in interval incidence reports.

Point prevalence reports, when viewed at repeating points in time with a rolling look-back period, tell a story describing the effectiveness of the care team's efforts in managing their target population according

to the standard of care. Point prevalence reports are accurate as of the date on which they were run; a month later both the denominator and the numerator will have changed.

Figure 5. Point Prevalence Reports with a Rolling Look-Back Period of 12 Months Repeated Monthly



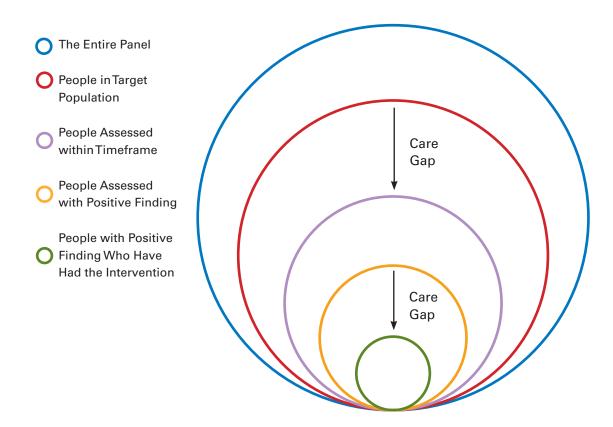
Using Point Prevalence Reports to Manage Gaps in Care

A set of point prevalence reports describes:

- Who has been included in the target population
- Which patients among the targeted population were assessed during the corresponding look-back period
- What was found on the assessment
- What was done to follow up on the items found on the assessment

The numerator of one report in this set becomes the denominator for the next report as shown in Figure 6.

Figure 6. Visual Representation of Care Gaps in Population Reporting Using a Set of Point Prevalence Reports



Each colored circle represents part of the total population.

- The blue outer circle represents the entire panel of active patients.
- The red circle represents the patients in the target population. An example of a target population would be all patients over age 18 with a diagnosis of hypertension on the problem list.
- The purple circle represents the patients who have been assessed within the time frame specified by the agreed upon guideline. An example would be all members of the target population with a blood pressure documented in the chart within the past year, or those whose 5-year risk of a cardiovascular event has been documented within the past year.
- The yellow circle represents patients with a
 positive finding on assessment. This would be
 people whose most recent documented blood
 pressure was > 140/90, or those whose 5-year risk
 of a cardiovascular event is > 7.5%.
- The green circle represents patients with a
 positive finding for whom the guideline-based
 intervention has been documented. An example
 would be patients with a 5-year risk of a
 cardiovascular event > 7.5% who have a statin
 on their active medication list, or are documented
 to be unable to tolerate statins.

It is important to point out that:

- The differences between some of the circles, for example, the number of patients in the target population and number assessed within the past year, represent care gaps. Other differences between circles, for example the number of patients assessed and the number of patients with a specific finding, are not care gaps. The most important numerators and denominators to follow over time are those describing care gaps.
- 2. Each circle (with the exception of the outermost and innermost circles) is both a denominator and a numerator. The yellow circle is the numerator for the percent of patients assessed who had a positive finding. It is also the denominator for the percent of patients with a positive finding who had the guideline-based intervention for that finding.
- 3. Interventions are usually documented as signed orders. In most cases the signing of the order (e.g., ordering a test or a medication), is considered synonymous with carrying out the intervention as represented in Figure 6 as the green circle. One exception to this general rule is ordering referrals in which referral tracking is an important part of care coordination to assure that the referral is completed.

Now that we have described the types of reports that healthcare delivery systems can generate to monitor their performance and discussed the basic components of clinical quality reports, we turn to report validation. It is important to note that the methods for report validation presented here were designed for use by delivery systems with internally written queries and, by extension, reports derived from patient lists in an EHR. While these methods may be adaptable for evaluating reports generated by analytics services, to do so would likely require working closely in collaboration with the analytics vendor.

Validating Reports

Case Study

The Medical Director for Quality at Happy Home Family Medicine created a point prevalence report with the help of her Database Analyst (DBA), showing, by provider, the percent of patients with diabetes who had their cholesterol tested in the past two years and, of those whose LDL was > 70, the percent on a statin. She shared the report with the providers, giving each of them their own data with the de-identified summary statistics for their colleagues. Each provider's report showed the names of their patients, along with the dates and values of the most recent LDL. The response was devastating. Every provider found patients on his/her list with incorrect dates and values for the last LDL. Others noted patients were missing from their report, while a number of providers found patients on their reports that were from another PCP in the clinic.

What went wrong? They found no errors in the report logic. The Medical Director went line-by-line through her own report, comparing each patient's last LDL value and date with the EHR data. She found 10 percent of the lines in the report contained an error, including patients she knew should have been in her report that were missing. One by one, the Medical Director and her DBA figured out and corrected the cause of each error. She lamented to herself that she should have validated the reports before showing it to the providers.



Sources of Error in Clinical Quality Reports

Clinical quality reports are produced through a complex interaction between sophisticated software applications and human operators. Just as it is essential in planning an EHR implementation to thoroughly test all of the components of the software in the clinic setting before "going live" to identify and correct errors, reports must also be tested before they can be relied upon. Validation is the process by which a report is tested, and it is crucial to success because organizations will rely on clinical quality reports to make decisions about resource allocation to support strategic goals. Just as clinicians function in a world of laboratory error and confidence intervals, clinical quality reports contain errors that must be reduced to an acceptable level if the reports are to be useful. There are a number of sources of errors in clinical reports.

- Data errors: A data error may entail missing information, or wrong information entered, or it may be correct information entered in a form the report does not correctly recognize.
- Programming errors: The logic built into the query itself may be faulty.
- Database complexity errors: Each data type is stored in a table in the reporting database. Tables are linked together based on the context in which they were entered. Laboratory results will be linked with the corresponding order for the test. Laboratory test orders will be linked to the encounter in which the orders were signed, and the encounter will be linked to the provider for the encounter. Orders will be also linked to the diagnosis code that was associated with the order. If the relationships between tables are not correctly accounted for in the report logic, the report may contain an error.

 Data definition errors: New laboratory tests often replace or supplement old ones, and when that happens the new test is given a new "component identifier." Even if there is no difference in the name of the test and its normal range, both old and new component IDs must be included, or the report will contain an error.

Different types of errors may occur with different frequencies in any clinical report depending on the cause. Errors that are common may produce an easily recognized distortion. However errors that occur in fewer than 10 percent of data rows in a report may be difficult to detect without a formal validation process.

A Formal Process for Report Validation

The fact that most clinical quality reports for population management are point prevalence reports means that each row of data in a report represents a unique patient in the target population because the patient is the unit of analysis. Reviewing the report for errors entails looking at the report row by row and comparing the information in the report to information in the EHR from which the report data were derived. This process of looking in the record for corresponding data for validation should not be confused with reviewing charts manually to gather data for clinical reports. Report validation is a job that requires teamwork between a database analyst and a clinician who understands the purpose of the report and how it was constructed. Looking into the EHR and understanding the places in which different information may be documented requires both the authorization to view the data, and the perspective of a clinician working in the delivery system for which the report was built.

For validation purposes it is useful to categorize clinical quality report errors into "inclusion errors," in which patients appear in the report with erroneous information, and "exclusion errors," in which patients and their data are missing from the report.

Inclusion Errors

Inclusion error identification requires going through the report row by patient row and verifying that:

- The patient belongs to the target population, and
- The date and value of the most recent activity by which adherence to the guideline is defined, is the same in the report as in the EHR.

An Inclusion Error ChecklistTool in Appendix A will guide you through the process of identifying inclusion errors.

The number of rows the clinician will need to review depends on the error burden that is considered acceptable; the more rows reviewed, the greater the probability of finding an error that occurs at a very low frequency within the report. Intuitively, the law of diminishing returns suggests that the chance of finding additional errors after reviewing a certain number of rows makes it not worth the effort. The science of sampling points to 30 as the number of rows reviewed that will provide 95 percent confidence that any error in the report occurring in more than 10 percent of rows had been found.¹⁸

It is important to be transparent about the process for correcting errors, and to consider rewards for clinicians who identify additional errors upon reading reports on their own patients. Once an error is found, it is important to document the information both by the nature of the error and the patient to which the information was attached so that the clinician and database analyst together can figure out what caused the error. Fixing errors will either involve changing the way the report is written, or changing the way data is managed in patients' charts.

Inclusion Error Examples

- An example of an inclusion error would be patients in the report who are not part of the target population.
 - Patients who do not have the target condition may be included in the report if the data definition for the clinical condition is an encounter diagnosis rather than a problem list entry, and the encounter diagnosis was entered in error. Once an encounter is closed it may be difficult, or even impossible, to change an encounter diagnosis.

Solution: Change the data definition of the target population to be presence of the condition on the problem list, which can be modified at any time by adding or deleting problem list entries.

 The patient may have left the delivery system, or be deceased, but the chart has not been updated to reflect the changed status.

Solution: Review the process by which changes in patient status are made to assure charts are updated as quickly as possible. Set a timeframe, such as every six or 12 months, to review for patient status changes.

"Inclusion errors" occur when patients appear in the report with erroneous information.

- A patient may be correctly included in the report, but the corresponding information in the report is incorrect.
 - The most recent date and value for a blood test is not included in a report because the test was ordered as a standing order, and the order was released by a provider at a different clinic.

Solution: Review and change the logic in the report by which patients are attributed to providers (and clinic) to assure that attribution is not over-written by the provider releasing the order for the test.

 There are multiple ways of ordering the same test (rapid onsite, standard lab, special send out) each with its own component identifier, but the report doesn't include every component ID.

Solution: Create a table of all the ways a test used in reports can be ordered with the corresponding component IDs to assure all are included in the report. Develop a process to review new tests at regular intervals to assure that reports remain accurate.

Other inclusion errors can be caused by workflow issues, which are errors caused by failure to note important clinical conditions in the chart, such as a missing problem list entry. Workflow errors will need to be corrected not only in the chart of the patient in which the omission was noted, but also by developing a process to identify all patients in the target population with similar errors in their chart.

Additionally, inclusion errors can be caused by faulty report logic. Errors resulting from the way the report was written will need to be fixed by the database analyst, and the nature of the fix will depend on the cause of the error.

Exclusion Errors

The fact that with exclusion errors the patient is not in the report means that the person validating the report must look elsewhere to identify excluded patients and ascertain the cause of the error. An Exclusion Error Checklist Tool in Appendix B will guide you through the process of identifying exclusion errors. Patients may be missing from a report for a number of reasons, including:

- A diagnosis is not on the patient's problem list.
- The logic for including patients in the target population may be faulty.
- The chart may contain a flag documenting that a patient has opted out of some aspect of the guideline-based population management program. If the report is structured in a way that removes such patients from the denominator, they will not appear in the report.

There are two ways to find these patients.

1. Review the schedule

Most clinicians can look at their schedules and identify patients they recognize as being in the target population. The clinician member of the report validation team should verify that all of the patients in the target population on his/her schedule within the past several months are also in the report.

"Exclusion errors" occur when patients and their data are missing from the report.

2. Develop complementary reports

A complementary report is one that creates a list of patients likely to be in the target population, based on criteria different from those used in the report itself, such as laboratory abnormalities characteristic of, or medications used primarily to treat, patients in the target population. The EHR records of patients on the complementary report who are not included in the target population list must be examined to determine whether they belong to the target population or not. If the patient identified on the complementary report should be included in the target population, their charts should be updated (e.g., by adding the condition to the problem list) so they appear on the target population list in the future.

Repeating the Validation Process

All reports should be validated when first written. There is little evidence on which to base recommendations for repeating validation at some specific interval; however, reports should be reviewed to look for disruption following software upgrades. Additionally, the greatest threat to reports other than major software upgrades is likely to be the component IDs of new laboratory tests and new medications. It would be wise for the service provider, or IT department, to provide a list of order menu changes to the quality improvement team at frequent intervals so they can determine whether the validity of important reports may have been altered.

Conclusion

The approach to creating and validating clinical reports for population management presented here is predicated on the assumptions that:

- 1. All reports contain errors, and
- 2. The ability to find and correct errors in both the data and the report logic is enhanced through a validation process involving the providers and care teams doing the work the reports are designed to monitor. Moreover, reports are potentially more accurate when clinical informatics is regarded as an integral component of the quality improvement process.

The implications of following a clear report validation process are twofold. Not only will valid clinical quality reports be useful to the delivery system for quality improvement purposes and resource allocation toward organizational goals, they will also accurately represent the delivery system's performance to third parties, such as payers or patients. Successfully using data for these purposes will help the delivery system stay viable and competitive in the evolving healthcare environment that puts a premium on quality, value, and data transparency.¹³

The staffing and other resources required to validate reports may act as a barrier in some healthcare delivery systems. However, the cost of failure to adequately validate reports, thereby placing financial resources and organizational credibility at risk, is invariably many times higher.

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Appendix A

Inclusion Error Checklist Tool

The critical element for finding inclusion errors is conducting a chart review to find patients who are in your report but should not be. Use this tool to guide you in finding and documenting inclusion errors.

- **Step 1**: From the records included in your report, systematically select patient charts until reaching the agreed upon sample size.
- Step 2: Fully review each chart listing all discrepancies, before moving to the next one, using the chart below.
- Step 3: Discuss discrepancies with the clinical team and database analyst/report writer.

Report Name:		Run Date:	Reviewer:
Patient ID	Does patient belong in report denominator?	Does patient belong in report numerator?	Compare the data in the report to relevant data in the chart. • For example, confirm that the patient was diagnosed with IVD and had the LDL result indicated in the report.

Appendix B

Exclusion Error Checklist Tool

Patients may not be in the report for a variety of reasons, such as the diagnosis is not on the patient's problem list, the report logic is faulty, or the patient has opted out of evidence-based guidelines. Use this tool to guide you in finding and documenting exclusion errors.

Run Date:	Reviewer:
	Notes
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