



690 North McCarthy Blvd., Suite 200
Milpitas, CA 95035
Phone: 408-957-3300
Fax: 408-957-3320
info@quantros.com
www.quantros.com

Joseph Martin
Executive Director
PA Health Care Cost Containment Council
225 Market Street, Suite 400
Harrisburg, PA 17101

Email submission

Dear Mr. Martin,

Quantros appreciates the opportunity to comment on the continued collection of laboratory data for the purposes of risk adjusting healthcare outcomes, as per the PHC4 published request.

Pennsylvania currently leads the nation in providing public reports that use clinically risk adjusted healthcare outcomes. The PHC4 Technical Advisory Group once again validated that there is demonstrated superiority in using lab data for risk adjustment purposes. With this as a foundation, Pennsylvania can guide the national movement to use clinical data and automated systems to drive improvements in patient care.

With more than 20 years of experience in collecting, validating, processing and managing laboratory results, Quantros is extremely knowledgeable about the specific questions that the Council has presented. The continued collection of lab results in a cost effective, valid manner will require the development of an infrastructure that supports both hospitals and PHC4. This infrastructure must be platform agnostic and, if developed using a third party vendor, can also include a set of value-added deliverables for PHC4 and providers alike.

Specific responses to PHC4's Request for Public Comment on Continued Collection of Laboratory Data follow this letter.

We thank you for the opportunity to provide comment to PHC4 concerning this important topic.

Regards,

Sanjaya Kumar, MD, M.Sc., MPH
President and CEO

Quantros Responses to PHC4's Request for Public Comment on Continued Collection of Laboratory Data:

1) What file format should PHC4 establish for the submission of lab data to the Council?

The file format should be well-formed and platform agnostic as well as offer security options, allow for information exchange and lend itself to data validation. The most appropriate format meeting these requirements is XML.

- To achieve a well-formed document specification, an XML schema can be designed to capture the following limited set of data elements for laboratory data – lab test code, lab collection date/time and lab final result. A parent child relationship can be established with patient identifiers in the parent node and each lab test as a child node with the corresponding lab data elements set as attributes to the lab test node.
- XML is known as a platform agnostic and well-supported technology across many industries including healthcare.
- The W3C has developed a set of specifications for the encryption of XML data elements using strong industry accepted encryption algorithms including AES-256. These specifications are also able to offer the creation of independent and interoperable implementations.
- An important factor to consider for an implementation of a laboratory data submission operation is whether two-way information exchange will be required. There are at least two types of information that could be transmitted back to the original submitter:
 - A response that the XML document was received, accepted and has passed schema and data validation rules
 - Once the data is matched to corresponding UB04 data elements and “scored” through a risk adjustment methodology, the scoring results should be transmitted back to the submitter for verification and analysis.
- Although data validation can be handled regardless of the file format used, it can be handled more efficiently and thoroughly with an XML document. An XML Parser can quickly identify an invalid document schema. As an extension to a larger set of ETL functions, the XML Parser can also validate lab test codes and lab values against reference ranges as it shreds and loads the document into a staging area of a clinical data warehouse. Many ETL tools have ready-made XML Parsers already included in their library of functions.

2) What are the issues the Council should consider in collecting lab data directly or through a third-party vendor?

The most important factor to consider in choosing between collecting lab data directly and outsourcing is the overhead cost of direct collection. This is an important consideration not just for PHC4 but also for Pennsylvania hospitals.

- Based on our experience with direct data collection and warehousing of laboratory data, we believe that a total of 5 FTEs will be required for PHC4 upfront for at least a 4-6 month engagement. If PHC4 chooses this option, there should be an expectation of a significant amount of time prior to the project start date to recruit contractors and/or full-time employees and bring them on board to supplement existing IT staff. The deliverable at the end of this engagement will be a clinical data warehouse to link UB and laboratory data and ensure referential integrity and perform validations on that combined data set. Depending on the outcome of an assessment of current technology infrastructure, it may also be necessary to purchase computer hardware and software assets to build the clinical data warehouse and manage the new data storage requirements. Following the completion of the project, there should also be an expectation that at least 1.5 to 2 FTEs will be required for ongoing support and maintenance of the clinical data warehouse and data operations.
 - If a third party vendor builds an operation on behalf of PHC4, that operation can leverage the vendor’s development resources and expertise, warehousing hardware and software technologies and support operations staff – all of which can significantly reduce the upfront cost. Also, the time to completion will be far less as the vendor’s engineering team and processes will already be in place to develop the clinical data warehouse operation.
 - It should also be noted that a third party vendor can also include in its proposal a set of value-add deliverables for PHC4 and providers alike. These additional features might include data management, productivity and analysis reports, alerts and notifications and linkage of data to other regulatory reporting requirements such as Core Measures.
- 3) What are the potential issues, including increased or decreased costs, for hospitals in manually abstracting or electronically downloading selected lab data for submission to PHC4?

Regardless of whether or not a provider chooses to use internal resources or a third party vendor, there will be upfront costs in order to implement a laboratory data interface or manual data collection process. If the decision is made to use internal IT resources, the laboratory data interface will need to be developed to PHC4’s published specifications. That interface will then need to be maintained by the internal IT resources. If a third party vendor is selected, there will be upfront costs to purchase that vendor’s interface technology and development work. In both situations, internal resources will also be required to perform some level of interface submission testing and this work will also incur upfront costs.

- If submitting electronic laboratory data is not feasible for a provider, then a tool to manually collect lab data will need to be developed. PHC4 will need to be responsible for publishing such a tool if a provider opts to submit laboratory data directly to PHC4

and direct submission is an option. Otherwise, the provider will need to contract with a third party vendor to develop and use a data collection tool. Currently, only 50% of Pennsylvania hospitals have a laboratory data feed for the Atlas application. It is more than likely that manual data collection will be required for some period of time while those hospitals not currently using an electronic laboratory data feed work to build one.

- Interface development may also increase or decrease depending on how lab data is to be standardized. LOINC codes may be adopted which can potentially decrease interface development cost for those hospitals that have Laboratory Information Systems (LIS) that support LOINC.
- Another issue is ensuring that only final results for the lab tests are collected and submitted – this is a requirement regardless of whether the decision is to collect the first value or the worst value. It is important that hemolyzed results are not submitted for those laboratory tests with a potential of being affected by hemolysis.

4) Are there any issues for providers regarding the submission of lab data for selected conditions that are included in the PHC4 public reports?

- One issue for a provider is the need to map their internal lab test code to an external standard code such as a LOINC code. A process will need to be developed to assist providers with this mapping process to ensure that appropriate tests are being selected. The provider will need to monitor and maintain this mapping to ensure that updates are made if changes to their LIS system affect it.
- Providers may also have difficulty producing a laboratory data feed if PHC4 decides to limit the lab data collection requirements to those patients that fall within the current definition of the PHC4 35 conditions. For a provider to filter their laboratory data in this way would require linking laboratory data to the patient billing data to identify those patients in the PHC4 35 conditions by either MS-DRG code or ICD9-CM diagnosis code. Although the volume of data to be submitted will be higher, it is more likely to be an easier implementation for a provider to submit all laboratory data for all inpatients. The identification of patient records that fall within the PHC4 35 conditions can occur within the PHC4 clinical data warehouse once the laboratory data is linked to the UB04 demographic data.
- A third issue is a provider's ability to review hospital performance prior to the data being publicly reported. The best approach is for the laboratory data to be collected and linked to UB04 demographic data as concurrently as possible keeping in mind that the patient records need to be discharged and final billed to ensure stability of the data. If PHC4 decides to only collect laboratory data at the conclusion of a calendar quarter and during a specific data submission period, then there may not be enough time to properly review the data completeness for that quarter's discharges or analyze the overall patient outcomes and hospital performance for each of the reported conditions. A third party vendor can collect and combine demographic and laboratory data over the

course of the quarter and then present the risk scores in a report format that emulates the public report.

- Another issue for providers is the ability to correct data. Laboratory data is not normally kept in an LIS for an extended period of time which means that if a correction to that laboratory data is needed it may have be stored outside of the LIS system and accessible to hospital data abstractors until the data is submitted and validated to PHC4.

- 5) What are the issues to consider regarding submission of the first or the worst lab values for selected lab tests administered early in the patient stay?

If the decision is made to have providers only submit the first value or worst value for the identified laboratory tests then there should be an expectation that the providers will have to incur more upfront and ongoing maintenance costs. It will be up to a provider’s internal IT department or a contracted third party vendor to collect, analyze and filter the raw laboratory data to extract and submit only the desired laboratory tests and results.

- Collection and submission of first value will be easier to program than worst value as the business rules for identifying first value will be less complicated – however, it is unclear if that simplification of business rules will translate into significant time and/or cost savings for providers as both options will require the collection and analysis of all laboratory data to ensure that only the appropriate tests and results are being submitted.
- Both approaches will also have to ensure that hemolyzed results for any of the lab tests are discarded and not submitted to PHC4.

- 6) What are the issues to consider in using the first of the worst lab values for selected lab tests administered early in the patient stay for the purposes of risk adjusting the data?

The main issue to consider is that the existing severity adjustment models built and maintained by Cardinal Health, Inc./ CareFusion and used for public reporting for the past two years are based on worst value.

- Although it is anticipated that migrating from worst value to first value will result in negligible shifts in risk adjustment calculation and assignment, this assumption should be rigorously tested and validated.
- It is also important to note that to build a new set of models to support the collection of first value will require the use of raw laboratory data combined with UB04 demographic data for an extended period for proper model development.

- 7) What are the potential options to consider in continuing collecting clinical data beyond the lab data for the cardiac surgery cases included in the Council’s *Cardiac Surgery in Pennsylvania Report*?

As it is clear that there will be a need to build a data collection tool for manual data entry of laboratory tests and results, an extension of that tool should allow for the manual collection of the Open Heart variables. Patient records can be identified as needing additional data collection by using ICD9-CM procedure codes to flag Open Heart cases.

- For direct data submission to PHC4 , it may be necessary to have providers submit the UB04 data and its corresponding list of procedure codes earlier in a quarter's submission period in order to have adequate time to identify Open Heart cases and manually collect the Open Heart variables.
- If a provider opts to use a third party vendor's data collection tool, then there shouldn't be any issues with a time delay for the provider so long as the third party vendor has the capability of collecting and combining demographic and clinical data from the provider.