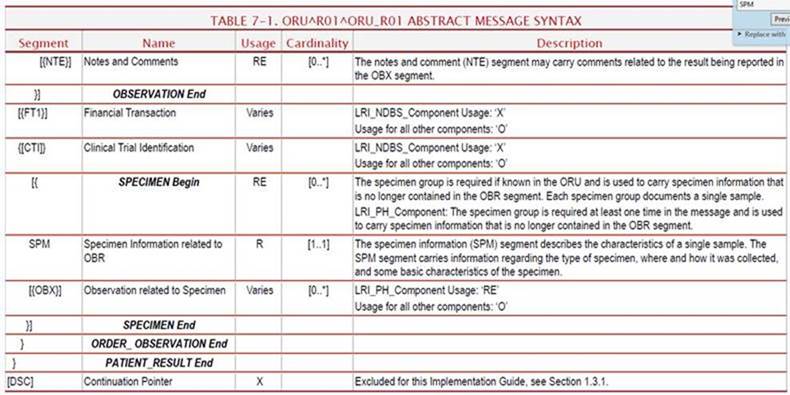
OO/PHER: Specimen details and PH 2/16/2017

**Question:**

There was a comment included in the ballot regarding specimen that sparked discussion on whether or not the SPM group should be required, thus making the SPM required. Currently in the guide, the Specimen Group is RE [0..\*] (required but may be empty, 0 to many repetitions), where if the Specimen group is present, the SPM is required. However, for the public health profile, there is an additional requirement that at least one SPM segment be present in each message. We are unsure of the intent of this additional requirement and so we are looking to gather some information from you on the importance of the SPM segment. See screenshot.

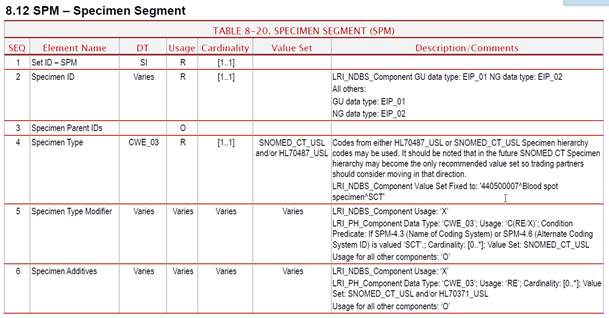


From your public health perspective, how important is it that you get specimen information?

What would happen if you didn’t get an SPM? How does that affect your usage of the ELR message or affect your practice? Is it important to get specimen information about every result? Is it important to get at least one specimen per message?

 Additionally, there are questions about whether or not the data element usages for SPM data elements are appropriate based on what information the lab will always have, sometimes have, or may not routinely have in order to require an SPM. For example, a lab may have a specimen ID (SPM2) but may not have Specimen type (SPM4). See screen shot below.

If the SPM segment is R (required), and a lab sends you an ELR message with only a Specimen ID and no Specimen Type, how would that affect your work?

…

All other data elements in the SPM have a usage of Varies (have to look at the profile constraints in the description) other than the Specimen Reject Reason and the Specimen Condition which are both RE.

**Summary:**

* Specimen information is crucial to PH business, core requirement
* **Sterile Sites & Reportability-**Some results are only reportable from sterile sites; not having this information requires additional work. EX: MRSA from nasal swab is not reportable, MRSA from blood culture is. CD4 counts from bronchial sources not reportable
* **Case Status-** Need to have specimen details prior to determining case status and then required in case notification to CDC
* **Work Flow Decision Support-** Used in workflow decision support to determine whether or not they need to trigger investigation.
* **Severity/Priority-** Categorization of disease severity (e.g., sepsis vs. meningitis)
* **PH Action-** Specimen details determines whether or not someone needs to be put isolation and slows down investigation
* Critical to case investigation
* Prioritizes investigations and follow up
* Without specimen (with sufficient detail) ELR is ineffective and slows investigations and PH action.
* **Burden-** Volume of messages received makes it too burdensome to have to routinely call for information
* Not including this information in the report to PH yields unnecessary additional steps for PHA and subsequently the lab and provider to go back and look up the info that should have been provided in the first place- significantly increasing workload
* Would have to review each report of a high volume condition or those found naturally in the environment (like group A Streptococcus and group B Streptococcus) and seek additional information from providers or labs (starting investigation) for things that are not causing invasive disease (or not reportable). If someone tests positive in Streptococcus pneumoniae a major number of strep throat (which is not a reportable condition and not invasive) would be identified only after review.
* **Onboarding and Processing-** Some PH receivers will fail messages not containing an SPM with SPM 2, SPM 4, and SPM17
* Some PH receivers will not onboard a facility without required SPM information, including ID, Type, Date Collected
* Missing specimen information can prevent automated processing
* States have to make state specific constraints that often yield complaints from partners or vendors. By ensuring that the needed information has sufficient usage and cardinality, you minimize the need for state specific constraints and maximize standardization.
* **LOINC-** To derive these from LOINC is not viable as most labs don’t use specimen specific LOINCs
* To deprecate the OBR components but not require SPM population is absurd.
* **SPHL-** From the PH Lab perspective: adding specimen specific LOINCs would be a huge effort. Many codes used are used because they can be used with various specimens.
* From State Public Health Lab: don’t see any situation where we would not include an SPM segment in a result message either an LRI or an ELR message. SPM 4 used for matching up order with specimens (Validation).
* **Other/Needs/Requirements-** It is important to get at least one specimen per message.
* Some Blood Lead reporting requires documentation of venous blood vs capillary blood
* One specimen per message is sufficient as long as all the tests/results in that message are from the same specimen.
* Having to call for more information is contrary to the intent of ELR
* Must have filler’s Specimen ID
* Specimen ID is helpful when calling a lab to retrieve the missing information
* PH should receive specimen Type and Source (SPM 4, 5, 7, 8, 9); need to address impediments
  + Confusion between type and source
  + Labs may not receive or request receipt of needed specimen information in an order
  + Due to harmonization of guide, vendors should have a standardized way of implementing
  + Need harmonization in SPM requirements across different use cases
  + Despite standards and IGs, there is still a wide variety of interpretations and implementations
* Specimen ID, Source, and Collection date are minimums
* Making SPM 4 not require is stepping backwards
* Keep existing requirement which is already being met by most labs
* Finally, we have not heard any reasons why specimen information should *not* be made R

**Specific responses:**

**T. Kittle from MS:**

“Regarding the highlighted questions, will the specimen information still be contained in the OBR segment?

For MS, it is important to have the specimen information. Some results are only reportable in sterile, invasive sites and not having the specimen information initially contained within the ELR message would add additional work in the course of the investigation. MSDH would need to know the source of the specimen prior to calling a case “confirmed”, “probable”, etc. in these situations.

It is not ideal to omit the specimen type from an ELR message. However, if the specimen ID was present, then the PHA staff could use this information to call the lab/provider to gain additional information about the specimen. I feel as though by not providing this information at the beginning (from the lab’s LIMS to the PHA via ELR), this adds unnecessary steps for the PHA staff and subsequently the lab/provider (as both have to stop what they are doing to gather/share information that should have been sent to the PHA in the first place if it was available in the LIMS).

I think it would be ok if the message only contained one SPM segment.

I hope I have addressed the highlighted questions and you could follow my responses. J Please let me know if I need to clarify/expand on them.”

**B. Storm from Ohio**

“FYI, for a HL7 2.5.1 in Ohio, a SPM segment is required.  Specifically, SPM-2 is accession ID, SPM-4 is specimen type, and SPM-17 is collect date.  If any of those fields are missing, the message will fail to import into our disease surveillance system.

Also, we only accept the first SPM segment.  For instance, if you have a microbial specimen SPM segment, it is ignored.  We recommend only sending one SPM per message.”

**E. Hartwick, Mi**

“Thanks for talking about this on the CSTE ELR call.   I think in general, we like the idea that this be required in the same way that it is currently as it does provide very useful information.

**IF** we had to pare it down to the bare minimums, I would say the Specimen ID, the source, and the collection times are our bare minimums.  And if we had to do without altogether, it wouldn’t kill our system, just make us sad in general. “

**R. Byers- ID**

“With regard to the HL7 LRI Ballot question, SPM.4 is extremely important as far as Idaho is concerned as several conditions are only reportable based on the specimen type.  For example MRSA from a Nasal Swab is not reportable but MRSA from a blood culture would be.  A similar issue would be on CD4 counts, CD4 counts from BAL (Bronchial sources ) are not reportable and are not loaded into NBS.

Trying to derive these from the LOINC is absolutely not a viable option as most labs do not use specimen specific LOINC codes and even if they did this would essentially require us to build and maintain our own LOINC specimen cross-reference table which would be a nightmare.

Dropping SPM.4 as a required field would be a serious step backwards in the ability to accurately communicate Laboratory reports and would significantly increase the public health workload.”

“Good Morning Erin,

As a follow-up on this I spoke to the Lab and they indicated that adding specimen specific LOINC codes to results would be a huge effort.  A lot of their analysis codes (ACodes) are not specimen type specific or will work with multiple different specimen types.  Therefore in order to map specimen specific LOINC codes they would need some type of lookup process to match the ACode and the specimen type to a table (which would have to be maintained as new LOINC’s are added almost daily) or they would have to create, test and certify a huge number of new specimen specific  ACodes.  This would also require a change in their work flow so either way would require additional effort and resources.

So my vote would be on keeping the existing requirement which is already being met by most labs.”

**J. Bareta, NM**

“For the Emerging Infections Program (you probably know as Tennessee is one of the EIP sites), specimen information on the ELR coming to DOH is critical to case investigation. The Active Bacterial Core surveillance program uses sterile specimen sites as a critical piece for case definition. As many investigations begin through the ELR, this piece of information clarifies the need to review a case or not. You can see the added burden to case investigators if they have to review all cases of group A Streptococcus and group B Streptococcus, normally found in the environment, but not causing invasive disease. If someone tests positive in Streptococcus pneumoniae a major number of strep throat (which is not a reportable condition and not invasive) would be identified only after review. We would see a huge increase in the need for chart reviews and that would be a waste of time and resources. The program also gets many Haemophilus influenzae cases from non-sterile sites such as eyes, ears, etc. In our foodborne program we can also get e.coli or other potential foodborne pathogens from non-sterile sites requiring a much more in depth review of cases. In summary, NMDOH Infectious disease epidemiology believes it’s crucial to receive specimen sites from our ELR reporting laboratories for our programs.”

**A. Sanders Kim- NY**

“The specimen segment should remain required as it is critical to public health response. Public health relies on specimen source to determine how cases are responded to. For example, invasive sites may be given higher priority for follow up. Due to the volume of results received, it is burdensome to call for specimen source information. Without the specimen information surveillance can be delayed while contact with the lab is made. Individual contacts for each result requires resources both at public health and the laboratory to respond to questions. The results are automatically filtered and prioritized when the specimen source information is available in the message.”

**A. Kayser- IN**

**“**I’ve spoken with a few of the program areas here in Indiana to provide feedback to questions asked on the SPM segment. Hopefully they are insightful.

*From your public health prospective, how important is it that you get specimen information? What would happen if you didn’t get an SPM? How does that affect your usage of the ELR message or affect your practice? Is it important to get specimen information about every result? Is it important to get at least one specimen per message?*

-          The specimen type is one of the most important fields for Lead Program Area as it is used to determine case statuses. This leads to severe underreporting of confirmed elevated lead results, which if not report can lead to a fine by state code.

-          For TB, specimen type is a required field for CDC reporting as well. It is an essential piece of information used for determining if a patient is infectious and therefore is they require public health investigation. This information is also needed for managing the patient as it determines treatment guidelines and clinical aspects.

-          The SPM segment is extremely helpful for invasive diseases because non-sterile specimen sources should not be reported, but sometimes are. Particularly in the case of meningococcal disease due to the time sensitivity of implementing control measures if specimen source has to be tracked down.

-          Summary: Specimen is very important for us in Indiana. When we do not receive the information, the epidemiologist must follow up to determine if an investigation is warranted.  When specimen source is not provided or not specific enough, it renders the ELR ineffective and slows down the ability to investigate and provide public health action, like with meningococcal disease. It is important to get at least one specimen per message.

*If the SPM segment is R (required), and a lab sends you an ELR message with only a Specimen ID and no Specimen Type, how would that affect your work?*

-          This would not cause a system error and the ELRs, besides Lead, would make it to their downstream systems. It would then be the responsibility of the Epidemiologist to contact the submitter/laboratory to gather more information and determine if an investigation needs to be done.”

**S. Smith- MA**

From your public health prospective, how important is it that you get specimen information?

We would consider it extremely important. MA has several constraints on the HL7 251 implementation guide, and requiring specimen source in SPM.4.1 is one of them. We would welcome any changes that negated the need for additional state-based constraints.

For several reportable diseases (Streptococcus pneumoniae, H. influenzae, MRSA, VRSA, Group A streptococcus, Group B streptococcus) we only require tests on sterile specimens (blood, CSF etc) because we are primarily interested in invasive infection – the only way we can ensure that ELR  we receive is what we require is if we get specimen source information in the report.

For STDs in particular, it has become very important to know specimen source because the PH epidemiologists triage their outreach work based on specimen source, among other factors (anal, pharynx, genital)

Our childhood blood lead program is insistent that they should know whether the blood is venous or capillary.

What would happen if you didn’t get an SPM? How does that affect your usage of the ELR message or affect your practice? Is it important to get specimen information about every result? Is it important to get at least one specimen per message?

We have a minimal dataset that will make a paper lab report acceptable, and specimen source, specimen ID (or accession number) and date of collection are part of that dataset.

One specimen per message is sufficient as long as all the tests/results in that message are from the same specimen.

Specimen collection date is also critical, given that epidemiologists routinely look at the difference between acute and convalescent titers for arboviruses; or consecutive tests over a period of time to determine if a chlamydia infection, for example is a new infection or a re-infection.

If the SPM segment is R (required), and a lab sends you an ELR message with only a Specimen ID and no Specimen Type, how would that affect your work?

If the result was one of the reportables described above, then someone from the PHA would call the ordering facility to find out specimen details – an increase in labor for both PHA and labs, which is entirely contrary to the intent behind ELR.

Finally, we have not heard any reasons why specimen information should *not* be made R”

D. Golson- TN

“As for the state lab, I do not see any situation where we would not include an SPM segment in a result message either an LRI or an ELR message.  We also would not accept an order without an SPM segment.  As you know the major advantage to the SPM segment over the use of other message fields to contain pertinent specimen details is that it provides better detail in a more structured format.  From the SPM, at present the most important piece of information we use from an electronic order is the specimen type (SPM-4).  We use this in our matching process for the electronic order and the actual specimen (i.e. it is part of the information our laboratorians use to valid the order is correct to the specimen received.  We in turn, use that same specimen type information in returning an electronic lab result.  We are also now exploring the use of the Specimen Reject Reason field (SPM-21).”

**S. Troppy-MA**

 “As for Massachusetts - We definitely want the specimen ID. That is critical. The specimen type (or specimen source, I’m assuming) is equally important. Even though all sources are reportable, something like an outpatient urine doesn’t really have a public health intervention compared to an inpatient blood. We also might be limiting confirmatory testing at MA-SPHL to invasive specimens, and it would be helpful to match with ELR data. I agree with Marion/TN that with the ARLN and ability to now access a lot more colonization testing, this will become even more important going forward.”

**N. Barrett-CT**

“SPM is critical for our work in PH. We must have information about the specimen (including several key data elements) and specimen “source”/type to be able to make informed decisions about the report and any follow up. Some reasons (and these may be repeats of comments made by others, sorry).

1. Our state reporting requirements include laboratory results as well as provider results (as do most if not all states). Characterization of reports into case classification (confirmed, suspect, probable, not a case) rely on lab results for nearly all of our reportable conditions.

1a. in addition, specimen information is required to be sent to CDC as part of national case notification or other CDC required reporting under grants.”

2. Specimen type or source, if I understand this correctly, is used in several ways: a. to determine if a disease is reportable. Some of our diseases, for example, the “invasive” pathogens, are only to be reported if the organism is identified from a normally sterile site. So we need that to be able to filter out non-reportable results. We also need to know that site/source for categorization of disease severity (e.g., sepsis vs. meningitis) and some reportables are only assess if they come from a list of sites, but not stool, etc.

3. If a lab sent only a Specimen ID and no specimen type, we would not be able to fully process the message content correctly. Also it would cause a lot of extra work for our program staff and for the lab as the staff tracked down the specimen type.

We rely on the SPM 4 & 5 and SPM 8 & 9 fields to give us this information.

Looking to other areas, like environmental testing for PH, source type is also important for case classification and management.

Hope this is helpful. My question: why would providing a specimen type be difficult. Is it the coding hierarchy to be followed?”

**C. Staes- University of Utah**

**“**I completely agree with Nancy Barrett’s comments below and the question: “Why is it hard to include information that is already present in a lab report output from a lab system?”

I see 2 issues:

1.       I believe the ELR message should include the information necessary for someone to act on the information from the receiving end (in this case public health).  Without the specimen information, public health is not able to distinguish between a positive result found in a skin specimen vs CSF. For some conditions, this has serious implications for limiting the ability to act on the information received.  In the very least, this information is needed in textual format.  I believe there are CLIA rules addressing the provenance of information being shared – removing the specimen information makes the information shared incomplete.

2.       The specimen information is required by systems to automate the processing of the results received.  We are asking for specimen information to be added to lab result information content in the eICR because it is necessary for automating the detection of a reportable event.  Removing this from the ELR message, will undermine the ability to automate lab message processing.”

**R. Altimore- WA**

“Just to play devil's advocate, from the lab's perspective:

* The ordering provider (the lab's customer) doesn't need specimen information on the lab report, they know what they ordered. (PH can confirm that on many paper reports there is no indication of specimen type/source.)
* If we use specimen specific LOINC codes for ELR to PH, why do we need an SPM segment?”

**W. Kemper- NC**

**“**From your public health perspective, how important is it that you get specimen information?

Extremely important.

What would happen if you didn’t get an SPM? How does that affect your usage of the ELR message or affect your practice? Is it important to get specimen information about every result? Is it important to get at least one specimen per message?

Within a disease event our disease surveillance system, ELR data are grouped for display by, and are deduplicated by, among other criteria, the SPM-2.2.1 (SpecimenID/FillerAssignedIdentifier/EntityIdentifier), SPM-17.1 (SpecimenCollectionDateTime/RangeStartDateTime) and laboratory.

The ability to group and deduplicate ELR data by specimen is critical for the following reasons:

* For some diseases, to meet CDC case definition requires that there be positive results for both a screening test and a confirmatory test on the same specimen.
* For childhood blood lead, when capillary blood specimens are used to confirm an elevated blood level, two capillary blood specimens drawn within 12 weeks of each other must have elevated results.  If two different capillary blood specimens drawn the same day have elevated results that would qualify.  But two lab reports for the same capillary blood specimen would not qualify.  Thus we need the SpecimenID in order to make that distinction.

There is no other field in the message other than SPM-2 that is a specimen identifier.  While the order number fields in the OBR segment, may sometimes have values similar to SPM-2.2.1 (SpecimenID/FillerAssignedIdentifier/EntityIdentifier, there can be multiple orders, with different order numbers, for the same specimen in the same message.

We require that at least one Order\_Observation group in the message has an SPM segment.  It is not necessary for every Order\_Observation group within a message to have an SPM segment because usually that would be redundant data.  Some laboratories choose to use one accession # for reporting culture identification results on the original specimen and a different accession # for each isolate for reporting susceptibility results, in which case the Order\_Observation groups for the susceptibility tests may have SPM segments with different SPM-2.2.1 values than the Order\_Observation groups for the culture.  There is nothing wrong with that, but for the purposes of our surveillance system we utilize the data from only the first SPM segment in the message so that all of the data from the message are grouped/deduplicated with the surveillance system by the same specimen ID.

If the SPM segment is R (required), and a lab sends you an ELR message with only a Specimen ID and no Specimen Type, how would that affect your work?

For childhood blood lead it is crucial that SPM-4 (Specimen Type) is populated.  Important business rules, differ by whether the specimen is capillary blood vs. venous blood.

For results that identify organisms that can cause invasive disease, it is crucial that SPM-4 (Specimen Type) is populated.  We apply different automated business rules based on whether the SPM-4 is a normally sterile type.  If a large volume of messages for those organisms were to lack a meaningful value in SPM-4 it would not be feasible to manually follow up on them to determine whether they are invasive disease.

We do not on-board ELR from laboratories that do not support SPM-4 for the use cases above.

SPM-4 (Specimen Type) is quite useful, but less critical, for other use cases too.”

Generic Responses:

**T. Safranek- NE**

“Erin/Riki:

Thank you for your heroic efforts to advance public health by optimizing the electronic health records systems that we have invested in the past 10 years.

I am writing to support instantiating the SPM segment as a core and key requirement as part of our public health electronic lab reporting implementation guide, with full support from HL7 and other certifying bodies.

I have visited with some labs who have yet to move to HL7 2.5.1.  Their software does not support the SPM segment.  I believe this requirement will motivate them to update their software to more current versions, or to invest and deploy “reconfiguration software” (i.e., interface engines) that will enable them to interface  with trading partners (like public health entities) with an SPM segment derived from their “pre-HL7 2.3.1” messages.  There is sufficient information in their existing messages that will permit them to create a “poor man’s” SPM segment, pending their implementation of modern IT systems that have the SPM segment baked into it.  I strongly endorse this move to require SPM in our implementation guide and in the HL7 system.

Please let me know if I can do more to support this cause.”

**M. Kainer- TN**

For CRE, getting specimen type is really important in order to subcategorize as colonization or infection.  
We would still want to get the report if it were missing, but would need to follow-up with the reporter to get clarification.  
With the ARLN and ability to now access a lot more colonization testing, this will become even more important.