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Dr. DeSalvo,

In your April 5 email you asked if we have a proposed minimum clinical data set definition. We thank you for reaching out to us on this topic. This appears to be a critical element of the draft ONC interoperability roadmap, and we agree that further clinician input is needed in defining a minimum clinical data set, or even if there should be a defined minimum. Our Medical Informatics Committee met the following week and discussed the topic at length. Below you will find a summary of our discussion.

The Committee would first like to clarify our concerns and also seek some guidance and clarity from ONC. While it is entirely possible to define a set of the most commonly used data elements, requiring their use, via a regulatory definition, in all exchanges of healthcare information is problematic. The likelihood of identifying a minimum data set that applies to all potential use cases is unrealistic and could be misleading. Therefore clarity and further guidance from ONC are needed in three areas.

1. Is the term "minimum data set" intended to address a commonly defined set of values that should be supported to express common clinical concepts? If that is the case, there already exists both a common *convenience set* of terms for problems (i.e., health concerns, conditions or clinical diagnoses) and a common order *convenience set* – the KP Problem subset and the LOINC Common Orders. However, these sets have challenges as well. The problem convenience set is not necessarily sufficiently expressive to handle the new terminology that is needed to describe care plans and care goals that are essential for identifying value-based outcomes rather than the current process-based constructs. The LOINC Common Orders should be investigated further to see how they perform.
2. Is the term "minimum data set" intended to address *classes* (categories) of data that are essential to structure for interoperable data exchange? If so, the Committee believes that this would have value; however, to truly address value-based outcomes, we need completely innovative and transparent discussions about the types of data required, not merely responses to a draft roadmap.
3. What is the overall intent of the minimum data set once established? Is it intended to be used for direct clinical care, outcomes-based research, clinical decision support, quality measurement, or all of the above? In any of these cases, adherence to a standard set of

metadata describing its provenance is required for the minimum data set to have true value for re-use and determining value-based outcomes.

Notwithstanding the above issues, the Committee recommends that ONC consider the inclusion of five information areas that should be conveyed in all communications:

1. Current Problem List
2. Current Medications
3. Current Allergies
4. Clinical Note
5. Contact information for all participants in the patient's care

It is critical to note that there are many subtleties tied to each of these areas that must be carefully considered and adjudicated by a consensus process before they can be exchanged meaningfully. Simply naming the data elements in each of these areas only supports a technical interoperability framework, but not necessarily an approach that leads to truly meaningful and useful interoperable information. These subtleties are discussed further below.

There are differing views of what information should be conveyed in a Current Problem List. Management and reconciliation of problems can result in errors of omission or commission unless "rules of problem list etiquette" are followed. There are many circumstances where specialists and other clinicians will edit the problem list inappropriately due to lack of understanding about how other clinicians use it. For problems (or its other synonyms), a true onset date (as opposed to the date it was recorded), as well as understanding if the problem is new or just newly documented is essential to evaluate the significance of any problem, and to help the next physician or other clinician who sees the patient to understand the history of the documentation of the problem. Further, one cannot assume all problems on a problem list are active—problem list maintenance remains challenging in most clinical settings. Of note, in many multispecialty settings where problem list etiquette has been established, the best practice is to have all contributors manage their own entries and those entries pertinent to their specialty; and that the primary care physician (if there is one) is the most appropriate person to manage the problem list as a whole. This is in contrast to existing Meaningful Use requirements, which suggest that all clinicians should be responsible for problem list maintenance.

The syntactic structure of Current Medications is perhaps the most complete and stable among all clinical elements. However, guidance is required to ensure that medications on a patient's medication list are accurate. It is common for active medications to disappear from a patient's list sometime between admission and discharge from an acute facility or during a specialist encounter. The patient's medication list may be little more than the doctor's wish list for that patient, and may represent more fiction than fact. An evolving best practice for medication list management, similar to that of problem list management, has been to recommend that specialists (who often have staff performing medication review and reconciliation) only manage medications they added, or medications used by their specialty, and otherwise to relegate medication list management to the primary care physician (if there is one). Again, this is in contrast to existing Meaningful Use requirements and the NQF quality measure for medication management. A critical data element that must be collected with each medication is the identity of the prescriber. This element is crucial for accurate management and reconciliation, yet it is not a required element in the C-CDA.

The experts in allergy medicine have struggled for decades to achieve consensus on the proper structure for representing Current Allergies in the medical record, and we still do not have agreement.

Unfortunately, these waters have been further muddied by the ONC defining a medication allergy entry as only medication reactions that are true allergies. While there is value in distinguishing a true allergy from an intolerance or sensitivity when it comes to drug-allergy decision support, failure to capture drug intolerances means that the allergy list no longer serves the needs of patients. Patients would justifiably be upset when their complaint about a particular medication is not documented, resulting in the same (or other physician) continuing to prescribe the same offending medication. What is most important at the point of care is that the patient's view of what substance causes problems for him or her is properly captured in the record. The capability to capture anything that the patient feels could cause harm, no matter what the mechanism, is what is needed. Any instance of an allergy, intolerance, or sensitivity should include the name of the substance and the nature of the reaction. However, there is no consensus on consistent use of allergy / intolerance severity level and comments. Thus, sharing only "penicillin" in an allergy list often results in complete avoidance of all penicillins and cephalosporins, when in fact some penicillins or cephalosporins may be tolerated. Additionally, the ability to provide further clarification in the record on exactly what is meant by "penicillin allergy" (e.g., diarrhea to augmentin vs. rash / anaphylaxis) is needed.

It is imperative that we exchange knowledge, not just data. For that reason, our Committee proposes that the most important item beyond the three outlined above is the unstructured Clinical Note. The item that the receiving physician or other clinician needs most is the clinical note containing the patient's story, the clinician's reasoning, and the plan. While third parties may not desire to collect this information today, we feel that the value will be demonstrated in the future as tools for managing narrative data improve.

We should also define the minimum data needed to establish and maintain contact information for all participants in the patient's care (address, phone, email, IDs, etc.), where that information is known and has been verified by the patient as being up-to-date. While the necessity of having up-to-date information is no different for contact information than it is for medication allergies, it is specifically called out here as review and updating of contact information other than for the patient, is not typically done. Given the recommendations above about certain problems and medications being managed in a more compartmentalized way—with the exception of the primary care physician—this information is critical to ensure true continuity of care.

For the data elements described above, and all data elements in the record, "unknown" should always be included in the accepted value set. Attempts to force clinicians to decide among inaccurate choices does not result in improved data accuracy.

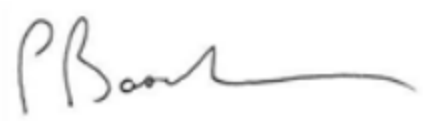
We urge ONC to seek guidance from the medical community to further define these and any other data elements that the community agrees would be universally worthwhile. The first test for the inclusion of any data element must be clinical relevance. In many cases, the data that third parties desire could be supplied from sources other than the clinical record. The clinical record should not always be the first target for those seeking data. Additionally, when transitioning care, there is a much richer data set that good clinicians are going to send and/or receiving clinicians are going to desire. Therefore, the easier it is for a clinician to query and locate data of interest, the lower the requirement to send data will be.

To summarize, overall the Committee believes that there is no clear path to a minimum data set that can cover all clinical use cases, or even the majority of clinical use cases, because such use cases are only now beginning to emerge, particularly for value-based care. Any attempt at a minimum data set would be naïve and falsely lead clinical application vendors into a state of unrecoverable complacency. Therefore, the Committee recommends that ONC consider the inclusion of five information areas,

described above, that should be conveyed in all communications. However, it is not simply the data elements within these areas that are important, but rather the ownership and management of these data that is most critical. Establishing some rules of etiquette and standard approaches for the handling of these data, based on best practices, would be a more meaningful and long term approach. We urge ONC to work with us and other clinicians to convene a process to move this work forward.

We thank you for seeking our input on this important issue, and hope that you will find value in our response. Should you have any questions, please contact Thomson Kuhn, Sr. Systems Architect, at tkuhn@acponline.org.

Sincerely,



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