“Problem Context” for HL7 Standards on AI Algorithm Development and Application

I. What is the “problem context” for use of AI tools in medical practice (as distinguished from use in research)?

A. The core idea is that AI tools must be carefully matched to an individual patient’s problem in the context of the patient’s complete problem list (PL). Each problem entry on the PL organizes underlying details about the problem, while the PL enumerates the patient’s other problems. Together, the problem entry and the PL organize all EHR data relevant to the problem context.

1. Effective use of both AI tools and alternative capabilities (see A.2 below) requires understanding what is meant by “problem,” how each problem on the PL relates to its surrounding situation (“context”), and what is required for a problem to be “carefully matched” with AI tools. **HL7 can help define standards for each of these elements.** These are not just technical standards but standards of conduct or behavior. HL7’s role would not be to establish or select these standards of care (which would be a governance role outside HL7’s authority) but to help define these standards for other parties to select and apply.

2. AI is one of three capabilities for information processing — human intelligence, artificial intelligence tools, and traditional software tools (including EHR and CDS tools) — available in medical practice. (“Information” is an umbrella term for both patient-specific data and general medical knowledge.)

3. Choosing which of these capabilities to use should be done carefully, in accordance with standards that HL7 could help define and disseminate. So “careful matching” in part means recognizing when we should turn to which alternative capability.

a) For example, a standard of care for doing a history of present illness might be that the clinician, before exercising clinical judgment, should first employ a problem-specific CDS tool to identify what data collect and what the collected data mean. That CDS tool typically can take the form of traditional software, without resort to advanced AI.

b) Another example is that a particular AI tool might be impeccable in its design and training data but still not be well-matched to solving a particular patient problem relative to alternatives most useful to
that patient. Alternative, an AI tool might offer essential analytic capabilities not available from human cognition or traditional CDS software.

c) Matching these capabilities with a problem requires that the problem be carefully defined, for which problem-orientation provides guidance and standards.

4. A threshold need is simply to identify AI tools potentially applicable to the patient’s problem. The expanding universe of available AI tools is already more than any clinician can keep up with. Therefore, some sort of CDS tool to navigate that expanding universe is needed. Such a tool would inform clinicians what AI tools are worth considering in a problem context and enable clinicians to compare the AI tools with each other and with non-Al alternative tools. The needed CDS tool can take the form of traditional software; AI is not needed for this purpose.

5. HL7 standards in these areas would protect against depending on the autonomous discretion of each clinician and the unfettered authority of each provider institution. HL7 standards could do much to guide EHR and CDS developers, enable uniformity and reduce the HIT learning curve, enhance interoperability, and thereby reduce burdens for clinicians, improve quality for patients, and improve the economics of care for all stakeholders.

6. The “problem context” is foundational for all other contexts. Recognizing the problem context is essential for not only meeting patient needs but for practicing medicine as a scientific discipline. The 20th Century’s leading philosopher of science, Karl Popper, viewed scientific inquiry as beginning in problems to solve, not in observations or concepts or theories.

B. Problem. In a problem-oriented system of care, the term “problem” means a health problem as experienced by the patient. A potential gap or discrepancy always exists between the actual problem experienced by the patient, the clinician’s personal concept of the problem, and what medical “knowledge” says about the problem in theory. Problem-orientation involves a constant effort to identify and narrow that gap. For example:

1. Misdiagnosis: A known diagnosis may fully explain the patient’s problem, but the clinician may be unaware of that diagnosis. Or else the clinician may be aware of the diagnosis but overlook it as a possibility due to cognitive errors and/or disorganized investigation. A good example of the latter is a case the POHR project team has been discussing, where multiple clinicians missed an endometriosis diagnosis for almost 12 years. Most of that delay likely would have not occurred had the clinicians followed problem-oriented standards of care. This kind of error occurs with not only diagnostic but treatment decisions (i.e. missing the optimal treatment option for the patient, choosing instead an option familiar to the clinician).
2. **Population-based medical knowledge**, which fits imperfectly with the uniqueness of every individual. Medical knowledge tends to capture what different individuals have in common (e.g. all diabetics have in common some dysfunction in blood glucose regulation), while myriad differences among those individuals are what matters most for decision making. For example, even when a standard “treatment of choice” seems to apply to patients labeled with the “same disease,” detailed data about them often leads to different decision making pathways and destinations for most of them — differences that too often are obscured in traditional evidence-based medicine and practice guidelines. Problem-orientation requires carefully identifying and analyzing the detailed data to individualize decisions on each problem.

3. **Fallibility of medical knowledge**: Current medical knowledge may be radically incomplete (e.g. current knowledge about long Covid), or simply erroneous (e.g. “knowledge” about stress as the cause of ulcers before the role of H. pylori was understood). Auto-immune conditions are a particularly important area where current knowledge seems to be radically incomplete. Problem-orientation enables better coping with, researching, and continuously narrowing gaps in medical knowledge.

4. **Medical culture**. Various biases and harmful attitudes are instilled by medical culture, above and beyond pre-existing biases and attitudes in human cognition and the surrounding society. In particular, patients have trouble being believed about their subjective symptoms when test results are negative and a biological cause is not evident to their clinicians. And doctors are “educated” to overvalue their expertise while undervaluing the expertise of nurses and other non-MD practitioners. Problem-orientation entails a constant assault upon such aspects of the status quo.

C. **Context and the Problem List (PL)**. The PL’s first purpose is simply to enumerate the patient’s complete health needs so that none are overlooked. Beyond that, the PL is a tool for health problems to be considered holistically and not in isolation from each other.

1. For example, multiple chronic disease problems often occur in clusters of related conditions (e.g. diabetes, kidney, and cardiovascular conditions). And other seemingly unrelated problems may still need to be taken into account for purposes of care plans.

2. As to care plans, they need to be conceived on a problem-specific basis and then analyzed and coordinated in light of other problems and plans. For example, an orthopedic problem may hinder the patient from doing exercises that would be part of an optimal care plan for some other problem. The PL is a tool for systematically taking into account the context of other problems. Context includes all sorts of details about the history of those other problems and the patient’s current life situation,
including SDoH. The POHR organizes all those details, and the PL serves as a table of contents to the entire POHR.

D. To reiterate, problem context is foundational for the other contexts (enumerated in part II below) for two reasons: solving patient problems is the root purpose of health care in all contexts, and problem solving is central to scientific theory and practice.

II. Alternative contexts for comparison

A. Patient care contexts
   1. Problems as experienced by the patient — This context is foundational, i.e. other contexts enumerated below must connect to it. If patient problems are overlooked or poorly defined, then other contexts become distorted or disconnected from patient needs.
   2. Provider (individual and institutional), which includes reducing clinician burden (RCB). The RCB context requires weighing the burden imposed by the task against the value of performing the task. The value is primarily the clinical value for patient care purposes, but other purposes may be relevant.
   3. Actions/tasks, which must be driven by solving patient problems, not serving the interests of other parties. Informational actions/tasks may be performed by human cognition and/or external IT tools, which in turn may take the form of traditional software and advanced AI. Carefully matching these alternatives to the problem situation is critical.

B. Economic contexts, e.g. for payers and providers (profitability/solvency), patients (affordability).

C. Research —
   1. Clinical research on physiology, disease, diagnosis, therapy (including drug & device development) for medical knowledge and evidence-based medicine
   2. Public health (e.g. epidemiology, SDoH)

D. Information/Reference —
   1. Traditional medical literature in journals, texts and libraries;
   2. Health information technology/tools (HIT), including practice guidelines in electronic form for use during patient care. Electronic guidelines can be designed to replicate traditional text-based guidelines (which are limited to medical knowledge), or can be designed to couple medical knowledge with patient-specific data, generating patient/problem-specific options and evidence.

E. Regulation of all the above, including both governmental regulation and standards-setting regulation.