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Federal Coordinating Council for Comparative Effectiveness Research
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Honored Members of the Federal Coordinating Council for Comparative Effectiveness Research:

As Medical Director of Allscripts Healthcare Solutions Inc, one of the largest Health Information Technology companies in the United States, I am humbled by the trust that our 150,000 physician clients have placed in us and our solutions. We are deeply committed to helping our clients improve the work processes, services and quality of care delivered in their practices.

I thank you for this opportunity to address you. I will keep my comments brief, and focused on a message that you may find unique.

For the past three years, in addition to my work with Allscripts as well as the care I continue to provide as a practicing family physician of > 10 years, I have volunteered my time to work as a member of the "Collaborative for Performance Measure Integration into Electronic Health Records" and have served on the Steering Committee for the past year as a representative of the Electronic Health Records Association. "The Collaborative" was started in 2006 by CMS, AHRQ and AMA - and has taught us a great deal about quality and outcomes research in healthcare. We are encouraged by the enthusiasm for the use of electronic resources, and have identified a set of key opportunities for improving the substrate from which these data will be drawn.

Simply put - the core problem is that electronic information sources often lack the granularity or scope that would be required to support the next generation of research that you and HHS, AHRQ and the NIH – as the organizations receiving the $1.1 billion for comparative effectiveness research - must facilitate. For example - I was speaking with a physician colleague in a hospital hallway recently. He expressed frustration with the clinical information system in his medical group – specifically with the reporting tools and his inability to ask research questions on the data that presumably resided in therein. After some discussion, it became clear to me that in fact the physician's displeasure was misplaced: the reporting tools were perfectly functional. The problem was <u>that the data in which he was most interested had not been captured in a manner that was reportable</u>.

Let's consider a simple example of this problem. Perhaps there is a new intervention that would help our patients quit smoking. In order to compare the effectiveness of this intervention with others (or a control group) - a researcher would need to capture information about our patients' smoking status both before and after the intervention, as well as any relevant information about the intervention.

Historically, this sort of research may have been conducted with a paper form inserted into the patient's chart and/or the review of a paper record by a clinician researcher. This researcher plays an important role: by <u>reading</u> the paper record, this person performs an <u>analysis of free-text information</u> in a clinical record and <u>translates it into data</u>.

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Of course the promise of Electronic Health records is that this manual retrospective review becomes unnecessary. The reality is that this is only possible if we can accelerate the definition of standards that would unambiguously define the data elements that would be required for a given research endeavor.

Many clinical systems use proprietary terms to represent clinical concepts, and also allow or encourage physicians to customize their systems in a very granular way. One option is to identify a patient married to a smoker through the use of an ICD-9 code (V15.89 Other specified personal history presenting hazards to health) – an option that isn't sufficiently granular for a researcher to adequately identify these patients accurately. Another would be to use a more specific SNOMED CT concept (Passive smoker - 43381005), which does allow the necessary granularity but are not broadly used by most medical providers today. And some providers even use a proprietary term such as "smoker in the home" (free text) or insertion of free text descriptors of the concept, both of which are just barely better than a paper record, as they require human or artificial intelligence to translate the intent of the clinician. You can see the challenge here.

So we embark on our research project by looking in our clinical system for all smokers - but we only know that they are smokers if this information is captured and maintained discretely by the system. How much does the patient smoke? How often? What is the intervention? Has the frequency of smoking decreased since the intervention? What other health outcomes are being monitored as secondary endpoints?

Researchers often view their work as the acquisition and analysis of data - so it is no surprise that much of the focus of outcomes research might be characterized as a set of questions that are asked of clinical data. While a human can translate an ambiguous question (is this patient a smoker?) - The computer is not nearly so forgiving.

We have a great opportunity to solve this problem with a set of simple yet essential interventions. With adequate support these initiatives, the promise of electronic systems can be fully realized and accelerated.

a) A key work product of "The Collaborative" is a draft specification for the Health Quality Measures Format (HQMF) - which would explicitly and logically describe the key data elements that the electronic record should be prepared to capture. A researcher, Payer, Public Health agency or care delivery organization would therefore be able to express this information in a proactive manner - thereby allowing the healthcare provider to "warn" the clinical system of the need for these elements. If expressed in this standard format - a clinical system could automatically consume these expressions and facilitate the capture of this information through the provider's usual workflow.

In this way - HQMF shifts the focus of research to the proactive definition of important data that would be required rather than the reactive task of making sense of ambiguous clinical statements.

Returning one last time to our example research question - there may be an expression in HQMF that might be paraphrased: "For all patients who are smokers (defined as Snomed CT concept 77176002) at any point in the five calendar years preceding 1/1/2009 - how many have received Medication X (RxNorm ID 12345) and are no longer smoking (SNOMED CT 281018007) now?" Note that even with this very simple example. if the electronic system can anticipate the need for these data elements, it can either map its proprietary

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terms to these reference elements or it can capture this information during the clinician's documentation process. The process of defining these elements would be identical for performance measures, guidelines and research initiatives, and would additionally facilitate the inclusion of "real-time" clinical decision support at the point of care.

b) Today's web developers rarely work directly in hypertext markup language (HTML). Indeed, the growth of the Internet has been largely due to the availability of tools that insulate web developers, bloggers and wiki contributors from the "code" that modern browsers interpret. Our opportunity is quite similar: electronic records systems will interpret HQMF, but we can't expect researchers, policy analysts or quality measure developers to write these machine-readable expressions. Rather - we need to develop an authoring tool that will, like the first web development tools, accelerate the creation and management of clinical guidelines, quality measures and proactive research questions. We have coined the term "MAAT" (Measures Authoring and Analysis Tool) to describe this solution. This needs to be achievable through efforts by people of all skill levels if we are going to achieve our goals. This will also allow consistency between the efforts that will be taking place in the three areas where comparative effectiveness funding was allocated through the legislation - HHS, AHRQ and NIH.

We support the work of the National Quality Forum (NQF) to carry forward the work of The Collaborative volunteers. Under an AHRQ grant, NQF has recently published an RFP to accelerate the revision of HQMF so that is can be incorporated in an IHE profile in the summer of 2009, and submitted to ballot at HL7 in September, 2009. We ask that the Federal Coordinating Council become familiar with this initiative, and to assist NQF to enhance the likelihood of success. Unfortunately, there is no parallel initiative to address the necessary development MAAT. We urge the Federal Coordinating Council for Comparative Effectiveness Research to consider methods for funding such an initiative. With government seed funding, and sufficient industry enthusiasm, such an initiative could parallel the evolution of HQMF as it works its way through the standards process over the next six months.

In light of the many millions of dollars we are all investing in the domain of Health Information Technology - it is ironic that we now are calling for rather modest investments in these two projects. This issue is in fact a keystone in the framework of the set of solutions that will enable us to incorporate quality measures, enrich clinical decision support, and perform outcomes analyses to compare the effectiveness of interventions, all for the ultimate goal of providing the best care possible to our nation’s patients.

Respectfully Submitted,

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