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We appreciate the opportunity to address the HIT Standards Committee's Clinical Operations Workgroup. As written testimony, I've attached the following documents:

- An overview of our testimony outlining our work with home blood glucose monitoring for patients with type 2 diabetes.
- A 2009 *Diabetes Care* article reporting the findings from a randomized clinical trial of a Web-based, collaborative diabetes care intervention.
- A 2004 *British Medical Journal* article examining patient experiences with a Web-based support program for home monitoring of blood glucoses.
- A 2010 *Journal of Biomedical Informatics* article describing our mobile phone-based system for home monitoring, which included wirelessly uploading blood glucoses.
- A recent 2011 *Diabetes Technology & Therapeutics* article qualitatively assessing patient experiences using the mobile phone intervention.

Thank you for the chance to share with you our experience of patient perspectives on medical device interoperability.

Sincerely,

Courtney R. Lyles, PhD

**HIT Standards Committee
Clinical Operations Workgroup
March 28, 2011, Washington, DC**

Medical Device Interoperability – Patient Panel

Good morning. My name is Dr. Courtney Lyles, and I am a post-doctoral fellow at the University of Washington in Seattle, where I work with Group Health Research Institute on improving care for chronic illness. Thank you for the opportunity to share our experience with medical device interoperability, especially for engaging patients in managing their chronic illness.

Over the past decade, our research consortium at the University of Washington and Group Health has conducted several trials of diabetes care management, with patients tracking their blood glucose at home using both Web- and mobile phone-based monitoring. Specifically:

- We gave patients access to their full electronic health record, including lab results, medical history, doctors' notes—and educational features on nutrition, medications, and physical activity.
- Patients engaged in secure electronic messaging and personalized goal-setting with dedicated diabetes care managers on primary care teams.
- And patients uploaded blood glucose values into their record to receive electronic feedback about trends—first wired through manually plugging in a glucose meter to the computer, then wirelessly through a Bluetooth-enabled smartphone application.

Our work has found significant associations between home monitoring in collaboration with a healthcare provider and improved diabetes outcomes. I'll describe some examples:

- In a 2009 study in *Diabetes Care*, we found home blood glucose monitoring, coupled with secure electronic communication with providers, improved glycemic control in patients with type 2 diabetes (by an average reduction of 0.7% in hemoglobin A1c). We know from a variety of surveys that uploading glucose meters is rarely done outside of specialty centers despite the fact that it has been available for over 20 years.
- In our qualitative assessments of experiences using these systems, patients found uploading their blood glucose values and the feedback their providers gave

them about trends extremely valuable. (We published these qualitative assessments in the *British Medical Journal* and *Diabetes Technology & Therapeutics*.)

- Our most recent work expanded home monitoring to include wirelessly uploading glucose levels through Bluetooth-enabled glucose meters and smartphones. This let patients receive ongoing care management through communication technologies, not just when sitting down at their personal computer. Patients uploaded glucose readings by connecting their glucose meter to a small Bluetooth device and using a personal health application on the smartphone. Once an upload was complete, they received an e-mail confirmation on their phone, with graphs of monthly, weekly, and 24-hour trends—and tables showing weekly and monthly averages, highs, and lows.
- Patients were enthusiastic about wirelessly uploading their glucose readings, particularly as part of a shared plan with healthcare providers. But due to resource constraints and lack of interoperability standards between devices, we built our system for only one cell phone platform and one glucose meter. So most patients had to switch to using at least one unfamiliar device—and that frustrated them. Patients strongly preferred using those glucose meters and mobile phones with which they were already comfortable. When patients disliked the glucose meter or smartphone we provided, the unfamiliarity with the devices formed barriers against their self-management of their diabetes: the opposite of our intent.

That is why we think that, to meet the needs of patients, it is essential to establish interoperability standards and meet patients' expectations about interoperability. Patients need interoperability, not only between electronic health records and consumer devices, but also between devices themselves, such as glucose meters and mobile phones. Patients should have the flexibility to choose which devices to use for remote monitoring and self-management, as it is one step toward adoption of health information technology and empowerment in co-managing their healthcare. In addition, device interoperability enables a seamless workflow between the patient's day-to-day management of their disease and the provider's guidance for long-term outcomes.

We appreciate the work of current organizations developing and promoting standards for home monitoring device interoperability. Further introduction of standards-based interoperability would lead to improvements in continuity of care and strengthen the patient-provider collaboration for disease management. Conversely, without the flexibility of patient choice of devices for remote monitoring and self-management, patients may not adopt new health technologies. Lack of such interoperability standards could lead to further fragmentation in the care experience and potentially disrupt patient-provider relationships.

Patients are increasingly engaging in healthcare through electronic health records. At Group Health Cooperative, 64% of the approximately 310,000 adult patients use an electronic health record that is shared with providers. Patients with ongoing health conditions such as diabetes and depression are much more likely to use these online services. Still, we lack the standards that would let our patients connect their online care to many of their personal medical devices, such as glucose meters.

Our experience aligns well with currently proposed meaningful use criteria in stage 3, including these:

1. Offer electronic self-management tools to patients with high-priority conditions.
2. Offer capability to upload and incorporate patient-generated data into the electronic health record and clinician workflow.
3. Electronic health records have ability to exchange data with personal health records using standards-based health data exchange.

We believe these criteria are appropriately in stage 3 rather than stage 2. This should give industry and researchers time to further tackle some of the usability challenges in home monitoring systems.

We would also, though, like to emphasize two other meaningful use criteria that are critical to the success of home monitoring:

1. We strongly support the currently proposed stage 2 recommendation for reporting patient preferences for communication medium. Home-monitoring devices are part of a system of communication and collaboration with healthcare providers. That system of communication in between office visits may be online, over the phone, or both. For individuals who have disabilities or do not speak English, communication may also include an interpreter or other care provider. We must understand our patients' preferences and abilities for communication in between office visits and build our systems of collaboration for home monitoring accordingly.
2. We also strongly support the currently proposed stage 3 measure of offering patients the capability to report their experience of care. Although home monitoring for conditions such as blood glucose levels and blood pressures are important uses of electronic health records, they will be meaningful only if we can keep the needs and preferences of patients first. To do this, we should extend

and prioritize measurement of patient experience to include home monitoring systems.

Home monitoring holds promise for improving health outcomes and care satisfaction for patients with chronic diseases. Increasingly, these illnesses are among the most common and costliest health problems in the United States. Patient needs and preferences must be kept at the forefront of these interoperability discussions to ensure that systems promote chronic illness self-management as part of everyday life. Without incorporating the quality of the patient experience into the processes for developing standards and subsequently improving them, we would risk weakening the potential impact of health information technology on reducing the burden of chronic illnesses. Patients' needs must be fundamental to the agenda and timeline for developing criteria for meaningful use in medical device interoperability.

I hope our experience provides insight into the patient perspective on medical device interoperability.

Thank you very much.