

Additional Questions for the Record

The Honorable Michael C. Burgess

1. In recommendation 9a of the report you cite, IOM states that if there is not sufficient progress, FDA should regulate electronic health records, health information exchanges, and personal health records. I want to ask about your understanding about why the IOM committee felt these items are medical devices within the purview of FDA.

- a. Let's start with health information exchanges. What about health information exchanges are medical devices? Is your view that devices that exchange medical records are medical devices within the purview of FDA?

Please see response to 1b.

- b. I am really trying to understand if the IOM believes that the entire health information architecture is a medical device. Can you start to tell me what software the committee did not consider a medical device?

The IOM committee was asked to look specifically at “health IT-assisted care,” defined by ONC as including “care supported by and involving EHRs, clinical decision support, computerized provider order entry, health information exchange, patient engagement technologies, and other health information technology used in clinical care.”

The IOM committee states on page 164 “health IT has multiple different characteristics [from conventional, out-of-the box, turnkey devices], suggesting that a more flexible regulatory framework will be needed in this area to achieve the goal of product quality and safety without unduly constraining market innovation” and calls for a “phased, risk-based approach” to regulation. The current model of medical device regulation, according to the committee, is insufficient for such complex products as health IT products.

- c. When the IOM Committee cites health information exchanges, what part of the definition of medical device is the Committee referring to? For example, are they saying a health information exchange is intended for use in the diagnosis of disease or other conditions? Or in the cure, mitigation, treatment, or prevention of disease?

See response to 1b.

2. Page 140 of the IOM committee report states "The committee could not identify any definitive evidence about the impact regulation would have on the innovation of health IT." Yet the committee appears to recommend that FDA could jump in and regulate electronic health records, health information exchanges, and personal health records.

- a. What evidence is there about the impact that implementation of this recommendation would have on innovation in these areas?

The IOM Committee believed that the evidence about the impact of regulation on health IT is unclear and could not be extrapolated from the literature in other fields. The committee underscores the importance of protecting patient safety as the reason for making this recommendation and expresses the need for regulation to not restrict positive innovation or flexibility, but instead to maximize transparency.

3. The IOM committee recommends an HIT error reporting system. There does not appear to be any discussion as to whether it is good to try to separate HIT issues from general care delivery system errors.

- a. Where is there evidence that you can separate HIT-related safety events from a category just called safety events? Is there not a danger in such separation of losing an understanding of the real causes and solutions for such errors?

The scope of the IOM Committee report was health IT-related patient safety events, so the intent was not to create separate systems. The committee states on page 163 "If a broader system for all adverse events is created, the spirit of the committee's recommendations should be recognized and considered."

- b. Can you give me an example of what you mean by an HIT-related safety error and how that does not involve non-hit issues?

The IOM Committee believed that HIT-related safety errors are adverse events that are related to the design, implementation, and/or use of a health IT product. An example of an HIT-related safety error is presented on page 125: "a new kind of error that can occur with IT which did not occur previously is the 'adjacency error,' in which a provider selects an item next to the one intended from a pulldown menu, for example picking 'penicillamine' instead of 'penicillin.'" Other examples from the report include:

- *pick-list problem: selection of the wrong item from a menu of options, whether it be a patient, test, or drug per the above example of penicillamine/penicillin*
- *alarm/alert problem: ignored alarms of potential problems*
- *availability problem: system outages (e.g., during a prolonged power failure) where the EHR or other health IT products are unavailable*

- *interoperability problem: inverted images where the image of a right arm looks like that of a left arm*