Many electronic health records (EHRs) have poor usability, leading to user frustration and safety risks. Usability is the extent to which the technology helps users achieve their goals in a satisfying, effective, and efficient manner within the constraints and complexities of their work environment.

The US Department of Health and Human Services’ Office of the National Coordinator for Health Information Technology (ONC) has established certification requirements to promote usability practices by EHR vendors as a part of the meaningful use program. To develop a certified EHR, vendors are required to attest to using user-centered design (UCD), a process that places the cognitive and information needs of the frontline user at the forefront of software development, and to conduct formal usability testing on 8 different EHR capabilities to ensure the product meets performance objectives.

Third-party ONC-authorized certification bodies are responsible for certifying EHR products. Vendors are required to provide a written statement naming the UCD process they used and describing the process if it is not a recognized industry standard. Vendors must also provide written results of their usability tests, including the number, clinical background, and demographics of the participants. The ONC has endorsed guidelines from the National Institute of Standards and Technology stipulating that usability testing should include at least 15 representative end-user participants. Reports must be made public once the product is certified. We analyzed these reports to determine whether usability certification requirements and testing standards were met.

**Methods** | The ONC maintains a web-based authoritative listing of all certified vendor products and the associated certification reports. Reports meeting the 2014 certification requirements were retrieved for the 50 EHR vendors with the highest number of providers (hospitals and small private practices) attesting to meeting meaningful use requirements with that product between April 1, 2013, and November 30, 2014, representing more than 90% of provider attestations during this period.
Results | Of 50 certified vendor reports, 41 were available for review (82%); the remaining 9 (18%) were not publicly available. Of 41 vendors, 14 (34%) had not met the ONC certification requirement of stating their UCD process (Figure 1), 19 (46%) used an industry standard, and 6 (15%) used an internally developed UCD process.

There was variability in the number of participants enrolled in the usability tests (mean [SD], 14 [10] participants; range, 4-51). Of the 41 vendors, 26 (63%) used less than the standard of 15 participants (Figure 2) and only 9 (22%) used at least 15 participants with clinical backgrounds. In addition, 1 of the 41 vendors used no clinical participants, 7 (17%) used no physician participants, and 2 (5%) used their own employees. Of the 41 vendor reports available, 5 (12%) lacked enough detail to determine whether physicians participated and 21 (51%) did not provide the required demographic details.

Discussion | Our findings reveal a lack of adherence to ONC certification requirements and usability testing standards among several widely used EHR products that were certified as having met these requirements.

Limitations include inclusion of a subset of vendors and products, sole focus on computerized provider order entry, and reliance on vendor self-reports.

The lack of adherence to usability testing may be a major factor contributing to the poor usability experienced by clinicians. Enforcement of existing standards, specific usability guidelines, and greater scrutiny of vendor UCD processes may be necessary to achieve the functional and safety goals for the next generation of EHRs.

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COMMENT & RESPONSE

Ramelteon for Delirium in Hospitalized Patients

To the Editor | In a From The JAMA Network article, Drs Perkisas and Vandewoude’s recommended caution in interpretation of our findings in the randomized placebo-controlled trial of ramelteon for prevention of delirium. The points that concerned them were (1) a nonsignificant baseline imbalance in the frequency of dementia in the placebo group and the ramelteon group and (2) that we did not clearly indicate to which treatment group 24 patients admitted to intensive care units were allocated. To clarify these points, we performed subanalyses of the original data.

Four of 8 patients with dementia in the placebo group and 0 of 5 patients with dementia in the ramelteon group developed delirium (P = .10). Although 13 patients had already been diagnosed with dementia at baseline, the number of patients showing a Clinical Dementia Rating (CDR) score of 0.5 or greater (indicating mild cognitive impairment or dementia) at baseline was 13 in the placebo group and 16 in the ramelteon group (Figure).

Ramelteon was associated with a lower risk of delirium among patients with a CDR score of 0.5 or greater (62% in the placebo group vs 6% in the ramelteon group, P = .003), with a relative risk of 0.15 (95% CI, 0.02-0.96), but not among patients with a CDR score of 0 (14% vs 0%, respectively, P = .24).

In the subgroup of 24 patients admitted to the intensive care unit, the incidence of delirium was 43% (6/14) in the placebo group and 0% (0/10) in the ramelteon group (P = .02).