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   Sommario/riassunto This document provides the empirical rationale for critical patient safety related usability guidelines for standardization and requirements for validation testing to ensure safety-enhanced design. These standardization guidelines are targeted at eliminating never events and

associated patient harm by proactively addressing and mitigating the root causes of use errors from Electronic Health Record (EHR) design and implementation elements, as characterized in our framework on the relationship between usability and patient safety (NISTIR 7804). Requirements for validation testing are instantiated through realistic use cases (that were developed in the course of this research) can be applied during design and evaluation of EHR systems and for user performance testing. The ultimate goal is to drive and empower effective and safe human performance in the use of EHRs. This research drew upon five different methods of empirical human performance data collection, utilizing cross-cutting analytic methods, with a diverse set of analysts from different disciplines, backgrounds, and perspectives. Researchers used this mixed method approach in order to capture user expectations, knowledge, and outcomes regarding EHRs. Human factors guidelines for standardization, which were explicitly derived from the empirical evidence obtained through field data collection, are provided to improve the safety-related usability of EHRs in three critical use risk areas. Ultimately, this research demonstrates that patient safety is negatively affected when critical safety tasks are performed with the support of poorly-designed EHRs, in part because mistakes and errors frequently occur, and in part because users who become frustrated and unwilling to trust the systems they are given are more likely to rely on potentially unsafe workarounds.