

User Centered Design

Criteria Covered:

§170.314(a)(1)	Computerized Provider Order Entry – Medications
§170.314(a)(2)	Computerized Provider Order Entry – Laboratory
§170.314(a)(3)	Computerized Provider Order Entry – Diagnostic Imaging
§170.314(a)(4)	Drug-Drug, Drug-Allergy Interactions Checks
§170.314(a)(5)	Demographics
§170.314(a)(6)	Problem List
§170.314(a)(7)	Medication List
§170.314(a)(8)	Medication Allergy List
§170.314(a)(9)	Clinical Decision Support
§170.314(a)(14)	Implantable Device List
§170.314(b)(2)	Clinical Information Reconciliation and Incorporation
§170.314(b)(3)	Electronic Prescribing

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Report Prepared by: Epic Systems Corporation

■ User Centered Design

Epic's development process features customer involvement in design and development, high standards for hiring and domain expertise among our developers, and centralized development in one location. We develop our own applications and do not acquire products or companies.

Our software is developed following an internally developed user-centered design process. The process includes:

- Training of software development staff, including immersive training in the clinical domains in which they work.
- Software design and development based on a deep understanding of the user, task, and environment.
- A collaborative design and development team made up of software developers, clinicians, usability professionals, users and operational stakeholders from healthcare delivery organizations, and other subject matter experts.
- End user feedback and design evaluation.
- Iterative design and feedback loops.

Key Principles

We create electronic health records because we believe that technology, elegantly designed and carefully implemented, makes a positive and measurable difference in the way healthcare is delivered. The key principles of our development process are driven by our commitment to building effective, efficient, and satisfying software.

We consistently reinforce our understanding of our users and their environments

All Epic software developers are required to go on immersion trips to client sites, where they observe workflows and interact with end users. This immersion helps them become experts in their applications and end users' needs and workflows.

Software developers receive training in healthcare, healthcare processes, and software usability. We employ clinicians in many roles, who provide feedback on designs and conduct ongoing education for non-clinical staff.

Our design process begins with the developer detailing how proposed development addresses the end user's goals, and that detail is grounded in the thorough understanding gathered through immersion and ethnographic research. Targeted user interviews are conducted to gather information about end users' perspective, tasks, and work environment in order to shape and influence design.

This principle corresponds to ISO 9241-210:2010 4.2: The design is based on an explicit understanding of users, tasks, and environments, 4.7: The design team includes multidisciplinary skills and perspectives, 6.2: Understanding and specifying the context of use, and 6.4: Producing design solutions.

We implement this principle in alignment with ISO 16982:2002 4.4: Direct involvement of users as a key factor, and 5.1: Methods that imply the direct involvement of users.

We involve our users throughout the design, development, and implementation process

Development projects are selected and prioritized based on feedback from Epic users. We open design discussions to members of the Epic community and their end users, holding conference calls and webcasts to solicit input. As development begins, application teams use webcasts to showcase new functionality as design iteration progresses from wireframe mockups to working product. These webcasts are open to all Epic organizations and allow them to evaluate new features in the context of their workflows. Other user research methods, including card sorts, preference testing, and eye tracking, are used to collect feedback and establish design goals. Epic's development teams benefit by receiving direct feedback at a point in the cycle where it is easier to incorporate improvements in successive iterations.

After our code is delivered to client sites, end users continue to offer constructive suggestions through standardized milestones in our implementation process. Once organizations are live, regularly scheduled assessments survey end users to highlight successes and opportunities for improvement. Findings from these evaluations are communicated directly back to application leads so they can be directly incorporated into future development.

This principle corresponds to ISO 9241-210:2010 4.3: Users are involved throughout design and development, 4.4: The design is driven and refined by user-centered evaluation, 4.5: The process is iterative, and 6.1 General (notably Figure 1).

We implement this principle in alignment with ISO 16982:2002 4.3: Methods and their use, 4.4: Direct involvement of users as a key factor, and 4.5: Available methods.

We evaluate our designs through usability testing throughout the design and development cycle

Customer staff who come to Epic for training and conferences have the opportunity to participate in usability labs to take part in formative testing and give feedback on in-process development. During Epic's Users' Group Meeting (UGM), Expert's Group Meeting (XGM), and role-specific Advisory Councils, we gather input and additional user test data from attendees on upcoming application workflows and features. Customers also provide feedback through remote usability testing for development that would benefit from evaluation outside the timeframes of UGM, XGM, and Advisory Councils, and for development whose target end users do not attend these events. Actual users with varying levels of industry and Epic experience participate and give feedback.

Usability testing takes place on wireframes, prototypes, proof-of-concept, and fully developed code. We perform both formative and summative testing. Formative testing early in the cycle informs broad design decisions. Summative testing on pre-release and released development is used to baseline and quantify usability, and to identify major areas for future focus and improvement. For some summative testing, we travel to sites across the country to conduct user testing at hospitals and clinics. We test with users from varying backgrounds, with varying levels of Epic experience and experience at their workplace.

This principle corresponds to ISO 9241-210:2010 4.3: Users are involved throughout design and development, 4.4: The design is driven and refined by user-centered evaluation, and 6.5: Evaluating the design.

We implement this principle in alignment with ISO 16982:2002, e.g. 4.6: Choice of usability method(s) and 6.2: Choice of usability methods based on life-cycle process.

We iterate continually to refine our designs

As developers begin working on each project, they follow an iterative design process that includes input from staff in informatics, user-design, and quality assurance roles. Customer and end user input is also incorporated as described above. Centralizing development in one location builds effective multidisciplinary project teams. Internal usability workgroups review user experience changes regularly.

After the design is reviewed, the development is programmed and tested for performance to help ensure exceptional response times. Before new development goes to our quality assurance team for testing, the code must pass review by other programmers. Following this review, quality assurance experts from every affected application complete functional, usability, and workflow testing. Issues are documented in our internal database, analyzed and prioritized, and assigned to developers to be addressed.

Throughout the release we focus on quality, beginning major development early in the release and concentrating on smaller enhancements and stabilization as the release progresses. We measure and manage quality at the levels of individual applications, as well as company-wide.

This principle corresponds to ISO 9241-210:2010 4.7: The design team includes multidisciplinary skills and perspectives, 4.5: The process is iterative, and 6.1: General (notably Figure 1).

We implement this principle in alignment with ISO 16982:2002, e.g. 4.2: Basic principles issued from ISO 13407, 4.3: Methods and their use, and 6.1: General.

We involve people with wide-ranging skills and perspectives to create robust solutions to intricate problems

Quality assurance staff members receive specific training in usability so that as they test development, they can also complete usability review. These training courses focus on heuristics, usability guidelines, and usability testing. We employ heuristic evaluations of existing and new UI designs, similar to the process prescribed by NIST usability guidelines. These evaluations involve expert review of the design's adherence to usability principles, such as matching between the system and the real world, user control and freedom, error prevention, and flexibility and efficiency of use. Usability testing and evaluation resources available to developers range from formal usability tests with end users from available customers, to simple ad hoc consultation with our internal User Experience designers.

Our design teams are built with the fluidity to guarantee that each project has the expertise it needs, and we couple this fluidity with a comprehensive system that tracks the experts that were consulted and their recommendations. Regular meetings with experienced subject matter experts further enforce our dedication to quality.

This principle corresponds to ISO 9241-210:2010 4.7: The design team includes multidisciplinary skills and perspectives, 4.4: The design is driven and refined by user-centered evaluation, 4.6: The design addresses the whole user experience, and 6.4: Producing design solutions.

We implement this principle in alignment with ISO 16982:2002, e.g. 4.5 Available methods, 4.6: Choice of usability method(s), and 5.1 Methods that imply the direct involvement of users.