# The TIGER Initiative

## Designing Usable Clinical Information Systems:

*Recommendations from the TIGER Usability and Clinical Application Design Collaborative Team*

**Technology Informatics Guiding Education Reform (TIGER)**
**www.tigersummit.com**

# Overview

The TIGER Initiative, an acronym for **T**echnology **I**nformatics **G**uiding **E**ducation **R**eform, was formed in 2004 to bring together nursing stakeholders to develop a shared vision, strategies, and specific actions for improving nursing practice, education, and the delivery of patient care through the use of health information technology (IT). In 2006, the TIGER Initiative convened a summit of nursing stakeholders to develop, publish, and commit to carrying out the action steps defined within this plan. The Summary Report titled *Evidence and Informatics Transforming Nursing: 3-Year Action Steps toward a 10-Year Vision* is available on the website at www.tigersummit.com.

## A COLLABORATIVE APPROACH

Since 2007, hundreds of volunteers have joined the TIGER Initiative to continue the action steps defined at the Summit. The TIGER Initiative is focused on using informatics tools, principles, theories and practices to enable nurses to make healthcare safer, more effective, efficient, patient-centered, timely and equitable. This goal can only be achieved if such technologies are integrated transparently into nursing practice and education. In order to meet the demands of an increasingly electronic and rapidly changing healthcare environment, it is essential to address the educational needs of the nursing workforce.

Collaborative teams were formed to accelerate the action plan within nine key topic areas. All teams worked on identifying best practices from both education and practice related to their topic, so that this knowledge can be shared with others interested in enhancing the use of information technology capabilities for nurses. Each collaborative team researched their subject with the perspective of "What does every practicing need to know about this topic?" The teams identified resources, references, gaps, and areas that need further development, and provide recommendations for the industry to accelerate the adoption of IT for nursing. The TIGER Initiative builds upon and recognizes the work of organizations, programs, research, and related initiatives in the academic, practice, and government working together towards a common goal.

## THE COLLABORATIVE REPORT

This report provides the detailed findings and recommendations from the TIGER Usability and Clinical Application Design Collaborative Team. For a summary of the work of all nine TIGER Collaborative Teams, please review "*Collaborating to Integrate Evidence and Informatics into Nursing Practice and Education*" available on the website at www.tigersummit.com.

The TIGER Usability and Clinical Application Design Collaborative Team analyzed how to further define key concepts, patterns and trends and recommendations to health information technology (HIT) vendors and practitioners to assure useable clinical systems at the point of care. This report describes the background, methodology, findings, and recommendations for future work in this area.

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# Executive Summary

The reality for nursing is that health information technology (IT) is not designed to support their work or thought processes. Products with good clinical design would support nurses every day in their practices. The current IT systems clinicians use were originally intended for finance, laboratory or other ancillary functions that do not support professional practice at the point-of-care. More important, a lack of *vision* and lack of *voice* is absent for what nurses need most. Information technology should provide evidence-based, patient-centric technology that allows interdisciplinary collaboration at the point-of-care. IT should be an *enabler* versus a *barrier*. To redefine reality, nurses must first understand the significance of usability and clinical application design that can shape the future of the products nurses use every day.

***Usability*** is crucial in the design, implementation, adoption and use of clinical products. Good usability results in products that are effective, efficient and satisfying to use. ***Clinical Application Design*** addresses how we integrate usability principles with evidence-based practice, interdisciplinary collaboration and knowledge discovery within a systems-thinking design. Both are necessary for IT to support safe, effective decision making. For the **TIGER Vision** to be realized, the profession must educate itself on usability and key clinical application design principles. This education will determine how well evidence and informatics is integrated into day-to-day practice.

The TIGER Summit, "Evidence and Informatics Transforming Nursing," held in November of 2006, revealed an aggressive agenda that consisted of a 10-year vision and 3-year action plan for nurses to carry forward into the digital age. Two critical and interdependent pillars to be further defined and acted on were:

- **Informatics Design**: Evidence-based, interoperable intelligent systems that support education and practice to foster quality care and safety.
- **Information Technology**: Smart, people-centered affordable technologies that are universal, usable, useful and standards-based.

These two critical components of informatics led to the development of a working collaborative to further define key concepts, patterns and trends and recommendations to health information technology (HIT) vendors and practitioners to assure useable clinical systems at the point of care.

**The Usability and Clinical Application Design Collaborative, was ranked as the highest priority and had the greatest number of volunteers (53.5%) of all the TIGER Collaborative teams.**

This speaks to the significance of the topic for practicing nurses and faculty today**.** Nurses who actively led and contributed to the collaborative cited reasons for their involvement to be: "*A good design can make the system easier to use and enhance clinical practice; Usability is a "make or break" part of a clinical informatics solution and "Many lessons from end-users as DESIGN is translated into PRACTICE. There is a definite need for standards and guidance."*

The focus on usability can lead to improvement of clinical IT products in three key areas: efficiency, effectiveness, and satisfaction. This means that appropriate design of IT can lead to more productivity, reduce errors, fit within workflow, improve accuracy, be easy to learn, and lead to more satisfied healthcare providers. TIGER recommends that nurses use the techniques described within this report in both purchasing decisions and to actively participate in IT product development efforts.

# Usability

**What is Usability?**
*Medical professionals have been trained to expect that some things just do not work, and they should devise ways to work around them, rather than notifying managers to change the system (Wears & Perry, 2002).*

*The lack of user friendliness is the key barrier to user acceptance (Staggers & Kobus, 2000).*

The origins of usability and its related concepts include psychology, engineering and computer science. The essence is to design tools and computer applications that match humans to their specific tasks (activities) for specific environments. Usability principles are applied widely outside health arenas, but healthcare has been slow in adopting these important principles, resulting in computer applications and technology that fits poorly into nurses' work.

**Specific Definitions**
Usability is one aspect of "human factors," a broad term about the interrelationships among humans, their tools, tasks and environments. Related concepts are pictured in Figure 1.

Human factors - is *the study of interactions among people, the tools people use and the environments in which they use them.* Researchers emphasize the importance of understanding human capabilities and limitations and how these fit with the design of tools for work (or play) in various environments. Human factors includes broad topics such as the layout of the controls in a car to match a petite driver, how the light switches in a room map to the lights they turn on, or designing an effective method to assure an accurate sponge count in an operating room.

Ergonomics is *the physical design and implementation of equipment, tools and machines related to human safety, comfort, and convenience*. Ergonomics principles are used to determine where equipment is placed in an ICU patient's room, which design of a computer mouse fits your hand best, or how well a new, wide ski works in powder snow.

Human-computer interaction (HCI) *is the study of how people design, implement, and use interactive computer systems and how these systems affect individuals, organizations, and society (Myers et al., 1996).* HCI principles include, among other things, how to design a computer screen (user interface) for nurses to detect adverse physiological events, the use of color consistently in an application for easier comprehension or the flow of elements within a clinical system to support nurses' documentation.

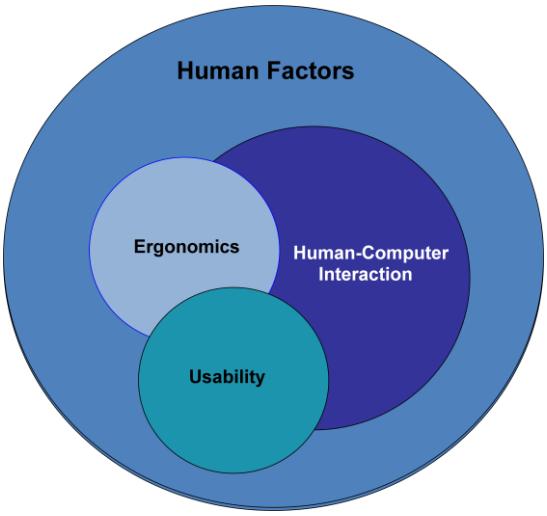



Figure 1. The Relationship of Human Factors Terms

Usability is *the extent to which a product can be used by specific users in a specific context to achieve specific goals with effectiveness, efficiency and satisfaction (adapted from* ISO 9241-11, 2006). Usability is centered on the fit between elements (Rubin, 1995). Usability topics include how easy a product is to learn, to remember, to use in everyday work or play and the effectiveness of a product for a specific task at hand. Usability can include how quickly nurses

determine the fluid balance in a patient over the last 4 hours using a new intake and output screen, how many errors nurses make when detecting physiological parameters in a current application or how easy a new infusion pump is to learn. Essentially, usability is about designing products that are easier to use by matching them more closely to users' needs and requirements in particular settings (UsabilityNet, 2006).

**The Significance of Usability**

Usability is crucial in the design, implementation, adoption and use of clinical products. Good usability results in products that are effective, efficient and satisfying to use (see Figure 2). More important, incorporating usability principles assists in the design of products that promote improved decision-making as well as patient and practitioner safety. When product usability is poor, the outcomes can be as drastic as missed diagnoses, committing serious errors, patient mortality, or extreme user frustration to the point of not using a product or even clinical information systems de-installation.

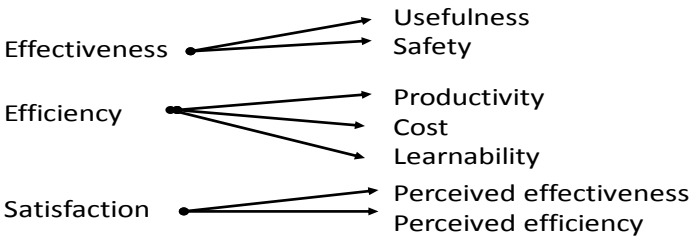


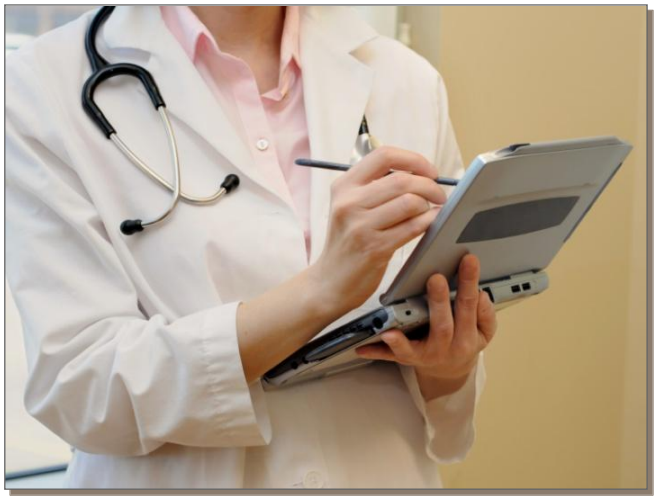

**Figure 2**

**Usability Goals**

Core usability principles include:

- An early and consistent focus on users of the product
- Iterative design processes (multiple versions matched to users, tasks and environments)
- Systematic product evaluations (with product users and metrics)

Major system users are identified early and representatives included in the design and evaluation process throughout the product's lifecycle. Including nurses early and often in system design assures that products are designed with nurses' goals, tasks (activities), and decision-making in mind. Product design includes multiple versions with systematic evaluations to determine flaws in design. Usability evaluations allow nurses to give feedback to designers in a structured manner. The product is redesigned using nurses' feedback and retested. Several iterations (versions) assure that a product is effective, efficient and satisfying to use. This process better ensures the product's fit to the users (nurses), tasks goals and the environment at hand. As can be seen, usability and the design of clinical products are inter-related.



# Clinical Application Design

Clinical Application Design builds on the sound principles of usability described above. Clinical Application Design addresses how we integrate usability principles with evidence-based practice, interdisciplinary collaboration and knowledge discovery within a systems-thinking design (Figure 3, *adapted with permission from the CPM Resource Center, 2008).* In essence, we are *applying* usability and other design factors that are critical to making information technology the stethoscope of the 21st century.

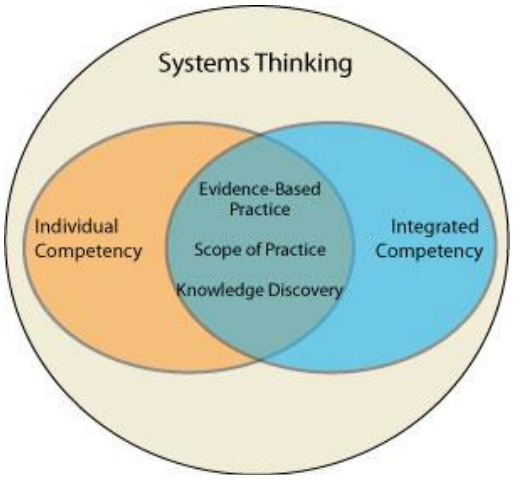



**Figure 3. Clinical Application Design Essentials**

First, evidence-based practice is an essential element of professional nursing practice today. Information technology and usability alone will not support evidence-based practice being lived at the point of care. Evidence-based practice (EBP) is defined as *"the integration of best research evidence with clinical expertise and patient values" (*Sackett, et al., 2000). Therefore, the IT systems nurses use must be able to integrate EBP into their design so nurses have the best research evidence *and* be able to apply their own clinical expertise as well as address the patient's values and situation at hand. The recent IOM Report *"Knowing What Works in Healthcare: A Roadmap for the Nation*" (IOM , 2008) addresses how we must strengthen our capacity for assessing evidence on what is known and not known about "what works" in health care and calls for assessing evidence as well as developing and integrating evidence-based clinical practice guidelines into daily practice. Clinical application design supports the principles of evidence-based practice and the integration of evidence-based clinical practice guidelines and other EBP tools into the workflow and thought-flow of the nurse and interdisciplinary team as well as speeds the translation of research into practice. Also, the integration of evidence-based practice with IT solutions enables clinical decision support at the point of care.

Second, interdisciplinary collaboration must be supported by a design using systems-thinking principles. Interdisciplinary collaboration is supported by IT clinical application design that supports integrated scopes of practice. *Integrated scopes of practice* delineate the competencies and accountabilities of the different disciplines represented on a clinical team and can bring the highest level of interdisciplinary collaboration. Integrating scopes of practice means that clinicians from different disciplines work together as an interdisciplinary team, with each member understanding and relying on the competencies and accountabilities of the others *(*Belmont, et al., 2003*).* Clarity on systems-thinking design, scope of practice and integrated scopes of practice are all critical to leveraging IT to enable interdisciplinary collaborative care.

Last, clinical application design should foster techniques for data-mining to allow nurses to analyze and create new knowledge. This is critical in leveraging IT for advanced practice. A whole new world of *knowledge discovery* is waiting for nurse executives, educators, researchers, informaticists, and practitioners as we prepare the nursing workforce to have crucial conversations about usability and clinical application design to influence the future of nursing and health care IT.

# Methodology

The TIGER Usability and Clinical Application Design Collaborative was charged with the following goals outlined in the table below:

**Usability and its Goals must:**

- Be informed by and/or positively transforms nursing workflow
- Include systems designed using known principles and processes
- Include work with system developers to maximize clinical system effectiveness

**Clinical Application Design and/or its Goals must:**

- Support evidence-based practice
- Enable collaborative and interdisciplinary care
- Provide seamless access to published literature and knowledge
- Support the creation of new knowledge (knowledge-discovery)
- Speed the translation of research into practice

For the **TIGER Vision** to be realized, the profession must educate itself on usability and key clinical application design principles. This education will determine how well evidence and informatics is integrated into day-to-day practice. To address these objectives, the TIGER Usability Collaborative established several work groups to address the specific issues relevant to each stakeholder.

**TIGER Usability Work Groups**

- Literature Review
- Case Studies
- Framework
- Provider & Vendor Recommendations

A roadmap was developed to reach the desired outcomes of providing clear recommendations for good usability and clinical application design for technology:

1. Synthesize a comprehensive literature review from nursing and other disciplines.
2. Collect case studies and examples that illustrate usability/clinical application design – consisting of good examples to follow and bad examples to avoid.
3. Develop recommendations for HIT vendors and practitioners to adopt sound principles of usability and clinical design for health care technology.

The Collaborative completed a comprehensive literature search, collected case studies and synthesized material into a framework comprised of four areas:

- Determining Clinical Information Requirements
- Safe and Usable Clinical Design
- Usability Evaluations
- Human Factors Foundations

Each area will be described in this report as to its significance for nursing, key points to consider, and recommendations for both HIT vendors and point-of-care practitioners.

Each workgroup was led by a chairperson and completed their research with the use of conference calls and web meetings, electronic survey tools, and conducted interviews. All TIGER collaborative teams created a wiki, an online website used as a tool to share their findings that all members could update (http://tigerusability.pbworks.com). Their conclusions are published in this report and were shared with colleagues through webinars that were held in late 2008. In addition, numerous presentations on this topic were given at local, national and and international conferences.

# Defining Clinical Requirements

Developing a clinical system that nurses will use starts with a clear understanding of the nurses role and the actions that they will need the system to help them perform. Requirements describe the *user* (in this case the nurse), their needs, and the demands of their work to product developers. Various analysis methods allow a complete description of the user population and their characteristics including: physical characteristics and abilities, users' goals, attributes of the work environment, typical activities or tasks, and current user experiences. Requirements analysis is important at the beginning of development activities to delineate the particular functions to be completed by the human-product-environment and tasks performed by humans to achieve their goals (Wickens et al., 2004).

### Why are Requirements Important to Nurses?

Requirements analysis provides information to system designers about the users in particular, allowing the product to be developed with real users in mind. This process is known as "user-centered design." User-centered design encourages participation with users who are directly involved in the design process. Nurses who already have an in-depth understanding of the healthcare delivery process should consider partnering with vendors to be co-developers, participating in requirements analysis methods to create tools that support professional practice and can be used effectively, efficiently, and safely in our healthcare system.

### Key Considerations

Requirements analysis is done through a systematic process that includes:

a) collecting data through observing the current workflow
b) interviewing end users (nurses), and
c) describing the practice, business needs, and desired goals to accomplish.

Requirements are established to assure that a product will perform to certain standards. In other words, requirements describe how you expect the product to act, and will allow you the validate that the technology is performing as intended.

There are numerous factors that must be considered in designing IT products for nurses. First, it is important to consider how the user (nurse) will interact with the product. *Human factors research* uses knowledge about the capabilities and limits of humans in order to guide the design of products, systems, and services (Nemeth, 2004). Computers should be designed to match the way that nurses organize their work, including thought processes or "thought flow". Too much information can be detrimental. Miller (1956) developed the "the seven plus or minus two rule"; meaning that the human brain can only process 5-9 items or chunks of information at any given moment. This rule is still valid more than 60 years later!

In addition to considering the capabilities and limitations of most people, the work environment might also contribute additional variables such as stress levels, group dynamics, mental workload, frequent interruptions, and information flow. As nurses rarely work in isolation but more commonly in an interdisciplinary team environment, technology products must be designed to accommodate the these various conditions (Traub, 1996). Clinicians need the ability to locate, manipulate and aggregate documentation effectively and efficiently.

**The American Academy of Nursing (AAN) calls for thoughtful development of Health IT**

The AAN, in collaboration with the Robert Wood Johnson Foundation and other nursing organizations has been instrumental in support efforts to improve how technology is developed and deployed in order to achieve an increase in the amount of time nurses and other providers spend time with patients. Check out the resources available at their website at www.aannet.org/files/public/facilitator_manual.pdf

# Defining Clinical Requirements

Another consideration is the allocation of tasks between the user (nurse) and the system. *Task analysis* is a requirements method that quantifies complex patient care processes by recording physical activities or tasks of patient care including time measurements, information processes, communication strategies, and motion patterns. A task is an activity that includes an immediate purpose, a machine output or consequence of action, and the human inputs, decisions, and outputs needed to accomplish the purpose. Task analysis is performed by recording the systems response to each user action. The generated flowcharts and task descriptions can be used to document how certain actions of the system or user result in error (Potter et al., 2004). Although task analysis can be a useful tool in understanding workflows, it may not adequately capture the complexity and the interrelatedness of the clinical workflows. Task analysis can be valuable in helping to distribute the workload between the activities that computers do best (computations, sorting, matching) and those that nurses do better (prioritizing, critical thinking). The Robert Wood Johnson Foundation has funded numerous studies related to task analysis and nursing workflow that you can review on their website at http://www.rwjf.org/pr/product.jsp?id=30051.

The importance of considering the nurses' workflow cannot be overstated. Clinical decision support tools must be integrated into workflow and clinical applications to avoid cognitive and/or task overload and provide timely support when the user (nurse) is most likely to make a decision.

## Key Recommendations for Vendors (Defining Clinical Requirements)

- Clinician representation on vendor development teams is critical. Recommend clinicians as vendor product managers to assure understanding of clinical needs and to develop efficient and effective requirements.
- Assure that requirements are written very clearly to avoid misinterpretation and clinical information requirements are met, particularly by developers (non-clinicians) who may hard-code designs.
- Consider the requirements of different skill levels of practitioners. A novice nurse may need prompts and guidance more than an experienced nurse. Allow nurses to choose their own level of support.
- Work directly with the organization's analysts and end users to validate requirements before building or customizing the product. As the product is being developed and/or customized, vendors should work with the organization to make sure that the specifications of the build are meeting their clinical and key stakeholder requirements.
- Create the relationship of a strategic business partnership with your customers. This vests both of you in achieving a good outcome. In addition, it allows you to enhance core competencies that might be absent within our own organization, but still allow you meet the needs of end-users and management.

## Key Recommendations for Health Care Practitioners (Defining Clinical Requirements)

**Selecting your team**

- Physician, nurse and allied health champions are critical in all phases of the project, beginning with requirements development and extending through systems maintenance. Make sure that you have comprehensive coverage and include all key stakeholders on the project team. This includes nurses, physicians, administrators, social work, respiratory therapy, billing specialists, rehabilitation therapists (physical, occupational, and speech language), pastoral care, and dietitians.

- Interdisciplinary teams are most effective at helping to strike a balance on clinical requirements. The dialogue between key players help all to gain a broader appreciation of the needs of each group. Use leaders with expertise in facilitation to keep the discussion productive and on schedule.

- The requirements process should be owned by clinicians, not the information technology (IT) department or the vendor. Because you are defining the healthcare delivery process, clinicians must be involved in requirements development and should maintain and/or change the requirements to meet practice standards and legal requirements.

**Analyze the system impact on user's workflow**

- Workflow includes identifying the five W's: Who, What, Where, When, and Why for each activity and for all information that is being collected and shared throughout the system.

- Complete a workflow analysis for each user type or department touching an electronic health record. Include all users in clinical information requirements (e.g. billing, medical records, unit secretaries, etc.), as these areas are often forgotten until problems occur.

**Use standardized terminologies**

- Use a common data dictionary comprised of standardized terminologies such as SNOMED CT® or LOINC. These terminologies are designed to support interoperability with other systems and healthcare providers. Create an organizational policy to use one common language and standard abbreviations.

- Use of text fields or “free text” should be used judiciously as will inhibit later analysis and knowledge development.

- Determine how systems will support evidence based practice/research (EBP/EBR). Embed evidence-based practice into clinical screen design to support the continuum of novice to expert clinicians.

- Include requirements for all desired reports during clinical information requirements development. Allow the end-users to review the report design prior to finalizing.

## Key Recommendations for Health Care Practitioners (Defining Clinical Requirements)

- Avoid the tendency to do a one-for-one replacement of existing paper forms. Avoid computerizing bad processes or creating poor workflow. All paper forms need to be analyzed with workflow analysis; this might be the perfect opportunity to improve cumbersome processes.

**Judicious use of customization**

- Customizations can be very costly and time-consuming for system upgrades and maintenance. Determine the ease of customizing the system to meet clinical information needs, who should be responsible for those customizations, and the degree of simplicity required to make changes.

- Consider the process for customization of the reports and the level of training/background required to write them. Vendor-only report design are likely to be redesigned later.

**Legal considerations**

- Documentation should include a mandatory electronic signature that does not allow others to reopen and modify records.

- A comprehensive audit trail should allow the provider to track documentation in all areas to identify who performed what function at what time.

**Tools - system setup and maintenance**

- Include technical requirements for all tools that ease the uploading and configuration required for system setup and maintenance. One of our participants provided this example: *"We recently had a department purchase a system without involvement from IT. Unfortunately, they did not consider system setup requirements, and the system did not have any kind of upload tool. This meant that all of the rooms and beds, physician information, services (orders) and inventory had to be manually loaded, one at a time. One of the reasons the clinicians selected the system was because they thought the inventory and menu features were so cool. They still don't have it implemented all the way because of the technical work required!*

# Designing for Safety and Usability

Minimizing error is one of the primary goals of usability and human factors design. The majority of system errors occur due to a system flaw rather than a worker issue. Designing safer more usable systems requires that users, developers and subject matter experts work together throughout design processes, leaving little room for interpretation about how technology should be designed and how workers interact with technology to complete work. System design processes should be based upon user characteristics, understanding problems encountered by users, and human information processing abilities as users interact with products in a specific environment to complete their work at hand.

## Significance of Safe, Usable Design

The design of safer, more usable systems is important because it facilitates error prevention and ensures that nurses provide the effective care (or other work) intended. Payoffs for using human factors approaches are fewer errors involving patients, healthcare personnel, and other users; decreased training cost; a better fit with the way nurses work and think; improved decision-making; reduced time spent redesigning systems that don't meet expectations; and greater user satisfaction. Human factors approaches are very relevant to nursing today because of the penetration of advanced technologies in the clinical setting, greater complexity of patient care, the amount of information generated in settings, and the high cost of litigation on the health care system. Medical errors are costly and suggested to account for nearly 100,000 deaths in the U.S. yearly (IOM, 1999). Using IT to improve patient safety and minimize medical errors is one of the key drivers for healthcare reform.

## Key Considerations

Healthcare has been slow to adopt usability techniques that have long been used by corporations outside health (Staggers & Kobus, 2000). This is unfortunate. In 2001 the Institute of Medicine reported that IT could facilitate the application of scientific knowledge to practice and provide clinicians with the tools and support necessary to deliver evidence-based care consistently and safely. It is imperative that better systems be developed to prevent errors and ensure clinicians provide the effective care they intend to provide (Leape et al., 2002). Staggers (2003) recommends incorporating human factors in the design of clinical information systems. This allows for correct data entry, display, and interpretation; contributes to sound clinical decision making; decreases the time it takes to complete tasks, training time, software rewrites, burden of support staff and user frustration. Vicente (2004) agrees. If human factors are taken into account, a tight fit between person and design can be achieved and the technology is more likely to fulfill its intended purpose. This is called a *system approach*, and encourages us to think about relationships between people and technology. Unfortunately, technology designers often focus on technology alone and too little on how people perform with technology (Vicente, 2004). This means that clinical users must work with designers to determine both effectiveness and efficiency of products and make redesign suggestions to enhance both of these usability goals (Staggers, 2003). Medical devices will be used safely and effectively only if the interaction of the operating environment, user capabilities, and device design is considered in the manufacturing of the device (Creedon et al., 1998).

If human factors are taken into account, a tight fit between person and design can be achieved and the technology is more likely to fulfill its intended purpose. (Vicente, 2004)

# Designing for Safety and Usability

## Key Recommendations for Vendors (Safety and Usability)

- Design with the end in mind: Make it easy to do the right thing and hard to do the wrong thing.
- Highly usable products provide a consistent look and feel across all applications. Identify or develop a style guide for designers to design for consistency.
- Using a style guide consistent with industry standards reduces development and training time. Following an industry standard makes a system appears easier to use to the user.
- Consider color blindness, ergonomics, and other human capabilities and limitations in the design of end-user equipment.
- Consider the environment in which the technology will be used. Location, temperature, surrounding objects will all affect the way technology will be used (*or not*) and how users create workarounds.
- Utilize evidence-based content sources and encourage clients to share best practices among each other.
- Clinical application development should be clinician-driven and not engineer-driven.

## Key Recommendations for Healthcare Practitioners (Safety and Usability)

- Ergonomics should be evaluated for each device (e.g., carts, hand-helds, workstations) so that the device fits the workflow rather than dictating it.
- Standardize organization-wide processes such as documentation, medication times, order sets, and alerts before EHR system implementation.
- Standardized templates allow for easier documentation; however, practitioners can become too accustomed to and ignore template details over time. For example, they get used to always selecting the default fields, and forget to customize the exceptions.
- Allowing free text medication orders or allergies can contribute to errors. For example, drug and allergy information selected from a formulary can use decision support systems that checks for conflicts.
- Partner with engineers to assess the robustness of wireless networks and devices. Adequate technical infrastructure is critical to prevent issues such as system unreliability, downtime, and “deadspace” that can interrupt patient care and clinician workflow. Develop a comprehensive back-up plan for network downtime or when devices cannot access the network.
- *Failure mode effects analysis* is a valuable, step-by-step process to identify potential risks and mitigation steps.

# Usability Evaluations

Once users and their requirements are understood, prototypes of products can be designed or systems redesigned. Evaluations are conducted to determine if humans can interact and perform functions safely and easily (Wickens et al., 2004). A *usability evaluation* is the process of having users' interact with the product or system to identify design flaws not noticed by designers. Evaluations are conducted early in the design cycle and throughout iterative designs of the product. Usability evaluation helps determine: excessive psychological or physical loads when humans interact with the product; ease to learn the product; the impact on efficiency, productivity, error-generation and job satisfaction; and the ease to remember how to use the system over several interactions (Wickens et al., 2004).

The purpose of usability evaluations is to detect flaws in the fit between the product design, the user and the environment.

## Impact of Usability Evaluations

Usability evaluations ensure that products are safe for nurses to use, efficiently designed for nursing activities and safe for patients. Usability evaluations can detect design flaws early in product development. Usability evaluations should occur early and often in the development process.

## Key Considerations

A user-centered design process is driven by the needs and characteristics of users and involves them in feedback sessions, also called *usability evaluations*. The purpose of usability evaluations is to detect flaws in the fit between the product design, the user and the environment. For this reason, it is important that *actual users* interact with products during usability evaluations. The evaluations can be as informal as observation or formalized feedback sessions. Either way, they should contain homogeneous users because each user group has unique needs and workflow.

User centered design is an iterative process where prototypes are developed, users provide feedback and products are improved. Evaluators should define specific goals for each usability evaluation, create a test plan and systematically capture and analyze data from the interaction with representative users. User feedback from the evaluation is used to redesign the product to make it more effective, safe, efficient and satisfying to use. In addition, usability experts should also validate and test products at frequent intervals to identify defects and areas for improvement.

Numerous areas are studied during usability evaluations. For example, are there too many clicks, or too many different colors that could confuse the user? Other examples of evaluation objectives include the amount of efficiency or productivity, reliability, habitability, user appeal and flexibility, and the amount of perceived training resource costs (Nemeth, 2004). Usability evaluations can also include assessing factors that make work easy or hard (Wears & Perry, 2002).

Usability evaluations provide an exceptional mechanism to test the product under duress. This means varying the amount, type and structure of information presented to the user under both normal and emergency conditions to optimize performance and maintain human confidence in the process (Levenson, 1986). Formal evaluation methods should be quantifiable, noting the kind of performance that must occur and how it will be measured. (Nemeth, 2004). Usability evaluations also allow developers to test for situational awareness in decision making. This accounts for all the interactions between a person and a system, together with the conditions that must be satisfied if the interactions are to be effective (Nemeth, 2004). Together these strategies can be used as a framework for constructive thinking to help healthcare teams perform patient safety analysis (Potter et al., 2004).

## Key Recommendations for Vendors (Usability Evaluations)

**Early testing costs less**

- Assess usability early and often in the product development lifecycle.
- Change introduced late in the systems development cycle is more costly than change introduced early.

**Define the usability testing team**

- Develop a formal team to be responsible for usability evaluations of all products.
- Observe actual users interacting with your products, especially if able to observe in a realistic environment.
- Testing is not the sole responsibility of organizations implementing product(s). Usability testing should be a part of every vendor's process prior to product release.
- Usability evaluations may be required and included in customer contracts.
- Prototype testing should be built into every project plan and should occur at defined intervals as the product is being created.

**High risk products**

- Conduct safety and error testing on all products. The robustness of testing may depend upon the risk of error. For example, the care plan on a medical-surgical floor may not demand as much robust testing as would medication order entry for NICU.
- Focus the most iterative design effort on high risk areas. High risk areas include drastically new features such as CPOE, functions that impact patient safety, or with users who might significantly impair product success or have high standards of acceptance. Iterative design can be most cost effective for high risk areas.
- Avoid *confirmation bias*, when the designer seeks out views that already support their own views or design direction. Confirmation bias is more often found in feedback sessions and focus groups, and can be prevented by have more than one person ask questions of the group, have a team debriefing of the information presented by the focus group, provide a transcript of the comments made in the focus group to discourage miss-interpretation, or not have the designer drive the feedback session.
- Consider the lessons learned from similar systems in other industries in order to understand their successes and failures and how that knowledge may impact your design.
- Once design alternatives have been identified, pick the best design with appropriate trade-offs. Trade-offs includes prioritization of the feature for the market, impact to future designs, and overall development effort.

## Key Recommendations for Health Care Practitioners (Usability Evaluations)

**Define the usability testing team**

- End-users need to be a part of the testing team along with clinical informatics specialists. Analysts can help to identify special situations during testing. All user types that will interact with the system should be considered in the usability evaluation.
- Users involved in defining clinical information requirements should test the product to verify the requirements and assure that it meets their needs.
- Request usability evaluation data from your vendor for commercially available products.

**Project planning**

- Include usability evaluation requirements in the contract with your product vendor.
- Include usability evaluations throughout your project plan at defined intervals as the product is being built and implemented.

**Comprehensive testing**

- Count the number of “clicks” and scrolling needed to complete common processes.
- Include typical scenarios to test patient safety functions. For example, include scenarios that validate clinical decision support tools are working within the appropriate workflow.
- Include printing capabilities as part of the usability evaluation. Look for how easy it is for the user to print, easy to read, and the workflow process to print.
- Plan on extensive testing after the system build is “frozen” before going live to make sure one “fix” didn’t break something else.
- Ongoing testing can provide an ideal way to improve the system, the staff education, and report system issues. It can be incorporated as a continuous product improvement process.

# Human Factors

The study of *Human Factors* (HF) is derived from multiple disciplines including engineering, psychology, information science, and aviation. Experts emphasize the need to understand human capabilities and limitations as people perform work, the design of tools such as medical devices that fit users' and work processes that enable safer, more efficient ways of performing work.

## Significance

Human factors helps us understand human behavior and complex decision making, performance in high stress jobs, capabilities and limitations of the human body, resource utilization in high workload areas, and human error in the system. If human factors are taken into account, a tighter fit between people and system processes can be achieved resulting in improved decision-making capability, less stress on the job, enhanced performance including error-prevention, enhanced human capability and fewer barriers to get work done, improved use of staff and safer systems.

## Key Considerations

The purpose of the human factors discipline is to promote the discovery and exchange of knowledge concerning the characteristics of human beings that are applicable to the design of systems and devices of all kinds (Bashshur & Lathan, 1999). HF impact various aspects of how users (nurses) interact with IT. First, HF focuses on the interrelationships between humans, the tools they use, and the environments in which they live and work (Weinger et al., 1998; Schneider, 2002; Staggers, 2003). Second, HF applies behavioral principles to the design, development, testing, and operation of equipment and systems (Meister, 1989). A subspecialty of HF, Human Factors Engineering (HFE), studies human behavior, human performance, human capabilities and limitations, human utilization, and human safety and health (Creedon et al., 1998; Foley et al., 2001; Schneider, 2002). Other terms that are often used interchangeably or considered closely related are ergonomics, usability engineering, and user-centered design (Stahlhut et al., 1997).

For the purpose of this report, we use the term "usability" broadly to mean the HF framework to evaluate how clinical users can influence the development of usable, safe, and effective IT systems. Usability addresses specific issues of human performance during computer interactions within a particular context. Usability goals may be expressed in terms of overall effectiveness, efficiency, and satisfaction concerning users' interactions with information systems.

Staggers (2003) describes three axioms of usability:

a) An early emphasis on users in the design, development, and purchase of systems;
b) Iterative design; and
c) Empirical usability measures or observations of users and information systems.

These axioms can be used as guidelines to incorporate the HF framework into your clinical setting. It is equally important to consider the types of errors that common in human factors research (see Figure 4).

**Three Types of Human Errors**

***Technical errors*** in which the action taken is not the action intended, arise from deficiencies of technical skill or from poor human factors design in the equipment or apparatus involved.

***Judgmental errors*** in which action represents a bad decision, arise from lapses in training or poorly developed decision making skills.

***Monitoring and vigilance failures*** in which the essence is a failure to recognize or act upon visible data requiring a response.

**(Cooper et al., 1984)**

Figure 4 - Three Types of Human Errors

As an example, consider the use of color within an application. Product designers must be careful with the use of color because of *color blindness* and *object based proximity* as demonstrated with the Stroop test. The Stroop test shows that if there are multiple dimensions belonging to an object, and one of these dimensions is irrelevant, there will be a disruption in performance. It shows that reaction time is lengthened if the wrong word for color (blue) is printed on a red card. Another example is a playing card (e.g., Ace of Spades) that is red instead of black. This confuses the user as there is a mismatch between the object and the typical color. This is an example of a *technical error*. For this reason, it is important that colors with symbolic meanings are used consistently with their meaning. For example red means stop or danger, amber is warning, and green means go or safety.

Color that stands out can be processed quickly by the user for decision making. Text in red might indicate to the user that the information is very important and a decision needs to be made. The same warning in light text or poorly placed might be unnoticed by the user, and they might fail to follow through on an important action. This is an example of a *monitoring and vigilance failure*.

The closer the clinicians are to the development process, the more likely that that the software will meet user's needs. Development time is lost if non-clinicians must spend time getting answers to clinical questions. Keep in mind that computer designers and clinicians speak different languages, are socialized in different roles, work in different environments, and have different motivators. A diverse team of clinicians and technicians can leverage the expertise of all to improve the product design. This rich set of sources help to provide the diversity of domain knowledge needed for usable products.

### Key Recommendations for Practitioners (Human Factors)

- ☐ Educate yourself and peers on human factors and usability principles; bring voice to addressing these principles in appropriate venues.
- ☐ Insist that your informatics team include a clinical informaticist or other team member with knowledge about human factors and usability principles.
- ☐ Devise methods to involve end-users in product design and implementation such as focus groups or observations to promote usable products and decrease resistance.
- ☐ Learn about ergonomics principles including how to position computers on wheels/walls or PC monitors to promote good posture.
- ☐ Consider the workspace requirements for humans to complete their work.
- ☐ Advocate for "single sign on" to limit the number of password/usernames one needs to remember per user/system.
- ☐ Evaluate device attributes such as battery life, use on all shifts (dimmer displays at night), display size, and purchase a variety of devices for best fit to tasks.

## Key Recommendations for Vendors (Human Factors)

**Adopt established usability standards**

- Use International Standards Organization guidelines for usability (ISO 9241-11).

- Consider disabled and older users. Design to Section 503 of the Rehabilitation Act of 1973. Always have an option to enlarge text size for easier viewing by individuals.

- Consider physical and sensory capacities such as vision, hearing, and manual dexterity of the user population. Consider how design factors can impact human performance such as the differences in the sounds of different alarms, requirements for reaching controls and legibility of the displays.

- If appropriate, provide some flexibility with user design of screen configurations. For example, a user definable home page that would allow the user to determine what order to enter assessment or other data so that user preferred workflow could be facilitated.

- Create a "documentation preview" mode that allows the clinician to see a narrative version of their point and-click documentation. Consider the limitations of human capability that needs to be taken into consideration when designing interfaces.

**Environmental concerns**

- Each different device should to be tested to ensure that the application looks and functions properly (see Usability Testing section of this report). The devices should be tested in a clinical setting and additional adjustments may need to be made.

- Visit the facility site to observe workflow. Focus the design on the user's desired workflow.

- Usability of specific software is only one factor that affects the overall usability of a solution used by clinicians in a particular healthcare agency. Other factors include hardware, training, system set-up, interoperability, clinical decision-support tools, and usability of other software products in the solution.

**Team diversity**

- The product development team, from conceptualization to delivering the product, should be a cross functional team with varied backgrounds and expertise. They should include software engineers, usability experts, analysts, documentation experts, education experts, quality experts, domain experts, and others clinicians are domain experts for clinical software applications.

- Computer designers and clinicians speak different languages, are socialized in different roles, work in different environments, and have different motivators. Team members may be employees, consultants, product reviewers, members of focus groups, members of test teams, or clinicians working at clinical trial sites. This rich set of sources help to provide the diversity of domain knowledge needed for usable products.

# Case Studies

Numerous case studies were collected from the TIGER Usability and Clinical Application Design Collaborative Team. The team asked for examples of both effective usability and clinical application design and implementation, as well as examples where lessons were learned and improvements could be made to the process. This section will highlight some of the attributes of successful clinical applications as well as factors to consider that can challenge the success and use of clinical applications.

Successful clinical applications shared these factors:

- User and key stakeholder involvement began early in the project with system requirements development and system selection.
- Clinicians worked with developers to create definitions, wording and graphics that represented work flow process.
- Vendors took the time to understand the workflow and processes of the end users, including how they see or "view" the information.

Unfortunately, the first case study (see box on right) did not follow these guidelines. Many of the recommendations provided in the "Recommendations for Healthcare Providers" throughout this report can help organizations avoid some of these common pitfalls. In contrast, the second case study demonstrates a different outcome when many of these recommendations were followed.

**Case Study 1: A Challenging Design**

A hospice facility wanted to improve efficiencies and enhance reporting.

**Selection process:**

- The system selection was made by high level management, not clinical users.

**Usability Challenges:**

- The clinical information system was designed for a different user population. In this case, the system was designed for the home health population versus hospice. System and screen content did not meet clinical needs.
- Interdisciplinary reports were up to 52 pages per patient, too unwieldy to read.
- Clinicians could not pull up information from previous visits, and had to re-enter data.
- Deceased patients could not be removed from lists (and remember…this was a hospice setting!)
- The organization had to purchase additional software to customize documentation to meet basic needs.

**Outcomes:**

- The organization ended up having to purchase/change clinical applications.
- The administration plans to select the new application (*not yet a lesson learned!*)

**Case Study 2: Best Practice Exemplar**

Three separate acute care hospitals in a healthcare system in the southern United States wanted a new clinical system after having used various systems in the past.

**Selection Process:**

- A Clear Vision: The new system had to support all disciplines, CPOE, evidence-based practice and clinical decision support at the point of care.
- An interdisciplinary team and leadership evaluated each system.
- Selected a "pre-configured" system that supported evidence-based and interdisciplinary practice
- Linked to large healthcare consortium for practice and content needs

**Usability Wins:**

- Multiple users analyzed the system: Bedside clinicians, ancillary departments; quality risk, legal and management.
- Users identified additional content needs. These were developed and tested before implementation.
- The system was tested/validated for usability, design and content needs.
- Developed a system to respond rapidly to end-users .

**Outcomes:**

- Standardized practice in 3 different acute care hospitals in 15 months.
- Showed significant improvement in core measures and nurse-sensitive outcomes.

A key factor for end-user acceptance is integration with existing systems. This affects:
a) User acceptance and system adoption;
b) Accuracy (fewer transcription errors, avoids duplicate documentation);
c) Patient safety due to synchronized, accurate information; and
d) Timeliness of information collection, reporting and use.

## CONCLUSIONS

Nurses and their interdisciplinary colleagues need innovative technology to simplify their work and provide them clinical guidance for the safety of their patients. This kind of innovative technology includes usability and clinical application design principles.

Usability is the fit between system users, their work and environments. Imperatives include engaging the users early and often in the clinical systems lifecycle; understanding users, their tasks and their environments, conducting usability testing and redesigning before implementation. These steps better assure smooth implementations and user adoption of complex clinical systems. Clinical application design meets systems-thinking requirements that are critical to the complex health care environments. Contemporary designs include evidence-based practice, interdisciplinary collaboration and knowledge-discovery.

Good usability and clinical application design is no longer a choice but a mandate to support safe, effective decision-making. ALL nurses including practitioners, researchers, educators, and leaders should become aware of these principles and give voice to them at every venue where it impacts end-users and patient care. Nursing informatics specialist can help educate nurses about usability. Together nurses and nursing informatics specialists can assure excellent clinical application design to meet point-of-care practice needs for the 21st century.

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