Human Factors and Quality Improvement

James Handyside, BSca,b,*, Gautham Suresh, MDc

BACKGROUND AND DEFINITION

An important conceptual framework for quality improvement (QI) that was proposed by Donabedian1 is one of structure, process, and outcome. Outcomes are the final results of interest (eg, the health status of patients). Process refers to the sequence and timing of activities that occur between providers and patients. Structure refers to the physical aspects and the resources of the health care setting in which the patients are cared for. It is important to pay attention to process and to structure in designing and implementing QI and patient safety interventions. A science that can help us understand and enhance the structural dimensions of QI interventions, and improve processes, is that of human factors engineering (HFE). HFE is defined as “The scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance” (International Ergonomics Association, www.iea.cc). Thus, HFE can be considered 1 of the basic sciences underlying QI.

The terms human factors and ergonomics are used interchangeably by some, whereas others differentiate the 2 terms. In common parlance, ergonomics is often used to describe the physical aspects (shape, dimensions) of work-related equipment and furniture. The scientific discipline itself is much broader, however, and is concerned with the human-system interface in any situation, and is not confined solely to equipment and furniture. The fundamental principle of human factor engineering is to design devices, processes, services, and the work environment based on the users’ requirement (user-centered design) that uses scientific principles, so that human performance is optimized.

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KEYWORDS

• Human factors • Quality improvement • Ergonomics
HISTORY OF HFE AND ITS USE IN HEALTH CARE

HFE emerged during World War II with the realization that the design of equipment with good displays and controls can prevent operator error, and that good training and adherence to procedures can enhance human performance. The principles of HFE are currently widely applied in planning, design, and operation in diverse fields such as aviation, space exploration, chemical manufacturing, the oil and natural gas industries, nuclear power generation, computer systems, automobile manufacturing, and manufacturing of household devices and personal devices. In health care, HFE has a rich history of application within anesthesia practice. In patient safety, the application of human factors and ergonomics to patient safety has become recognized as a vital component of optimal practice. The use of this approach, however, in designing and implementing QI interventions and improving clinical care is not widespread, even though these issues, like patient safety, have concerns about the human-system interface at their core.

The recognition of human user requirements in the design and deployment of QI interventions can ensure the success of such interventions. In particular, the rapid adoption of the electronic health record and the rapidly growing interest in its potential to improve the quality of health care through features such as computerized provider order entry and decision support create a substantial need for the principles of HFE within the health care arena.

APPLICATIONS OF HFE IN IMPROVING HEALTH CARE QUALITY AND SAFETY

Human factors science can be applied to improve the quality of health care through:

- The analysis of errors, near misses, and adverse events, to understand causal and contributory factors better.
- The development of preventive interventions in response to an error or an adverse event, and through design of improved work environments, processes, and equipment.
- Proactive prevention of medical errors.
- Improvement in efficiency, timeliness, and accuracy of work processes in health care, and decrease in stress.
- Implementation of best practices or potentially better practices, and change management during QI projects.

Analysis of Incidents

When a medical error occurs, whether it harms the patient (an adverse event), or not (a near miss), it should be investigated to identify the factors that contributed to its occurrence. An important component of such an investigation is an exploration of the human factors that have contributed to the incident. A systematic inquiry should be made into the exact circumstances surrounding the incident: the lighting; the noise level in the environment; the physical locations of the equipment, the patient, and the involved health professionals; any malfunctioning of equipment; and the level of alertness and fatigue among the health professionals involved in the incident. A list of factors that could potentially have contributed to the occurrence of an incident, and that should be systematically investigated, is provided in Table 1.

Development of Interventions to Improve Safety

After the analysis of an incident is completed, the health care team usually develops some hypotheses about why the incident occurred and what factors might have contributed to it. Based on these hypotheses, a review of the literature, and, if
possible, the experiences of other institutions that have dealt with similar problems, the team usually decides to implement some safety interventions. These interventions should be designed according to the principles of HFE. For example, an investigation into an infusion pump error in a neonatal intensive care unit (NICU) may reveal that the error occurred because of poor lighting in the area where the infusion pump was placed and because the nurse experienced numerous distractions when she was trying to load the infusion tubing into the pump and program the infusion rate into

<table>
<thead>
<tr>
<th>Table 1</th>
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</thead>
<tbody>
<tr>
<td>List of potential causal and contributory factors to errors and adverse events</td>
</tr>
<tr>
<td>Use during the investigation of a patient safety incident. Check the items that you believed played a role in the case. Add comments if needed.</td>
</tr>
<tr>
<td><strong>Work environment</strong></td>
</tr>
<tr>
<td>Staffing levels and skills mix</td>
</tr>
<tr>
<td>Workload and shift patterns</td>
</tr>
<tr>
<td>Equipment design, availability, maintenance</td>
</tr>
<tr>
<td>Ergonomic factors</td>
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<td>Administrative and managerial support</td>
</tr>
<tr>
<td><strong>Task factors</strong></td>
</tr>
<tr>
<td>Task design and clarity of structure</td>
</tr>
<tr>
<td>Availability and use of protocols</td>
</tr>
<tr>
<td><strong>Individual (staff) factors</strong></td>
</tr>
<tr>
<td>Knowledge and skills</td>
</tr>
<tr>
<td>Motivation and attitude</td>
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<tr>
<td>Physical and mental health</td>
</tr>
<tr>
<td>Emotional state and stress</td>
</tr>
<tr>
<td>Rule violations</td>
</tr>
<tr>
<td><strong>Institutional factors</strong></td>
</tr>
<tr>
<td>Economic and regulatory context</td>
</tr>
<tr>
<td>Medicolegal environment</td>
</tr>
<tr>
<td><strong>Organization and management</strong></td>
</tr>
<tr>
<td>Financial resources and constraints</td>
</tr>
<tr>
<td>Safety culture and priorities</td>
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<tr>
<td>Policy standards and goals</td>
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<tr>
<td>Safety culture and priorities</td>
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<tr>
<td><strong>Team factors</strong></td>
</tr>
<tr>
<td>Verbal communication</td>
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<tr>
<td>Written communication</td>
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<tr>
<td>Supervision and willingness to seek help</td>
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<tr>
<td>Team structure and leadership</td>
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<tr>
<td><strong>Patient and patient's family factors</strong></td>
</tr>
<tr>
<td>Condition (complexity and seriousness)</td>
</tr>
<tr>
<td>Language and communication</td>
</tr>
<tr>
<td>Personality and social factors</td>
</tr>
</tbody>
</table>

the pump. Therefore, the interventions to be implemented to prevent similar errors in the future should include improved task lighting in the vicinity of the infusion pumps, the use of infusion pumps that have brighter screens that are visible in the dark, and methods to prevent nurses from being distracted when performing critical tasks during their shift.

**Proactive Prevention of Medical Errors**

Prevention of errors can be accomplished by the application of HFE to the purchase of new equipment, and the design of new facilities, operating rooms, and patient spaces. Sometimes, an existing patient-care area can be altered using HFE principles to enhance efficiency and safety. Processes can also be designed de novo or redesigned using HFE principles. The design of medical devices and surgical and endoscopy instruments requires the use of HFE. The use of heuristic checklists such as the ones described later can help in proactively designing products and processes for efficiency and safety.

**Improvement in Efficiency, Timeliness, and Accuracy and Decrease in Stress**

Delays can be decreased and efficiency (the amount of work output for a given amount of energy and resources expended) can be improved through the use of HFE. For example, when health professionals perform their work, if the required equipment is within easy reach, fully functional, easy to use, and optimally arranged spatially, work will result in less fatigue, and be accomplished faster and more accurately with fewer errors. For example, when a nurse practitioner is inserting a central venous catheter, the patient’s bed (radiant warmer or incubator) should be at the optimal height, there should be adequate lighting at the insertion site, there should be an adequate space (preferably a dedicated procedure table) for the equipment to be laid out, the equipment should be placed close to the operator’s dominant arm, a waste receptacle should be available in close proximity, and cognitive aids should be used that eliminate reliance on memory (such as a checklist of required equipment, procedural steps, precautions, and the ideal depth of catheter insertion). Ensuring all these will enable the catheter insertion to be performed quickly, without errors, and with minimal fatigue experienced by the operator.

**Implementation of Best Practices or Potentially Better Practices and Change Management**

The introduction of potentially better practices based on evidence involves first the development of those practices and then implementation, standardization, and ongoing measurement. Ensuring that unit staff adhere to the desired changes and practices requires more than an in-service training session, a notice at a meeting, or a communication book. Such change must be integrated into the current system in a way such that the operator can easily perform the task, and is reminded or otherwise guided to perform this task. Such is the domain of the behavioral science arm of human factors.

One useful model of HFE in clinical work was proposed by Karsh and colleagues (Fig. 1).

Several tools are used in HFE for specific purposes. For example, hierarchical task analysis (HTA) is used to analyze the task requirements necessary to accomplish goals and identify the operator or user demands for successful task completion. Incident reviews and root cause analysis (RCA) (see article by Ursprung and Gray elsewhere in this issue) are used to analyze contributing factors and causes of adverse events. Although there are standards for the inclusion of human factors review in the design
and development of medical devices, for instance, there are few regulated or voluntarily accepted standards.\textsuperscript{11} The clinical team is thus charged with the integration and operational issues that come with such variation.\textsuperscript{7}

In applying the principles of HFE to improving safety and quality, the 4 key questions to be asked are:

1. Are the requirements of the users (patients, their families, health care providers, and other participants involved in this effort) understood?
2. Does the design of the process/device/service/workplace meet the anticipated needs of the users?
3. Does the design facilitate efficient, accurate, and error-free performance by the users?
4. Does the design achieve the best compromise between efficiency, effort, accuracy, safety, and costs for that specific situation?

**UNDERSTANDING USER REQUIREMENTS**

The capacity of a system to allow users to perform their tasks safely, effectively, efficiently, and enjoyably is known as usability.\textsuperscript{12} Usability engineering is the application of scientific methods for improving system development, and such methods are currently widely used in systems that involve human-computer interaction.\textsuperscript{13,14} Similar methods can also be used for the design and improvement of devices, work processes, and physical environments in health care.

The methods of usability engineering\textsuperscript{15} consist of: (1) characterizing how easily a user can carry out a task using the system, (2) assessing how users attain mastery
in using the system, (3) assessing the effects of systems on work practices, and (4) identifying problems users have in interacting with systems.

To understand the requirements of users, several methods can be used. Users (patients, their family members, or health professionals) can be asked to complete questionnaires, be interviewed in person, or be asked to participate in focus groups in which their requirements are discussed. Users can also be observed while they are using a medical device (such as in infusion pump), or receiving or providing a service (such as insertion of a central venous catheter, neonatal resuscitation, or using an electronic medical record system), to identify if fundamental human factors principles are violated and how efficiency, accuracy, and stress-free performance can be achieved. Videotape assessment is a powerful tool to gather information through direct observation. When studying users as they use a device or a computer system, it can be useful to ask them to talk aloud about what their thoughts and reactions are as they proceed through the steps of usage. Subsequently, the users’ comments can be correlated with the specific design features that elicited the comments. This approach can help identify good and bad features of the design. If a database of error reports or quality problems exists, the collection of reports can be reviewed to identify patterns that might signify specific types of human factors problems (eg, illegible labels on breast milk containers, leading to recurrent administration of the wrong breast milk to infants).

After estimating the requirements of users, a prototype of the newly designed or altered work process or device can be provided to users, and reactions to the prototype can be assessed in the ways listed earlier. For example, if the NICU QI team is working on the prevention of nosocomial infection, and they observe that alcohol gel dispensers in their unit are placed in locations that are not convenient for their nurses, they might develop a prototype of a method to provide alcohol gel dispensers in locations immediately adjacent to incubators (eg, mounting the dispensers on the bedside poles on which intravenous infusions are hung). In testing prototypes of such work processes, the reactions of the users can be assessed and measures can be obtained of efficiency, accuracy, and effectiveness (time taken to perform a task, the frequency of errors, successful completion of a task). This information will provide guidance about how the prototype can be redesigned and refined.

In all methods of testing users’ experiences so that the findings can inform design and redesign, users should be selected so that they are representative of the ultimate target population of users, and the context of the testing should be as realistic as possible. As far as possible, user observations should be carried out in the actual clinical environment of the NICU in which improvements are planned.

EXAMPLES OF APPLICATION OF HFE PRINCIPLES IN THE NICU

Neonatal intensive care is complex and involves many technological systems and subsystems, whose reliability is, in part, determined by natural limitations in human performance. Therefore, neonatal intensive care provides numerous opportunities for the application of the principles of HFE, particularly to minimize the potential for human error. Since 2002, through the Vermont Oxford Network’s collaborative project to improve the quality and safety of neonatal care, Neonatal Intensive Care Quality (NIC/Q), the authors have been promoting the use of human factors science to improve patient care. As part of the NIC/Q project, the NICU Human Factors Checklist Series16 (described in detail in Table 2) was developed. These checklists allow NICUs to proactively assess, using HFE principles, whether or not their systems of care are optimally designed and to identify opportunities for
improvement. They also enable NICUs to make changes that reduce the potential for error, thus improving patient safety. A secondary purpose was to educate users on human factors and help to build a culture that focuses on system reliability. These checklists are based on a method called heuristic evaluation,\textsuperscript{14} a usability inspection method in which the system is evaluated from well-tested design principles such as visibility of system status, user control and freedom, consistency and standards, flexibility, and efficiency of use.

Ideally, the checklists should be administered by a small multidisciplinary team of people from the NICU and from other relevant disciplines (such as biomedical engineering, purchasing, environmental services). The team can conduct a walk-through in the NICU and perform assessments using the checklists. After a discussion among the team members, each item on the checklist is assigned a grade based on the best judgment of the team.

A. This characteristic is adequate at this time.
B. This characteristic is being modified or changed.
C. This characteristic requires further investigation.
D. This characteristic is not adequate.

In addition, for each of the items on the checklist, the team should reflect on and review any adverse incidents or near misses in their unit related to that checklist item. Efforts can then be made to correct those characteristics that are not adequate, by modifying the design of the device or the process, or by replacement with a new device or process. An example of the complete checklist for labels and displays in the NICU is provided in Appendix 1.

### Table 2

<table>
<thead>
<tr>
<th>Checklist Topic</th>
<th>NICU Examples</th>
<th>Key Human Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical alarms</td>
<td>Pulse oximeter, monitors, intravenous pumps, ventilators</td>
<td>Parameter setting and response behavior</td>
</tr>
<tr>
<td>Labels and displays</td>
<td>Drugs, breast milk, monitors</td>
<td>Image characteristics, size, color</td>
</tr>
<tr>
<td>Procedure following</td>
<td>Daily care, line insertion and care</td>
<td>Omission affordances, reminders, checklists</td>
</tr>
<tr>
<td>Device usability</td>
<td>Medical devices and equipment</td>
<td>Usability heuristics and testing</td>
</tr>
<tr>
<td>Alertness</td>
<td>Hours of work, fatigue effects</td>
<td>Fatigue countermeasures, awareness</td>
</tr>
<tr>
<td>Warnings</td>
<td>Signs, stickers, labels</td>
<td>Design, placement, content</td>
</tr>
<tr>
<td>Paper forms</td>
<td>Orders, charts</td>
<td>Process guide and communication</td>
</tr>
<tr>
<td>Team performance</td>
<td>Crisis response, obstetrics/perinatal</td>
<td>Performance shaping factors, communication pattern</td>
</tr>
<tr>
<td>Unit design</td>
<td>Bedspace, headwalls, single-patient rooms</td>
<td>Process and proximity, communication</td>
</tr>
<tr>
<td>Physical ergonomics</td>
<td>Posture, layout, visual demand</td>
<td>Adjustability, visibility, maintenance</td>
</tr>
</tbody>
</table>

**Clinical Alarms**

Devices in the NICU with alarms include cardiorespiratory monitors, ventilators, pulse oximeters, incubators, and infusion pumps. Checklist items for the assessment of
alarms in an NICU include audibility, probability matching behavior, silencing, and suspension behavior and controls.¹⁷–²⁰

**Labels and Displays**

Printed labels are frequently used in the NICU for medications, laboratory specimens, and breast milk; visual displays and signs are used to convey important messages about the patient (eg, the patient’s name and gender, isolation precautions, developmental care measures to be followed), medical equipment (eg, signs that indicate the size and insertion depth of an endotracheal tube), or the environment. Thus, labels and displays often carry safety-critical information. Ideally, labels and displays should use text that is sufficiently large, with adequate contrast between the text and the background, using unambiguous terms that cannot be confused with other terms. Specific checklist topics include visual characteristics, legibility, readability, redundancy, emphasis, and salience.²¹–²⁴ The complete checklist for labels and displays is provided in Appendix 1, as an example of the checklist series.

**Procedures and Task Guidance**

Procedural controls are an important error prevention measure in the NICU, and often the most feasible safety intervention. With human error in general,²⁵,²⁶ and specifically with NICU incidents, omission of procedural steps has been identified as a common error type. The checklist for procedures and task guidance facilitates the review of omission affordances for specific errors and the use of reminders and checklists.²⁷–²⁸

**Device Usability**

The provision of care in the NICU involves the use of numerous medical devices that perform various functions critical to patient safety. Each unit has its own mix of devices, which makes the context of use and review of equipment unique to each environment. The checklist for device usability uses a heuristic approach to guide usability review, or testing, for devices that are in service, or as a guide to support evaluation and safety considerations related to the procurement of new equipment.¹⁴,²⁹

**Alertness**

The effects of fatigue on performance have been well established and the NICU is a 24/7 operation with some staff categories known to work 24-hour shifts. This checklist directs attention to the deployment of preventive countermeasures such as shift design and rotation, and operational countermeasures such as napping and light exposure.³⁰,³¹

**Information Systems**

The introduction of automation into health care through tools such as the electronic medical record, computerized provider order entry, and information management systems, to improve safety and quality, has the illusion of removing the role of the human and their concomitant failings from the system of care. A recent review³² cautions about the folly of such an illusion, however, and suggests that such development increases the need for human factors and especially training, interface design, and interaction design. Particular attention should be paid to understanding the workflow patterns of clinical work before introducing automated systems. An in-depth understanding of such workflow patterns and how they might be altered with the perturbation caused by the introduction of the new information system can enable the smooth introduction of such systems.
Physical Environment

The physical environment (e.g., lighting, noise, distraction, reach, position) influences the ability of a health professional to perform his or her task successfully, accurately, and efficiently. Physical dimensions of NICU work are affected by the position of equipment and patients. The performance of tasks inside an incubator affects visual acuity and posture. Physical ergonomics has been shown to adversely affect quality and product defects during manufacturing.33 With many NICUs now building new patient-care areas and with the increasing trend to build single-room NICUs, the design of the physical environment becomes especially important. The construction of these new NICUs offers unique opportunities to design the physical layout optimally from a human factors perspective. Although providing patient care in individual patient rooms may provide significant advantages, it can also have undesirable effects on monitoring of patients and on team interactions.

In recent years there has been increasing interest in the application of methods of lean production (best known as the method responsible for the success of the Toyota Production System) to health care.34,35 An important principle of lean methods is that a clean, well-ordered workplace facilitates optimal work and the improvement of work. A methodology used in lean production is the 5-S system, which consists of sort, set-in-order, shine, standardize, and sustain. Sort means that all items in the work environment should be classified as being essential or nonessential, and unnecessary material causing clutter in the workplace should be removed. Set-in-order means that the remaining necessary materials and equipment should be organized, labeled, and laid out, preferably using visual cues (the visual workplace) in a way that facilitates work and minimizes wasted motion and effort. Shine indicates that the workplace should be clean and well maintained through regular inspections. Standardize refers to the use of standard layouts in the work environment and standard processes of accomplishing work. Sustain refers to the need for 5-S methods to become an integral and deep-rooted part of the organization, not a transient fad. This result can be achieved through promotional and communication campaigns in the organization, and through 5-S training of all employees.

Device Design

The opportunity for the application of human factors science begins with the concept and design of devices. Usability of devices often seems to be an afterthought. For example, 1 in-depth analysis of an early design of a patient-controlled analgesia device indicated a complex and confusing control process that likely contributed to many errors.36 Device design can be evaluated to assess the following basic concepts: is the display visible and legible, and are the controls logically positioned? The use of usability heuristics such as those evaluated by Zhang and colleagues,29 and originally developed by Nielsen and Mack14 for use in computer software, can improve the likelihood that a novice review will identify usability shortcomings in device design. However, it is likely that a more informed and expert review is necessary to perform a thorough evaluation to counteract political and administrative priorities involved in large capital acquisitions.37

Product Selection and System Design

There are requirements for human factors review in the design of medical devices.11 However, even with this requirement, studies have shown a potential for a wide range of usability and design-related errors to occur with contemporary infusion pumps.29,37 One recent analysis of incidents in the NICU38 also indicated that human factors
usability problems played a role in errors involving ventilators. Most administrative and clinical personnel who are charged with purchasing decisions are not sufficiently skilled in understanding human factors principles to be able to evaluate scientifically the different equipment choices under consideration. Therefore, they should seek the advice of human factors experts, given the widespread and long-lasting effect of such purchase decisions. If there is a significant cost differential among reviewed products, a decision may need to include an estimate of cost/benefit for the life of the device, to convince decision-makers to overlook these financial disparities. An evidence-based review, however, may also provide the rigor needed for an informed decision. Evaluations should consider user requirements and be based on a comprehensive understanding of how a product will be used and obtained with methods such as HTA.

**Introducing Change**

Often the introduction of a change in a QI project involves only the education of providers. However, a QI project informed by human factors science would include other interventions, based on the relevant situation, equipment, processes, and environment. For instance, a frequent quality deficiency involves the omission of steps or practice requirements. To simply provide education may miss the opportunity to introduce other changes to equipment, materials, environment, or procedural (cognitive) aids that follow from an analysis of omission affordances.

**SUMMARY**

HFE presents a formidable contribution to QI in the NICU. The science behind the fundamental principles concerning the design of work systems that match the needs of the people who work in them is sound and is applied widely in other safety-critical situations. Early application of HFE in NICUs has shown the usefulness of these methods for frontline teams working to improve quality, reliability, and safety. The inclusion of human factors considerations in the design of structure and process has the potential to improve outcomes for patients and families and to improve the comfort and usability of work systems for providers who work in them. New technologies and continual change must be informed and designed through the application of HFE methods and principles to realize the full potential of QI.

**APPENDIX 1: LABELS AND DISPLAYS**

This checklist has been developed to facilitate a unit’s assessment of human factors that relate to labels and displays and error potential in the NICU. The intent is to provide you with guidance in your review of materials, processes, equipment, and environment. Feedback on this checklist and label- or display-related errors should be conveyed to the author, Jim Handyside at jim@improvisionhealthcare.com. See the Human Factors Checklist Series Overview (see Table 2) for general information and instructions about these checklists.

**Human Factors of Labels and Displays**

Labels and displays communicate essential information, from patient identification to physiologic status or drug dosage. The way in which this information is visually presented is important in minimizing the risk of error. Perception is not just the automatic translation of what we see. We often infer or assume certain meaning based on our expectations or the context of the present
situation or what has happened in the past. Making the visual presentation as clear as possible is essential to ensure that the correct meaning is understood.

Under ideal conditions most labels or displays seem adequate. There are times when conditions are not ideal: lighting is low, labels are partially obscured, or glare disrupts the image. The demographics of most organizations suggest that aging further heightens the need for a cautious approach to how information is presented, with a decline in visual acuity with age.21,45,46

Several label-related errors are reported in the medical errors system at www.NICQ.org. The following illustrates some of the reported issues:

- Frozen breast milk received from a referring hospital in a different container than is normally used. A nurse obtained a similar nonstandard container of breast milk from the freezer and fed the baby before noting that the label indicated the milk belonged to another patient.
- Wrong breast milk labeled with similar patient’s name and sent to NICU.
- Giving breast milk to wrong patient (similar last names on label).
- Near miss: laboratory labels were placed at the wrong patient’s bedside.
- Breast milk was thawed, warmed, and gavaged in the wrong infant. The label was wet and faint; the names were similar.
- Breast milk container did not have the required patient identification label. The handwritten label was covered by a “Thaw” sticker.
- Patient’s bedside drawer had a carton of Enfamil with iron 24 cal/oz in it and a half-empty bottle on top of the bedside table. Patient was ordered Enfamil with iron 20 cal/oz. Both kinds of bottles have yellow labels.
- A near miss occurred in which a vial of phenylephrine was placed on an anesthesia cart in the bin in which atropine is to be stored. The stocking technician made the mistake, which was identified by the anesthesiologist. The 2 vials are almost identical in appearance, but in 2 different classes, and confusion could have resulted in a death.
- A gavage tube feeding by a pump was given via the respiratory lavage port of a Ballard in-line suction catheter, despite all lines and ports being appropriately labeled. The Ballard lavage port allows any size syringe or extension tubing to be connected.

Attention to human factors of labels and displays reduces the likelihood of error. Other aspects of labels and displays are also important, such as the process for ensuring that correct labels are applied, education on the content of device displays and how to interpret them, and the use of bar code labeling systems. This checklist addresses human factors related to how information appears on the label or display. It is also important to recognize, as the tube feeding incident described earlier illustrates, that labeling alone is not always adequate and other control measures should be used whenever possible.

Examples of labels include medication labels, breast milk, specimens, embossing cards, patient identification, equipment labels, tubes, and containers.

Examples of displays include screens, liquid crystal display (LCD) panels, and monitors associated with syringe pumps, ventilators, pulse oximeter, cardiorespiratory monitors, isolettes, and other devices.

**Labels and Displays: Human Factors Principles**

The visual presentation of information requires a consideration of the physical characteristics (how information is presented) to ensure that it is communicated with the least
possibility for error. The following principles apply to all forms of visual communication, including labels and device displays. These principles will serve as a guideline as you work through the checklist. Although many may be intuitively obvious, they are based on research reported in the literature on human factors and applied psychology. These principles should be consulted for guidance as you work through the checklist, as an aid to conducting other safety analysis (eg, RCA) or when considering new labels and displays.

The principles are listed under these categories:

- **Design of message:** physical features of the label or display (eg, typeface, size)
- **Message transmission:** environmental factors (eg, viewing angle, lighting)
- **Message receipt:** personal factors (eg, visual ability, situation knowledge).

### Design of message

Legibility of the message on a label or screen display affects the user’s ability to discriminate among or recognize letters, numbers, and other characters. It is influenced by shape, size, contrast, color, and the quality of printing, reproduction, or projection on the screen.

- Use simple and familiar fonts. Sans-serif fonts (eg, Arial) are more legible than serif fonts (eg, Times New Roman).
- Avoid fonts that have characters that are similar (eg, letter “O” and zero “0”).
- Use of all upper case letters reduces legibility and should be avoided unless the text is brief.
- Limit the use of bold or italic type.
- See table for character height and viewing distance.

<table>
<thead>
<tr>
<th>Viewing distance (in/ft) (m)</th>
<th>Character height (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 in (0.7)</td>
<td>2–5</td>
</tr>
<tr>
<td>3 ft (0.9)</td>
<td>3–7</td>
</tr>
<tr>
<td>6 ft (1.8)</td>
<td>7–13</td>
</tr>
<tr>
<td>20 ft (6.1)</td>
<td>22–43</td>
</tr>
</tbody>
</table>

- Avoid using black on dark red, green, and blue.

Avoid the use of color in low-light conditions. Do not rely on color as the only distinguishing characteristic; provide redundancy to ensure meaning is clear.

Readability refers to the ease of reading words or numbers when the individual characters are legible.
Avoid the use of italics or bold for long strings of text.
Vertical space between lines should be greater than 25% of the overall font height.
Use ink that will not smear under conditions of use.
Labels should be printed on nonglossy paper. If labels are protected by plastic it should have a matte finish to reduce glare.
Ensure that the placement of labels on curved surfaces does not distort text to adversely affect legibility.
Place labels in a position that minimizes damage to the message.
Highlighter, borders, or underlining can be used for emphasis but should not distort the message text or be the only distinguishing characteristic.
Icons can be an effective supplement to printed text when they are clear and understood. Icons should not be used alone; always provide a text description to reduce confusion.
Bar code labels must also include readable text.

Message transmission
- Labels and displays should be viewed at 90° to the line of sight.
- Labels and displays should be oriented horizontally or easily moved to that position.
- If displays are viewed in low light, the device should have an illuminated display screen or have supplemental lighting.
- Task lighting should be available for reading labels when ambient lighting is maintained at low levels.

Message receipt
Comprehensibility is a measure of how reliably someone interprets a message. It depends on prior knowledge, language skills, expectation, habit, routine, location, and the context in which the message is viewed.
- Keep messages on labels brief and concise
- Avoid ambiguous words and abbreviations.
- Provide redundancy in the message (eg, name and identification number; supplement color-coding and symbols with text).
- Have someone test-read labels to verify clarity of meaning.
- For items that look similar, add unique markings and store in separate places.

Using the Label and Displays Checklist

Preparation
Before you begin a walk-through it will be helpful to:
- Identify and obtain all relevant policies, procedures, guidelines, and protocols directing the use of labels and devices with displays.
- Compile an inventory of important safety-critical labels and displays in the unit.
- Identify any recently recorded incidents or near misses involving labels or device displays.

Assessment Team
- This checklist can be conducted in 2 separate walk-through assessments: 1 with attention focused on labels and the other for device displays. Responsibility and job titles may vary in your unit; use discretion in forming the assessment team but include people in the know and those who have the authority to make changes.
• The core team for the labels assessment should include those people in your unit who are involved in the creation and use of labels: nurse, clerical support, pharmacist, other support personnel.
• The core team for the displays assessment should include those people who set up and use device displays: nurse, respiratory technician, biomedical engineer.
• Ad hoc members: physician, nurse educator, administrative leader, purchasing representative.

Responses
Grade your assessment under each question using this scale. Your responses will not be evaluated but rather used by you to help plan and direct necessary changes to improve patient safety. Each question has subpoints to guide your assessment.

A. This characteristic is adequate at this time.
B. This characteristic is being modified or changed.
C. This characteristic requires further investigation.
D. This characteristic is not adequate.

For each of the questions note if there have been any incidents or near misses in your unit related to the question topic.
Record notes while on the walk-through.

HUMAN FACTORS CHECKLIST: LABELS AND DISPLAYS

Point-of-care ergonomics
Are processes established to ensure correct labels are applied?
• Prepared labels are accessible and well marked.
• Label printing equipment and materials are organized and marked to minimize confusion.
Grade:
Notes:
Are labels legible and readable?
• Labels follow principles for legibility and readability.
• Verify this by finding and examining labels in use.
• The conditions of use do not damage labels or otherwise interfere with readability.
• Bar code labels include readable words corresponding to the code information.
Grade:
Notes:
Are product labels unique and clearly marked?
• Labels with similar color schemes are supplemented with clear and unique markings and stored separately.
Grade:
Notes:
Are display screens on devices legible and readable?
• Devices are positioned horizontally and at right angles to the line of sight.
• The whole display screen is visible with no obstruction.
• Test the readability from angles and distances that would be encountered while providing care.
• Adjustments to display content and characteristics are consistent with human factors principles.
Grade:
Notes:
Point-of-care environment

Is there adequate ambient or task lighting available to read labels?
- Overhead room lighting is adequate when on and supplemented with task lighting if required.

*Grade:*  
*Notes:*

Are device displays illuminated with minimal glare?
- LCD panels have back lighting, or supplemental lighting is available if needed.
- Screens are set with adequate brightness and contrast; color choice matches human factors principles when possible.
- Ambient or task lighting does not produce distracting glare on screens.

*Grade:*  
*Notes:*

Individual human factors

Are staff familiar with human factors principles for message design, transmission, and receipt?
- Handmade or nonstandard labels are consistent with human factors principles.

*Grade:*  
*Notes:*

Are staff aware of their personal vision characteristics and do they make adjustments to accommodate?
- Staff know how to adjust lighting or displays if required.
- Staff know when to adjust displays to meet their visual capacity and when displays should remain standard.

*Grade:*  
*Notes:*

Team and group factors

Is there a process for communicating changes in labels or displays?
- Staff alert each other about changes they make in labeling or individual adjustments they make to displays.
- Display screen content and layout are standardized whenever possible.

*Grade:*  
*Notes:*

Are people using standard abbreviations, symbols, and color codes?
- Use of abbreviations is avoided (preferred) or standardized.
- Symbols and color are used only to supplement a message that is also provided in words.

*Grade:*  
*Notes:*

Organizational and management factors

How are labels, labeling systems, and devices with displays selected and implemented?
- Human factors principles are used as criteria in the selection process.
- Trials of labels and devices include evaluation of legibility, readability, and other human factors in consideration of error potential.
Is compliance with established procedures for labels and displays periodically reviewed?

Grade: [ ]
Notes: [ ]

REFERENCES