

values are generated, using equation (3), the stated viscosities should be corrected to the temperature at which the standards are currently measured.

vided when justified by evidence and expert opinion. Please submit comments and suggestions to Colleen E. Brennan, R.Ph. at CYB@usp.org.

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METHOD II. MEASUREMENT OF VISCOSITY USING A NONROTATIONAL RHEOMETER

Alternative, nonrotational rheometer procedures for measuring rheological properties of non-Newtonian fluids include slit rheometers, small amplitude oscillatory shear-based rheometers, and capillary breakup elongational rheometers. Equipment manufacturers generally provide detailed procedures, and these instruments and methods may be appropriate for use after users complete characterization and validation studies for both the equipment and the material under test. ^{▲USP33}

Add the following:

▲〈1066〉 PHYSICAL ENVIRONMENTS THAT PROMOTE SAFE MEDICATION USE

PURPOSE OF THIS CHAPTER

The work environment has been identified as one of the most commonly reported factors contributing to medication errors reported to the United States Pharmacopeia (USP). This chapter describes optimal physical environment guidelines that promote accurate medication use and improve the performance of persons involved in the medication use process (e.g., procurement, prescribing, transcribing, order entry, preparation, dispensing, and administration of medications) in any practice setting. The accuracy of the medication use system is the result of interactions between humans, the physical work environment, equipment employed, and procedures performed. This chapter focuses on one aspect of this system: the characteristics of the physical environment that can promote accurate medication use. Standards are provided when justified by evidence and expert opinion.

GENERAL CHAPTERS

General Information

BRIEFING

〈1066〉 **Physical Environments That Promote Safe Medication Use.** This proposed new general information chapter describes optimal physical environment guidelines that promote accurate medication use and improve the performance of persons involved in the medication use process (e.g., procurement, prescribing, transcribing, order entry, preparation, dispensing, and administration of medications) in any practice setting. This chapter focuses on one aspect of the medication use system: the characteristics of the physical environment that can promote accurate medication use. Standards are pro-

FACTORS TO CONSIDER WHEN ASSESSING PHYSICAL ENVIRONMENT NEEDS

There are five work system elements that interact and have an influence on each other, and may affect the importance of meeting the physical environment standards.

- (1) What are the characteristics of the individual performing the work (e.g., visual and hearing acuity, age, experience level, distractibility, and level of attention)? Humans vary in their responses to the physical environment. Therefore,

the ideal is to make it possible to modify the physical environment on an individual basis, so it can be adapted to match the needs of the current user in a way that will optimize the accuracy of their performance.

- (2) What tasks are performed, and what characteristics of these tasks contribute to unsafe patient care? Are there opportunities for workarounds and overrides, which may be used if the worker is pressured by excessive workload or interruptions?
- (3) What tools and technologies are used to perform the tasks, and do they affect the likelihood of medication errors? Are the tools and technologies readily understandable and available when needed? Is a bar code verification system present? Automated medication dispensing devices? Electronic medication administration records (eMAR)? Unit-dose packaging? Ready access to patient- and medication-related clinical information? Are tools and technologies user-friendly? Have they passed usability tests, and failure mode and effects analysis (FMEA)?
- (4) What aspects of the physical environment promote safety or, conversely, serve as sources of error?
- (5) What in the organization prevents or allows exposure to hazard, and what promotes or hinders patient safety?

Because of their interrelatedness, work design should consider all these elements. Whenever one work element changes, there will be implications for the other elements (10). This general chapter focuses on recommendations for the physical environment.

PHYSICAL ENVIRONMENT GUIDELINES FOR MEDICATION SAFETY ZONES

Sensory interference, such as extreme temperatures, noise, poor lighting, glare-producing surfaces, interruptions, and clutter can interfere with the work of nurses and pharmacists (40, 7, 14, 15, 16). Similarly, these physical attributes would be expected to affect the performance of other health professionals involved in the medication use process.

Methods for Assessing the Physical Environment

An illuminance meter (also referred to as a light level meter or photometer) is an instrument that consists of a photodetector and a digital or analog display that measures illuminance in lux or foot-candles (fc) (24). Illuminance meters should be recalibrated annually (25). Lighting levels should be measured in medication safety zones using point illuminance measurements. The photodetector sensor should be placed in the area where the critical medication task is performed (e.g., a work counter inspection location), with the worker standing in a normal working position when the measurement is taken (24). Measurements of medication storage areas should include light levels at the top, middle, and bottom shelves, because levels depend on the distance from the lighting source. Photometers are commercially available or management engineers may be able to provide them.

Sound level meters capable of reading from 0 to 200 decibels (dB) (A scale) should be used to measure sound levels. The meters should be calibrated prior to each use. Measurements are taken by holding the meter away from the body while standing in a working position, and pointing the meter at the source of sound.

Illumination

Proper illumination levels can improve both accuracy and efficiency of performance. Prescription filling accuracy improved significantly from 2.6% to 3.8%, when lighting levels in a busy outpatient pharmacy were increased from 450–1460 lux (45–146 fc) (7). One study found that pharmacists rating lighting levels as at least adequate detected significantly more errors (38%) when filling prescriptions (18). In addition, as visual fatigue increases over a shift, more light is needed. Pharmacists using task lights to increase illumination had a 10.7% reduction in product verification errors (18). Medication errors due to low lighting may be avoided. For example, one incident report showed that poor lighting contributed to Patient Controlled Analgesia (PCA) administration tubing that was not

screwed in tightly to the base, causing medicine to run onto the floor. This resulted in uncontrolled patient pain (23). A study of lighting in a retail pharmacy detected an error in strength and dosage form on the same prescription: dicyclomine 10-mg capsules were used to fill a prescription for 20-mg tablets. The lighting level for the shelf where the medications were stored was measured at 22 fc (16).

The recommendations described here consider the level of task visibility required, the need for speed and accuracy during medication handling, and worker comfort (27). Architects and lighting engineers can consult the Illuminating Engineering Society of North America (IESNA) reference “Lighting for Hospitals and Healthcare Facilities” for details about lighting medication areas (25). It is important to note that the illuminance levels recommended in the IESNA reference are below those listed in this standard, which are based on evidence of relationships between lighting levels and medication errors. Fluorescent cool white deluxe lamps or compact fluorescent lamps are recommended, because they have a color rendering index of 80 or more (24, 25). Fluorescent lamps also have a high efficacy, and emit more lumens per watt than incandescent lamps (25).

Task lighting is required in areas where critical visual tasks are performed. If task lighting is not available, then workers can cast shadows on the work space (25). Critical tasks include reading small print on labels and handwritten prescriptions, and inspecting medication dosage forms. Because individuals perceive lighting levels differently, adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels (e.g., unit-dose package labels) are encountered (18). Key healthcare provider work areas for which lighting levels are important are computer order entry (e.g., physicians or pharmacists), prescription filling, inspection, and counseling. Illumination levels for computer order entry areas should be at least 750 lux (75 fc), with higher levels recommended when handwritten orders are read. Lighting should be positioned so there is no glare on the computer monitor that may make it difficult to view the screen ac-

curately (37). Prescription filling areas, inspection stations (double-checking), and counseling areas should have illumination levels between 900–1500 lux (90–150 fc) (7, 16). These standards are all above the minimum of 200 lux (20 fc) for accurate reading of medication labels set by the American Society for Testing and Materials International (ASTM International). An ASTM International standard prescribes a legibility test requiring that the name and amount of the drug on the label be legible in 20 fc of light at a distance of about 20 inches (500 mm) by a person with 20/20 unaided or corrected vision (3). Lighting levels should be increased where the workforce has an average age beyond 45-years-old to optimize legibility (general recommendation for treatment of presbyopia, 26). Healthcare providers should also have a magnifying glass available for labels with very small script, and where low lighting levels are unavoidable. Using a magnification lens along with a task light reduced pharmacist product verification errors by 22% compared to a control group (18).

Key nursing work areas where lighting is important include the following: medication order review, medication selection, preparation, and administration. These tasks may take place in one or more locations on the nursing unit, such as the nursing station where patient charts are stored, the medication room, or a patient’s room. Transitional lighting is recommended for medication areas in nursing stations to avoid dark spots and bright spots next to dim areas. Luminance should enable good color rendering (color rendering index of 80 or more) to assist with proper medication checking (25). Task lighting can help achieve appropriate levels of lighting and should be included on mobile medication carts (including those used with bar code verification systems). Glare should be controlled (25).

Illumination levels for medication rooms on nursing units should be 1000 lux (100 fc) based on the complexity of the

task and the need for accuracy and speed (24). Lighting level recommendations are summarized in *Table 1*. Lighting levels can decrease by 25% over a 2-year period, so it is important

that lighting fixtures are cleaned routinely to maintain recommended luminance levels. Burned out or flickering bulbs should be promptly replaced (25).

Table 1. Lighting Level Recommendations for Healthcare Settings

Work Area	Illumination Level	
	Lux	Foot-Candle (fc)
Computer order entry (37, p. 408)	1000	100
Handwritten order processing (37, p. 408)	1000	100
Medication filling and checking (pharmacy) (7, 16)	900–1500	90–150
Patient counseling (pharmacy) (7, 16)	900–1500	90–150
Sterile compounding and preparation (7)	1000–1500	100–150
Pharmacy medication storeroom (25)	500	50
Medication preparation area, e.g., nursing station (2)	1000	100
Medication administration work area (e.g., cart surface) (2)	1000	100

Proper lighting is also essential at the point of care. Attempting to be patient- and family-friendly may run contrary to the necessary lighting conditions for safe medication administration. Administration of medication at night under low luminance to avoid disturbing the patient or family is an example of an unsafe practice. Task or spot lighting must be available, so that visual confirmation of the correct patient (reading armband), medication, and administration site is not compromised.

Interruptions and Distractions

Workplace organizers need to be aware of the impact of interruptions and distractions, so that they may design workspaces to counter their effects. Nurses frequently cite distractions and interruptions as contributing to the incidence of medication errors (43, 44, 23). Interruptions and distractions have been associated with higher prescription dispensing error rates in an ambulatory pharmacy (15). According to the

USP MEDMARX Data Report (23), distractions continue to rank high (45% range) as contributing to medication errors in hospitals and health systems.

Prevention of interruptions and distractions may be accomplished by providing staff with the ability to control their exposure to these disturbances. Workers can be allowed to adjust features of the medication safety zone to maximize their concentration, attention levels, and to optimize their performance. Individuals have different levels of distractibility, which can be measured by taking an embedded figures test (paper and pencil test), or workers can be sensitive to their own need for a distraction-free work area (15). Heightened worker awareness of the adverse impact of interruptions and distractions can help minimize problems. Workers can be trained to avoid interrupting co-workers for nonurgent reasons, while they are performing medication-related tasks. Co-workers asking for assistance were found to be the most frequent source of interruptions in a pharmacy study (15). Techniques to decrease interruptions and distractions include visual cues (such as wearing orange safety vests), physical barriers, and the use of checklists that assist attention focus or refocus (32).

Medication safety zones should be located in areas where the potential for distraction and interruption is minimized.

Sound and Noise

The Environmental Protection Agency recommends peak sound levels of 45 dB during the day and 35 dB at night (9). The World Health Organization guidelines state that background sound levels in a patient room should not exceed 35 dB (4). Ear protection is required when workers are exposed to sound levels averaging 90 dB.

The standard for sound levels in medication safety zones is set at the level of conversation, 50 dBA. This is intended to ensure that critical verbal information can be heard accurately (6). Healthcare providers should be sensitive to their individual need for quiet, depending on the task being performed, and they should have a quiet area available to promote accurate performance. Total elimination of noise is not feasible or desirable.

Noise is recognized as a serious health hazard to hospital patients, and it is also recognized as an interference with effective work performance. While most studies of the effects of noise in the work environment have been conducted in non-healthcare settings, noise levels as a contributing factor of stress for nurses is increasingly being documented. In healthcare facilities, sources of noise can range from overhead paging systems, equipment alarms, heating, ventilation, air-conditioning (HVAC) systems, plumbing, and ice machines. Noise has been cited as one obstacle to the effective performance of nurses (19). An in-depth study developed a noise map of a hospital, and found sound levels of 55 dB, which is 10 dB above EPA recommendations. Average sound levels in other hospitals have been measured between 45–68 dB, with peaks between 85–90 dB (42). A study of sound levels during shift changes measured 113 dB (11).

The following features may affect accuracy when dispensing medication: predictability; controllability (12); type of task (simple vs. complex) (5); multi-tasking; distraction due to

noise, which may mask environmental cues and the worker's internal voice, used to rehearse and recall important tasks (33, 34). Out of 58 studies, 7 showed that noise improved performance, while 29 showed that it impaired performance (17). Unpredictable but controllable sounds and noise were found in one study to improve prescription filling accuracy, contrary to previous research (14). This may indicate that some environmental stimuli are needed to maintain proper alertness and attention of workers.

Noise and other sensory interference can be reduced by employing activities, tools, and principles developed by a number of different disciplines, including human factors, ergonomics, and engineering—many of which are already being used by some healthcare organizations. The effect of these and other design characteristics of nursing workspaces on patient outcomes and facility performance are being studied under a research project (http://www.pebbleproject.org/pebble_data.php) sponsored by The Center for Health Design, a nonprofit research and advocacy organization, and a network of 11 healthcare providers (www.pebbleproject.org/pebble_faq.php). The project reported decreases in medical errors, as well as patient transfers, nosocomial infections, patient falls, and medication usage (41). Reducing noise by installing materials that absorb sound, such as ceiling, wall materials, and carpeting, when permitted by infection control guidelines, can be accomplished at modest cost. Acoustical engineers can provide additional methods for noise reduction.

Physical Design and Organization of Work Space

Ergonomic design of the workplace environment can influence the ability of providers to utilize information and perform tasks (2). Counter height, height of supplies, and lighting changes in lower drawers and cabinets that decrease visibility of products can contribute to errors if improperly adjusted. The provision of adjustable fixtures can improve efficiency as well as safety.

Work counter clutter is an indicator of disorganization and a lack of sufficient space to perform key tasks. A study found that more dispensing errors occurred when medication storage containers were placed on shelves in a cluttered fashion (less than one inch between distinct drugs) (16). Older workers have more difficulty discriminating between different items. (29).

Medication Safety Zone

A medication safety zone is defined as a critical area where medications are prescribed, orders are entered into a computer or transcribed onto paper documents, and where medications are prepared or administered. Examples are the work surface of a medication cart on a nursing unit, any location where prescribing decisions are made, the work surface of an automated medication dispensing device, a pharmacy where prescriptions are inspected, and patient homes where medications are prepared, administered or consumed. The patient's bedside in a hospital is an important medication safety zone with unique challenges.

One medication safety zone is the medication preparation and administration area, which should be analogous to the cockpit of an airplane. Information must be readily available and user-friendly in order to increase ease of information synthesis. Access should be efficient, with materials and records readily available at the proper sites (i.e., drug information and patient specific information used to make a decision about drug administration should be near each other to support fact finding) (2). Information and components within the space are arranged according to specific principles that promote correct choices and decrease distractions when seeking information.

As described in the human factors literature (38), these principles include the following:

Importance Principle—Important components should be placed in convenient locations. This includes information systems near the medication zone so that lab results, drug information, vital signs, and pertinent patient information

are readily obtained. Information regarding equipment function and trouble-shooting is located near or on the equipment to provide a quick answer to problems.

Frequencies of Use Principle—Items that are used frequently are easily found and accessible. This prevents “workarounds,” in which alternate equipment is used as a substitute.

Function Principle—Items that are related to a function are grouped together. Examples include syringes, needles, and alcohol swabs; and IV tubing and connectors that are used in preparation of infusions. It is important to ensure that supply levels are maintained and that product expiration dates are routinely checked.

Sequence of Use Principle—Items are placed in an order that supports the sequence needed to perform the task correctly, (e.g., sterile gloves are in or with sterile dressing kits; needleless connectors are with the IV administration sets; and epidural medications and epidural supplies are all in one place).

Beside medication administration areas should follow the same design as the centralized medication safety zone. Distractions are an even greater challenge at the bedside, and measures should be taken to minimize them whenever possible. Information and supplies should follow the same principles and be placed in a noncluttered area with correct lighting. Sharps containers should be placed within easy reach and out of high-traffic areas. Each bedside should be standardized in design, so that information and supplies do not need to be relocated when moving from one patient bed to another.

The incorporation of lean operation techniques to enhance desirable, value-added activities and eliminate the undesirable, often invisible activities that result in waste in the work process, is one approach to workspace redesign (1). An efficient and effective workplace is less conducive to errors. Lean techniques to eliminate waste and save time include the following:

- *Visual Controls*: keeping work processes and indicators in view to allow everyone to understand the status of the work system at a glance.

- *Streamlined Layout*: optimizing the sequencing of work processes through facility design.
- *Point-of-Use Storage*: locating supplies, equipment, information, and procedure rules in convenient locations (31).

Simplifying and standardizing the patient-care environment and equipment decreases the cognitive load, making slips and lapses less likely to occur during routine tasks by minimizing decision and manipulation time (31). Standardization can be used for facility and room design, medical equipment (e.g., IV infusion devices), and medication areas (e.g., medication delivery and storage of patient-specific medications). Ensuring ready access to clinical information, both patient-specific and medication-related, is essential for all areas in which steps in the medication use process occur.

Medication safety-related tools and technologies, such as automated medication dispensing devices with point-of-care bar code verification and an integrated electronic medication record, can decrease or avert medication errors. Constraint and forcing functions are an effective means of reducing error, particularly for high-risk medications and situations. The simplest of these do not require technology. For example, sealing neuromuscular blockers in an intubation kit lessens the chance of a paralyzing agent being administered to a patient without a means of ventilation support. An enteral product that is physically unable to connect to an intravenous tubing luer lock connector would avert a wrong route error, even if the nurse was working in low-light conditions and initially misidentified the intended route for the tubing. (39).

The availability of medication safety technology is never a substitute for safe medication practices within a medication safety zone. Reports have warned of errors due to safety checks, such as smart infusion pump drug libraries and alarms, being routinely bypassed. (35).

DEFINITIONS

Working Conditions—Working conditions include the physical environment, workforce staffing, workflow design, personal/social factors, and organizational factors (21). The focus of this general chapter is on how the physical environment can be designed to improve safe medication use.

Physical Environment—The physical environment consists of the surroundings that can affect one or more human senses (30).

Distractions—Distractions occur when there is a continuation of work while responding to anything that diverts or disturbs attention, such as a telephone call or question from a co-worker (15, 32).

Illumination Level—The illumination level is the rate of light energy emission falling on an area as measured by a photometer with an illuminance sensor in lux or foot-candles (fc) (7) and indicates brightness. A lux is a unit of illuminance, measured in lumens per square meter (28). A foot-candle (fc) is lumens per square foot (24), and is also commonly measured by light meters. The term candela replaced foot-candle as the International System (SI) measure of luminous intensity (25), and represents one lumen per steradian (lm/st).

Color Rendering Index (CRI)—The color rendering index is an expression of how a light source affects the color appearance of objects or humans compared to how they would appear under a reference light source (25).

Interruptions—Interruptions are the cessation of productive activity before a task is completed due to an externally-imposed reason (15).

Noise and Sound—Noise is defined as an auditory stimulus that bears no informational relationship to the task at hand (8, 14). Sound is a change in volume that has some informational relationship to the task at hand (14). A quiet work environment is defined as an area where noise is absent and the worker is free from disturbance.

Physical Design and Organization of Work Space—Accuracy of medication preparation may be influenced by the amount of work space in which a worker can process one medication order at a time, with only those items involved in the process in the active work area.

Ergonomic Design—Ergonomic design refers to a work space that accommodates each individual's capacities and limitations, allowing them to work safely and efficiently (20). This includes an optimum ambient environment and adjustable furniture.

Crowding—Crowding occurs when multiple workers utilize the same work space, adversely affecting the amount of space available for each to organize, and also increasing the negative factors of distractions, interruptions and noise.

Human Factors—Human factors involve the application of information about human behavior, abilities, capacities, and limitations to the design of tools, systems, tasks, and environments that result in safe, productive, comfortable, and effective human use (37).

Constraint—Constraint is a rule stating under what conditions an action is allowed or prohibited (<http://webmm.ahrq.gov/case.aspx?caseid=93>). Constraints are used in designing procedures or tools to prevent unsafe practices.

Forcing Function—Forcing function is an aspect of a design that prevents a target action from being performed, or that allows its performance only if another specific action is performed first. Forcing functions need not involve device design. One of the first forcing functions identified in healthcare was the removal of concentrated potassium from hospital units. This was designed to eliminate the risk of inadvertent preparation of intravenous solutions with concentrated potassium, an error that has produced a small but stable numbers of deaths over the years (13).

Medication Safety Zone—The medication safety zone is a critical area where medications are prescribed, orders are entered into a computer or transcribed onto paper documents, or

where medications are prepared or administered. The characteristics of an optimal physical environment for accurate medication use will apply to medication safety zones.

Lean Production—Lean production is the increase of high-quality work output, while eliminating waste and decreasing resources, time, and errors (45).

Workaround—A plan or method to circumvent a problem (as in computer software) without eliminating it. See MERRIAM-WEBSTER ONLINE (www.Merriam-Webster.com) copyright 2005 by Merriam-Webster, Incorporated; <http://www.merriam-webster.com/dictionary/workaround>

Override—To neutralize the action of (as an automatic control). See MERRIAM-WEBSTER ONLINE (www.Merriam-Webster.com) copyright 2005 by Merriam-Webster, Incorporated; <http://www.merriam-webster.com/dictionary/override>

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