Applying the FGI Guidelines to Spaces Where Invasive vs. Noninvasive Patient Care is Delivered

Each year, the Facility Guidelines Institute (FGI) receives numerous inquiries from designers, infection preventionists, and other clinical staff looking for guidance on where patient procedures can and cannot be performed in hospitals and outpatient facilities. Although FGI continues to strengthen our standards for new construction and renovation of areas where patient care is provided, the question of where patient procedures can be performed is not one the Guidelines for Design and Construction can precisely answer, nor is the Guidelines language written with this intent.

The Guidelines requires health care organizations to perform a functional program and a safety risk assessment during the planning and design phases of every project. One of the primary objectives of conducting these owner-driven assessments is to actively engage clinicians, infection preventionists, and other care providers in the design process. The assessments challenge the project team, which includes clinical staff and designers, to consider how the built environment will support the organization’s allocation of space for invasive and non-invasive procedures. In particular, the infection control risk assessment portion of the safety risk assessment is essential to assure the new or renovated space will support infection prevention practices.

Using the Guidelines to determine design requirements for the types of procedures planned for a new or renovated space can be daunting. Depending on the procedure types, different floor/wall/ceiling surfaces, air exchange rates, and clearances as well as different locations for hand-washing or scrub stations and variable numbers of medical gas outlets may be required. To help decision-makers identify which spaces need which special physical environment features, the Guidelines provides a limited glossary definition of “invasive procedure” (see the last page) and, in the 2018 Hospital and Outpatient Guidelines documents, a table (right) that lists some basic procedures performed in examination/treatment, procedure, and operating rooms (this list is not exhaustive).

On one end of the spectrum is the operating room (OR) environment, which is classified as a “restricted area” and needs the maximum environmental control requirements. At the other end is the examination room or emergency department treatment room, where diagnoses and simple treatments are provided. Between these two room types is the procedure room, which is the space type most likely to present a conundrum to design teams and health care organization leaders—how should these rooms be classified and designed? The tricky part is determining when an OR may be required for procedures that otherwise could be safely performed in a procedure room. The 2018 table states that any procedure during which the patient will require physiological monitoring and is anticipated to require active life support must be done in an OR. “Active life support” was intended to mean that a machine is providing basic respiratory or circulatory functions (the patient is unable to either breathe and/or circulate blood on their own or unable to do so sufficiently to preclude physiologic damage). Respiratory assistance with
general anesthesia or mechanical ventilation are examples of what the Health Guidelines Revision Committee intended by “active life support.”

In the 2018 Guidelines for Design and Construction of Hospitals and Guidelines for Design and Construction of Outpatient Facilities, a new imaging room classification system was introduced to help designers and clinicians determine what room types are needed for a new imaging facility. The imaging classes correspond with the exam/treatment, procedure, and operating rooms: Class 1 imaging room for diagnostic procedures, Class 2 imaging room for diagnostic and therapeutic procedures, and Class 3 imaging rooms, which are ORs with mobile or built-in imaging equipment (the latter is defined as a hybrid OR), for invasive procedures (i.e., surgery). Like the conundrum of the procedure room described above, the distinction between
when a Class 2 and a Class 3 imaging room is needed is the most difficult to determine. The 2018 edition also includes a table (left) to help users understand the differences between these imaging room types.

While guidance is provided in the Guidelines for newly constructed procedure and Class 2 imaging rooms, the final decision must be based on a clinical assessment of procedures to be performed in the rooms and the environmental needs of the most stringent procedure that will be performed in a given space. With nearly constant advancements in non-invasive medical procedures, even the best plans may change before a new facility is occupied, so the
recommended goal is rooms designed to flex so they can support procedure types health care organizations may want to perform in them in the future.

How a space is used after occupancy is something the Guidelines cannot control. For example, a cardiac catheterization may begin as a procedure where a catheter is inserted into an artery or a vein in the groin, neck, or arm and threaded through blood vessels to the heart. However, in some instances, the procedure may be converted to a surgery in which closure of holes in the heart, repair or replacement of heart valves, balloon valvuloplasty, or other invasive procedures are performed. As the invasiveness of the procedure increases, so do the infection control requirements of the Guidelines. A room designed for one level of procedure that is used for a more invasive procedure is no longer the safest environment for patients or staff. Thus, a health care organization should assess how often their cardiac cath procedures turn into open heart surgery to determine how many Class 2 and Class 3 imaging rooms are needed.

A reminder: Keep in mind that the FGI Guidelines requirements are developed and adopted for use on new construction or major renovations of hospitals, outpatient facilities, and residential health, care, and support facilities. They are not intended to be applied retroactively or used to evaluate whether an existing space is appropriate for the procedures being performed in it. These decisions are the responsibility of the health care organization and the enforcing authority(ies). FGI will continue to work with national associations, authorities having jurisdiction, health care organizations, and the design community to provide the best guidance we can for specifying elements of the built environment for safe patient care.

Further Information
Should you wish to delve deeper into how to determine whether a facility needs a procedure room or an operating room or a Class 2 or Class 3 imaging room, FGI has produced a series of continuing education webinars (offered through MADCAD), two of which explore this issue in greater depth. For more information, visit www.fgiguidelines.org or fgi.madcad.com/webinars. To sign up for access, please visit fgi.madcad.com.

The tables in this article are excerpted from the 2018 FGI Guidelines for Design and Construction of Hospitals. The same tables also appear in the 2018 FGI Guidelines for Design and Construction of Outpatient Facilities as Table 2.1-5 (Examination/Treatment, Procedure, and Operating Room Classification) and Table 2.1-6 (Classification of Room Types for Imaging Services). An error in the tables has been corrected on the errata sheet for each document; download current errata sheets from this page on the FGI website.

2018 FGI Guidelines glossary definition of invasive procedure: A procedure that is performed in an aseptic surgical field and penetrates the protective surfaces of a patient’s body (e.g., subcutaneous tissue, mucous membranes, cornea). An invasive procedure may fall into one or more of the following categories:

- Requires entry into or opening of a sterile body cavity (i.e., cranium, chest, abdomen, pelvis, joint spaces)
- Involves insertion of an indwelling foreign body
- Includes excision and grafting of burns that cover more than 20 percent of total body area
• Does not begin as an open procedure but has a recognized measurable risk of requiring conversion to an open procedure

Note: Invasive procedures are performed in locations suitable to the technical requirements of the procedure with consideration of infection control and anesthetic risks and goals. Accepted standards of patient care are used to determine where an invasive procedure is performed. “Invasive procedure” is a broad term commonly used to describe procedures ranging from a simple injection to a major surgical procedure. For the purposes of this document, the term is limited to the above description. The intent is to differentiate those procedures that carry a high risk of infection, either by exposure of a usually sterile body cavity to the external environment or by implantation of a foreign object(s) into a normally sterile site. Procedures performed through orifices normally colonized with bacteria and percutaneous procedures that do not involve an incision deeper than skin would not be included in this definition.

*An error in the procedure room “use” description in Table 2.2-1 was corrected on the 2018 Hospital Guidelines and Outpatient Guidelines errata sheets on September 13, 2019. The corrected table was added to this guidance sheet on October 24, 2019.