Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) on the use of endoscopy simulators for training and assessing skill

The PIVI (Preservation and Incorporation of Valuable endoscopic Innovations) initiative is an American Society for Gastrointestinal Endoscopy (ASGE) program whose objectives are to identify important clinical questions related to endoscopy and to establish a priori diagnostic and/or therapeutic thresholds for endoscopic technologies designed to resolve these clinical questions.

Additionally, PIVIs may also outline the data and/or the research study design required for proving that an established threshold is met. Once endoscopic technologies meet an established PIVI threshold, those technologies are appropriate to incorporate into clinical practice, presuming the appropriate training in that endoscopic technology has been achieved. The ASGE encourages and supports the appropriate use of technologies that meet its established PIVI thresholds.

The PIVI initiative was developed primarily to direct endoscopic technology development toward resolving important clinical issues in endoscopy. The PIVI initiative is also designed to minimize the possibility that potentially valuable innovations are prematurely abandoned due to lack of use and to avoid widespread use of an endoscopic technology before clinical studies documenting their effectiveness have been performed. The following document, or PIVI, is one of a series of statements defining the diagnostic or therapeutic threshold that must be met for a technique or device to become considered appropriate for incorporation into clinical practice. It is also meant to serve as a guide for researchers or those seeking to develop technologies that are designed to improve digestive health outcomes.

An ad hoc committee under the auspices of the existing ASGE Technology and Standards of Practice Committees Chairs develops PIVIs. An expert in the subject area chairs the PIVI, with additional committee members chosen for their individual expertise. In preparing this document, evidence-based methodology was used, with a MEDLINE and PubMed literature search to identify pertinent clinical studies on the topic. PIVIs are ultimately submitted to the ASGE Governing Board for approval, as is done for all Technology and Standards of Practice documents.

This document is provided solely for educational and informational purposes and to support incorporating these endoscopic technologies into clinical practice. It should not be construed as establishing a legal standard of care.

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GENERAL CLINICAL AREA OF THIS PIVI AND BACKGROUND

This PIVI reviews the current literature on simulator use in endoscopy and assesses what data are required to support a wider adoption of their use for endoscopy training and skills assessment. Specifically, the following two questions are considered:

1. How much benefit must be demonstrated from the use of simulators to justify widespread adoption into standard endoscopy training?
2. How reliable do simulator-based assessments need to be as a predictor of patient-based skills to justify their use in credentialing and recredentialing for endoscopy?

Training

Since the early days of flexible endoscopy, educators have recognized the potential for simulators to enhance the training of students to gain proficiency. What began with crude static models to provide familiarity with basic dials and endoscope handling has evolved in the past 15 years into a wide array of ex vivo animal tissue and computer virtual-reality simulators. The development and capabilities have been well chronicled in the literature, as have many efforts to demonstrate their usefulness, particularly in the area of training.[1,2]

The theoretical benefits of simulator training are intuitive. They can provide a student with a relaxed opportunity for repetitive practice of skills including those that might not be encountered with sufficient frequency during the course of a standard training program. Improving basic skills before actual patient experience could result in reduced patient discomfort.[3,4] For certain higher risk procedures such as ERCP, there is the potential for reducing risk to patients undergoing procedures in which novices are participating. Manpower limitations of available endo-

scopic educators or cost considerations of the increased time that trainers must spend away from their clinical duties would support the use of simulation tools that might either shorten the learning curve or allow students to do more of their instruction independently.

Although the use of simulators has become much more widespread, particularly via the use of ex vivo–based hands-on training courses by the ASGE at its national training facility at the Interactive Training and Technology Center in Oak Brook, Illinois, and at many regional courses throughout the world, there is no consensus to date on just how much of a role they should play in standard training.

The question of how good simulators need to be to warrant their use depends on many variables. It begins with a consideration of what are the unmet needs that simulator use might address and a thorough review of their current capabilities. Comparisons of the efficacy of simulator-based education with standard methods alone can only be made after learning curves are established for standard instruction, by using objective measures that encompass technical and cognitive skill components of a particular procedure. Ultimately, the decision about whether to incorporate these technologies into a training program must rely on data regarding the magnitude of training benefits, any cost savings resulting from accelerated learning, the initial and ongoing expenses associated with the simulator work, and the local needs of the institution.

Assessing skill

The endpoint of endoscopic training is the acquisition of competency to perform procedures independently. Professional societies charged with educating future endoscopists, and the public at large, have a vested interest in ensuring that the individuals credentialed to perform endoscopy are able to provide high-quality care. Key to this need for quality assurance is the impetus to move from subjective assessments of trainees' skill to more objective and validated means of doing so before they are credentialed.

Much effort has been devoted, and much more is still required, to define which specific skills are required to become competent in each procedure, to determine minimal standards of proficiency, and to devise ways to objectively assess whether an individual has met that threshold.

Controversy over what constitutes sufficient training for a particular procedure and how many procedures trainees require to perform with supervision can be resolved if there emerges the following two items:

1. A consensus as to what minimum level of clinical performance constitutes competence to perform the procedure independently in the community. Presumably this would derive from benchmarking data about clinical performance of the particular procedure by practicing endoscopists.
2. An assessment tool that can measure a trainees' skill and reliably predict whether the individual is able to perform procedures at that minimal level of acceptable competency defined above.

Recently, investigators validated such a tool for measuring trainee performance in colonoscopy on actual cases and, from this, defined minimal competency benchmarks.[5] The development of a simulator-based assessment tool that could similarly reliably predict competent performance would be of enormous value. It would allow an unbiased and reproducible measure for credentialing purposes and ensure patients that the individuals performing their endoscopy, regardless of specialty, have been trained to sufficient standards of quality.

THRESHOLDS RECOMMENDED FOR THIS PIVI

Threshold for incorporation of a simulator into training

For an endoscopy simulator to be integrated into the standard instruction for a procedure, it must demonstrate a 25% or greater reduction in the median number of clinical cases required for the trainees to achieve the minimal competence parameters for that procedure.

The principal way in which simulators can have a meaningful impact on training would be for them to lead to a significant acceleration of the learning curve to the achievement of competence.[6-8] For colonoscopy, current simulators have demonstrated a benefit in skill acquisition for the first 20 to 80 cases performed by novices but *no reduction* in the median number of cases required to achieve technical and cognitive competency.[3,9] With improved realism of models and perhaps more rigorous simulator experience, the consensus of the PIVI committee was that some modest impact on the learning curve could realistically be achievable. A threshold was chosen that was thought to be both theoretically attainable and also sufficiently high to justify the expense and effort involved in purchasing simulators and incorporating them into the training program. This panel opined that given the expense and effort involved, a reduction in training times or procedure numbers of at least 25% would be required. A more modest 10% benefit was felt to be insufficient to justify the investment in simulation devices by training programs and, based on the results from the existing literature, a 50% reduction in training times/number of cases was thought to be unattainable by any simulator in the near future. Although a reduction in the learning curve of more than 25% is desirable, given both the data on current models and the anticipated expense required to develop simulators that could produce a greater impact on the rate of skill acquisition, current expert consensus arrived at the threshold of 25%.