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WHITE PAPER

ASGE EndoVators Summit: simulators and the future of endoscopic training

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Interest in the use of simulation for acquiring, maintaining, and assessing skills in GI endoscopy has grown over the past decade, as evidenced by recent American Society for Gastrointestinal Endoscopy (ASGE) guidelines encouraging the use of endoscopy simulation training and its incorporation into training standards by a key accreditation organization. An EndoVators Summit, partially supported by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health, (NIH) was held at the ASGE Institute for Training and Technology from November 19 to 20, 2017. The summit brought together over 70 thought leaders in simulation research and simulator development and key decision makers from industry. Proceedings opened with a historical review of the role of simulation in medicine and an outline of priority areas related to the emerging role of simulation training within medicine broadly. Subsequent sessions addressed the summit's purposes: to review the current state of endoscopy simulation and the role it could play in endoscopic training, to define the role and value of simulators in the future of endoscopic training and to reach consensus regarding priority areas for simulation-related education and research and simulator development. This white paper provides an overview of the central points raised by presenters, synthesizes the discussions on the key issues under consideration, and outlines actionable items and/or areas of consensus reached by summit participants and society leadership pertinent to each session. The goal was to provide a working roadmap for the developers of simulators, the investigators who strive to define the optimal use of endoscopy-related simulation and assess its impact on educational outcomes and health care quality, and the educators who seek to enhance integration of simulation into training and practice. (Gastrointest Endosc 2019;90:13-26.)

Interest has grown steadily over the past decade in the use of simulation for acquiring, maintaining, and assessing skills in GI endoscopy.[1-4] Recent guidelines from endoscopy-focused organizations, such as the American Society for Gastrointestinal Endoscopy (ASGE),[5] have encouraged the use of endoscopy simulation training, and it is now mandated during training by accreditation organizations in certain jurisdictions, such as the Accreditation Council for Graduate Medical Education (ACGME) United States.[6,7]

On November 19 and 20, 2017, the ASGE hosted an EndoVators Summit, partially supported by a grant from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) at the ASGE Institute for Training and Technology in Downers Grove, Illinois. The purpose of the summit was to define the role and value of simulators in the future of endoscopic training and to reach consensus regarding priority areas for simulation-related education and research and simulator development. Over 70 thought leaders in simulation research, simulator development, and endoscopic education and training and key decision makers from industry gathered to review the current state of endoscopic simulation and the role it could play in endoscopic training.

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A representative from the NIH (D.K.A.) opened the proceedings with a historical review of the role of simulation in medicine and an outline of priority areas related to the emerging role of simulation training within medicine broadly. He addressed the potential value of simulation for training, maintenance of endoscopic skills, and certification and remediation of both trainees and practicing endoscopists. The following take-home messages were emphasized to the summit participants: (1) Although simulation is useful in helping trainees acquire skills, it may also provide value for practicing specialists in the prevention of skill decay and in learning new endoscopic skills, utilization of new technologies, and in managing clinically rare adverse events; (2) Applications of simulation that might improve clinical outcomes and reduce adverse events are of paramount interest; (3) More information is needed on the processes of acquiring new skills within practice and on preventing skill decay; (4) Simulation research priorities include advancing patient safety, enhancing the quality of health care, and establishing the most effective methods for skill acquisition and maintenance by skilled practitioners.

After these remarks, the summit program was organized into 2 sessions, with each session comprising 3 to 4 lectures from domain experts. The sessions were as follows: (1) current status of endoscopic training and (2) simulation and endoscopy.

Subsequent breakout sessions with faculty and attendees were held to collectively discuss central issues pertaining to the incorporation of simulation into a standardized endoscopic training curriculum, development of simulators for advanced endoscopic skills, and the needs of industry for simulation training in new technology.

This white paper provides an overview of the central points raised by the presenters, synthesizes discussions on the key issues under consideration, and outlines actionable items and/or areas of consensus reached by summit participants and society leadership pertinent to each session. The goal is to provide a working roadmap for the developers of simulators, the investigators who strive to define the optimal use of endoscopy-related simulation, and assess its impact on educational outcomes and health care quality, and the educators who seek to enhance integration of simulation into training and practice.

SESSION 1: CURRENT STATUS OF ENDOSCOPY TRAINING

Lecture 1A: Current methods of endoscopy skill acquisition

For novices and experienced endoscopists alike, learning to perform an endoscopic procedure or technique requires acquisition of cognitive (knowledge and recognition), technical (psychomotor), and non-technical (expertise and behavior) skills.[8] Cognitive skills encompass knowledge and the application of endoscopically derived information to clinical practice.[8-10] Technical skills are the psychomotor activities required to carry out a procedure, such as torque steering.[8-10] Non-technical skills, also known as *integrative competencies*, include core skills such as teamwork, leadership, communication, professionalism, and decision making that "allow individuals to integrate their knowledge and technical expertise to function effectively within a healthcare team, adapt to varied contexts, tolerate uncertainty, and ultimately provide safe and effective patient care."[8] Non-technical skills also include safety-related competencies such as knowing when not to proceed, when to call for help, and crisis management skills. An explicit understanding of the competencies required for performance of high-quality endoscopic procedures and techniques is essential to the development of a framework for endoscopy training and assessment. Cognitive and non-technical skills often are underemphasized early in the training process, although these are critically important attributes of a competent endoscopist.

Acquisition of endoscopy-related skill is achieved through a process of deliberative practice. Deliberative practice is the systematic and purposeful repetitive performance of desired skills, coupled with rigorous skills assessment and specific formative feedback that informs further practice, with the ultimate goal of achieving expert-level performance.[11] Repetition and feedback have been identified as the 2 most important features of effective simulation-based learning.[12] The predominant teaching strategy of endoscopy instructors remains direct demonstration of a technique by the instructor, with subsequent practice by the trainee and real-time performance feedback. Formative periodic skills assessments can identify areas that require further practice. Didactic materials including lectures, courses, endoscopic atlases, journals, and videos are increasingly available online and are widely integrated into current training. To date, most of these didactic teaching strategies make very limited use of embedded assessments or other interactive learning opportunities. Less-common teaching strategies include practice regarding troubleshooting unexpected challenges, demonstration of mistakes and improper technique as counter examples, and opportunities for trainees to learn by teaching. Another underappreciated educational method involves tracking educational and clinical outcome data to guide where more training is needed. This is particularly germane to practicing endoscopists interested in maintaining their skills or learning new techniques.

The setting of endoscopy education today largely remains the endoscopy unit, where trainees practice on real patients under the guidance of an experienced preceptor. Concerns regarding patient safety and training efficiency have prompted by the endoscopy community to reconsider this training model. Simulation-based education offers an alternative and complementary approach to current training models. Simulation can provide a lifelike environment to train and assess endoscopic skills. As an instructional strategy, simulation can be used to replace or amplify real experiences with guided experiences that replicate aspects of the real world in an interactive fashion.[13] Simulation should be grounded in sound educational theory and provide an experiential learning opportunity in which learners can engage in deliberate practice to improve performance. The rationale for using simulation should be based on evidence with regard to the potential benefits for learners, preceptors, and the quality of care; these benefits should outweigh associated costs.[5]

Research and development priorities. (1) Investigate the effectiveness of various simulation-based educational strategies and models for cognitive, technical, and non-technical skills acquisition to understand the optimal use of simulation for teaching various specific skills related to endoscopy. (2) Develop guidelines for specific endoscopic procedures that outline best practices regarding integration and use of simulation throughout training to facilitate adoption by training programs.

Lecture 1B: Unmet needs of endoscopy training

This lecture detailed unmet needs in endoscopic training and the role of simulation in addressing them. These include improvement in cognitive skills such as training in sedation and recognition of pathology. Simulation also can improve technical skills, shorten learning curves, and accelerate skills acquisition. In particular, it offers an educational platform to assist kinesthetic learners who learn best through hands-on practice. For those who have completed fellowship and/or residency training, simulation may enhance skill maintenance and training in new techniques as well as remedial training. Simulation also may provide a more objective approach to competency-based training. Finally, simulators may be useful in the training of endoscopy trainers. With regard to simulation, the hierarchy of validity evidence, including face, content, construct, and predictive validity[14] was reviewed, and the need for predictive validity evidence for any simulation training curricula or assessment tool was emphasized.

Simulation is particularly useful for training in areas that are encountered infrequently during clinical training. The rising use of anesthetist-provided sedation will negatively impact endoscopic trainees' experiences in performing before-sedation assessments and in providing conscious sedation and after-sedation care. Similarly, there are limited opportunities during training for identifying, describing, and managing low-frequency lesions (eg, early gastric cancer, nodules in Barrett's esophagus, focal flat colon dysplasia in patients with inflammatory bowel disease). Simulation-based learning modules that focus on lesion recognition, description, and/or classification as well as on management decision-making skills, and that offer self-assessment and feedback may facilitate acquisition of these essential skills.

With the adoption of a competency-based model for postgraduate education, gastroenterology training programs are obliged to ensure that trainees are competent to perform high-quality endoscopic procedures independently at completion of training.[15] Great strides have been made in recent years in the development of direct observational skills assessment tools with strong validity evidence for endoscopic procedures including colonoscopy,[8,16-23] ERCP and EUS.[24] However, there remains a need to develop parallel simulation-based skills assessments with strong predictive validity evidence and that correlate with existing quality metrics. Potential advantages of simulation-based assessments include their objective nature and the ability to test performance for procedures that are performed infrequently or those that are associated with increased risk of adverse outcomes, such as ERCP, polypectomy for large or flat polyps, and hemostasis. There also remains a need for the development of metrics and assessment tools for many common therapeutic techniques such as endoscopic bariatric therapies and ablation of Barrett's esophagus. Furthermore, a feasible data collection platform is required to facilitate widespread implementation of common assessment tools and metrics across training programs, and to collect longitudinal aggregate assessment data. This will support competency-based education by enabling determination of specific milestones for endoscopists at varying training levels and facilitating comparison of trainees across programs.[8] Additionally, it will enable long-term outcome studies assessing the impact of simulation training.

For more advanced trainees and practicing endoscopists, there is a need for the development and validation of simulators to accelerate learning of more complex procedures (eg, ERCP and EUS) and emerging procedures (eg, bariatrics, peroral endoscopic myotomy) and techniques (eg, mucosal resection and pseudocyst drainage). Additionally, there is a need for improved realism of existing computerized modules, including improved haptic capability to ensure a more realistic learner experience, and for incorporation of more troubleshooting scenarios and complex cases to increase relevance to the skilled practitioner.

In terms of unmet needs, the best use of resources for simulator development and deployment will be for emerging procedures and techniques and for those procedures in which clinical experience and teaching least prepare trainees for competent endoscopic practice, such as cannulation of native papillae in ERCP and complex polypectomy skills. There are a few therapeutic endoscopic techniques for which data exist linking outcomes to ongoing experience levels. For example, Freeman et al[25] showed that individuals performing fewer than 50 sphincterotomies per year have a higher rate of after-sphincterotomy bleeding. However, data regarding other procedures and techniques (eg, hemostasis) are lacking and require further study.

For many new devices, both the training models and curricula are developed by the device manufacturers themselves, in some cases, under U.S. Food and Drug Administration direction. Collaboration with professional societies represents an opportunity to help guide development of the educational content, simulator models, and assessment metrics and subsequent validation of such training modules to ensure safe and effective adoption.

Remediation programs for practicing endoscopists such as those with low adenoma detection rates have been shown to be effective.[26] Simulation training targeting upskilling and remediation for practicing physicians who fail to meet benchmark quality standards is, therefore, a desirable area for development. Further exploration of other target areas for upskilling and remediation of practicing endoscopists and examination of how simulation can best be incorporated into remediation and upskilling programs are required.

Another issue in the field of simulation relates to access and cost. Simulation will not have widespread impact unless it is accessible. Delivery of cognitive training tools via mobile telephone applications or via online modules appears to be a promising and cost-effective area to pursue. Additionally, summit attendees agreed on the need for further development and proliferation of inexpensive portable simulators to teach and assess simple deconstructed skills to trainees, and that can be integrated in a thoughtful and deliberate manner throughout training. Further, they supported the need for development and validation of short, feasible, mobile, simulation-based learning modules targeting specific skills to promote uptake of simulation across endoscopy units and training programs. Research demonstrating the long-term impact and value of this model of training for training programs and practitioners is also important to justify the financial investment in simulation.

Research and development priorities. (1) Development of simulators for more complex and higher-risk procedures, less frequently encountered therapeutic interventions, and newly introduced procedures. (2) Development and validation of simulation-based curricula targeting skill maintenance and remediation of skill for practicing endoscopists. (3) Development of low-cost, portable simulators, feasible for widespread distribution and use along with development and validation of mobile simulation-based learning modules to facilitate local access and promote uptake of simulation across endoscopy units and training programs.

Lecture 1C: Assessing competency and the potential role of simulators

The need to replace currently used subjective global assessments with more objective skills assessments is now widely accepted. However, skills assessment tools with strong validity evidence that are predictive of performance on real patients are available only for certain procedures. Direct observational assessment tools have been developed to allow proctors to rate key cognitive, technical, and non-technical aspects of procedures by using previously defined criteria. These include the ASGE Assessment of Competency (ACE) in Endoscopy for EGD and colonoscopy,[16,17] the Gastrointestinal Endoscopy Competency Assessment Tool (GiECAT)[18-20,23] and the Mayo Colonoscopy Skills Assessment Tool (MCSAT)[21,22] for colonoscopy, The EUS and ERCP Skills Assessment Tool (TEESAT) for EUS and ERCP,[24] and the Direct Observation of Procedure Skill (DOPS) tools[27] that are used in the United Kingdom and are now available for EGD, colonoscopy, flexible sigmoidoscopy, ERCP, EUS, polypectomy, hemostasis, PEG, dilation, and stenting.[27] These structured, direct observational assessment tools can be used in the clinical setting to monitor the learning curves of trainees to assess competence. They provide a framework for teaching, help trainers identify specific deficiencies, and facilitate provision of detailed performance-enhancing feedback.[8] Research examining use of such tools for simulation-based training is limited.

It is well-known that assessment of skills or outcomes can be used to guide teaching and learning. To realize the potential of using simulation-based assessments in clinical practice, several factors need to be in place. The most critical of these is the goal of developing simulation-based assessments that predict high-quality patient care. To accomplish this, it is necessary to ensure that the assessments developed measure the right variables—those tied to the clinical outcome metrics that are capable of being tracked during real procedures subsequent to the training and simulation-based assessment. Benchmarking data about these clinical performance metrics are needed to go beyond skills assessment alone, to measuring competency. This presentation emphasized the important distinction between assessment of skills and of competency. ASGE's Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) document recommended that simulator-based assessment tools should be procedure-specific and predictive of independently defined minimal competence parameters from real procedures with a kappa value of at least 0.70 for high-stakes assessment.[5] Of course, a simulation-based assessment can have more immediate application as a formative assessment tool before such predictive validity allows its adoption in competency-based summative assessment. Ideally, assessment should be incorporated throughout the endoscopy learning cycle, in a thoughtful manner, from training to accreditation to independent practice to help ensure integration of teaching, learning, feedback, and assessment.[8]

Assessment using simulation is appealing because it offers a proxy for clinical encounters and permits objective, reproducible and standardized assessments at the "does" level of Miller's pyramid.[28] At present, there are a number of direct observation assessment tools with strong validity evidence for use within the clinical setting for several endoscopic procedures, as described earlier. However, there is little validity evidence to support the use of such tools to measure performance on a simulator. Additionally, there is limited validity evidence for simulation-based assessment of endoscopic skills, and no simulation-based assessment currently meets the PIVI criteria for a skills assessment tool.[5] Current simulation-based assessments include performance metrics and motion analysis. Research evaluating the validity evidence of computer simulator-derived metrics (eg, visualization, patient discomfort) has yet to demonstrate that these metrics can discriminate meaningfully between endoscopists across all levels of skill,[16,29-40] and 2 moderate-quality studies indicate that these metrics do not correlate with blinded expert-based assessments of performance.[41,42] Performance metrics derived from tasks performed on mechanical part-task endoscopic simulators (eg, accuracy, time) are also being evaluated as a measure of technical skills.[43] However, further validity evidence is required before they are adopted broadly. Assessments based on motion analysis objectively quantify performance by using information derived from motion tracking devices that measure movements of the endoscope and/or the endoscopist (eg, path length, number of movements).[44] Research on motion analysis as an assessment tool within the simulated setting is limited,[45-49] and further validity evidence of this technology and resultant metrics is required.

There is need for the development of simulators with improved haptics capability to ensure a more credible operator experience and for incorporation of more complex and difficult simulated cases to help better discriminate skill levels. These developments may allow simulation-based assessments that are predictive of clinical outcomes. A limitation of current simulation-based assessments is their focus on technical skills. Incorporation of assessments targeting lesion recognition and management decision skills are needed as well as assessments targeting other endoscopic non-technical skills such as situation awareness.

A promising target for improved simulation-based assessment is for high-stakes and lower-volume procedures, because these can be integrated into intensive hands-on curricula to ensure learners are meeting progressive milestones during training. They can be used in a summative manner at the end of training to ensure minimal competence before endoscopists perform procedures on patients.

The ASGE Skills, Training, Assessment, and Reinforcement (STAR) program for practicing endoscopists was described as a paradigm of how such performance assessments can be created and applied in the context of a minimum curriculum that fully incorporates simulation for both training and assessment. The STAR program was created to enhance practicing endoscopists' skills at therapeutic endoscopy in a particular area of interest such as EMR or endoscopic suturing. The curriculum for each program features a blended learning format combining online, before-course, evidence-based, didactic materials and a weekend of live hands-on simulation-based training by using ex vivo models. Attendees underwent written testing of the before-course didactic materials and the cognitive and non-technical aspects of the procedure taught during the in-person course. Additionally, a performance assessment on the ex vivo model is conducted at the end of each course, during which learners must demonstrate technical aspects of the skill of interest. If successful, learners receive a certificate of completion. The assessments used are performance assessments and not tests of competency. To evolve into the latter designation, they would need to be coupled with subsequent outcome data from clinical practice following the course.

The STAR program represents a good example of thoughtful integration of assessment into an endoscopy curriculum. However, there remains a need for long-term outcome studies assessing the impact of such programs, which are developed for non-trainee learners, regarding the safety, quality, and outcome of care. It is also unknown what potential role proctoring and/or telephone mentoring could play in helping translate learned skills to the clinical environment. Currently, there is limited evidence regarding the effectiveness of simulation-based education programs for practicing endoscopists learning new techniques, upskilling, remediating skills that have been demonstrated to fall below accepted quality standards, or maintaining seldom-used skills. Such evidence is important to help define the value of simulation for practicing endoscopists, to guide its integration into practice, and to enhance acceptance of simulation among practicing endoscopists. It is also essential for credentialing bodies who are tasked with ensuring that individuals are qualified to perform procedures independently within the clinical environment.

Research and development priorities. (1) Investigate the feasibility and implications of building on competency-based assessment to develop a certification process that would require an audit and possibly proctoring of real procedures. (2) Explore the practice gaps related to the acquisition and maintenance of skills by practicing endoscopists to identify targets for simulation training. (3) Explore barriers to simulation adoption among practicing endoscopists as well as methods to incentivize, recognize, and reward such adoption. (4) Examine which training and mentoring strategies best achieve success among practicing endoscopists.

SESSION 2: SIMULATION AND ENDOSCOPY

Lecture 2A: Existing simulators, strengths, and limitations

The use of simulation to teach GI endoscopy dates back to the 1960s.[50] Currently, there are numerous endoscopic simulation models, with wide variations in adaptability, availability, and cost.[51,52] The ASGE Technology Committee has published a detailed review of commercially available endoscopic simulators that appears in this issue of *Gastrointestinal Endoscopy*.[51] Despite the shift toward simulation training and the potential benefits of simulation,[1,3,4] a 2014 survey revealed that less than half of adult gastroenterology programs in the United States use simulation, and it is mandated in only 15% of programs.[53]

There are 5 types of currently available endoscopic simulators: (1) inanimate static models or mechanical simulators, (2) computer-generated (virtual reality) models, (3) ex vivo (explanted organ) animal models, (4) in vivo (live) animal models, and (5) hybrid simulations.[51,52] Each training model has its advantages and disadvantages and is best suited for training and/or assessing specific tasks and levels of learners. Educational goals should guide decisions regarding which simulator to use for training and assessment. Particular simulators, such as virtual reality computer-generated models and live animal models, are useful for training across all endoscopic procedures.[1] Additionally, computerized simulators are able to provide objective performance metrics that can be used for assessment and feedback, although the validity evidence for currently available simulator-generated metrics is poor.[16,29-40,54,55] Education in basic endoscopic procedure elements (part-tasks) such as endoscope handling, retroflexion, and torque steering can be delivered by using simple and less expensive inanimate part-task trainers.[56,57] Gaining familiarity with the endoscope and learning a procedure at the same time creates an increased cognitive workload and slows skills acquisition.[58] Before doing procedures on humans, trainees performing on a mechanical simulator until a certain level of proficiency is achieved may shorten the learning curve and improve patient safety. Part-task simulators (including mechanical and ex vivo models) are useful in teaching and/or reinforcing certain skills sets or components of a procedure, such as polypectomy or bleeding control, because they deconstruct the skills set, allowing the learner to focus on the task at hand.[59] Furthermore, performance metrics derived from tasks performed on part-task endoscopic simulators (eg, precision, speed) are showing promise as a means to assess fundamental endoscopic technical skills.[57,60] Finally, more complex clinical events and behaviors, such as teamwork, benefit from use of more sophisticated hybrid simulations that use inanimate or computerized simulators, in conjunction with simulated patients and endoscopy team members.[61]

Current simulators are limited in their ability to train and assess cognitive and non-technical skills. Furthermore, these aspects of endoscopic competence often are underemphasized during simulation training in favor of practicing technical maneuvers. Practice in basic lesion recognition is possible on a number of the currently available computer simulators, although training and assessment of lesion recognition and management decision-making skills are not automated, and lessons must be instructor-driven. Similarly, for ex vivo simulators, trainers can incorporate a myriad of detail regarding accessory use, electrosurgical generator settings, and component steps for complex techniques into hands-on demonstration, practice, and assessment. Current simulators also are limited in their ability to impart exposure to varied pathology and varied manifestations of common findings, and in the detection of lesions in difficult-to-visualize locations. Non-technical skills training is discussed in Section 2C.

In deciding which simulator to use for a given training goal or stage of training (eg, preclinical, trainees, practicing endoscopists, and advanced training), one should consider both the capabilities of the simulator and of the training program that will be used to support the model. Simulators can be used to teach and/or reinforce multiple training tasks, depending on how they are integrated within a curriculum. Ultimately, the choice of simulator must reflect the desired educational goals and the available educational and financial resources.

Research and development priorities. (1) Development of new simulators with strong validity evidence that are capable of discriminating between endoscopists with small differences in skill and that correlate closely with competence in performing live endoscopy procedures in a reproducible, accurate, and reliable manner, preferably with a kappa of 0.7 or higher.[5,62] (2) Development of comparative efficacy trials assessing long-term educational and clinical outcomes to help clarify which simulators are best for training specific procedures and/or tasks, the instructional design principles that optimize transfer of skills to the clinical setting, and the cost-effectiveness of simulation training. (3) Development of new simulation models and modules to address current unmet needs, with an emphasis on expanding the capability of simulation to impart cognitive and non-technical skills and the development of simulators for more complex procedures such as ERCP and EUS, and low-volume, high-stakes therapeutic techniques. (4) Development of simulation-based cognitive training tools to aid in the acquisition of lesion recognition and management decision-making skills (eg, capsule endoscopy, flat polyps), particularly for less frequently encountered pathology findings.

Lecture 2B: Validation of simulation in endoscopy training

Data indicate that the use of virtual reality endoscopy simulation training for novice endoscopists aimed at developing basic endoscopic skills can improve subsequent clinical performance.[1,3,4,63-67] Additionally, a simulation curriculum that incorporates mentored training and instructional feedback has been shown to provide a distinct advantage compared with self-regulated learning in the acquisition of endoscopic skills.[12,67,68] Randomized controlled trials have indicated measurable transfer of skills to the clinical environment and possible potential benefit in shortening the learning curve to competency in some circumstances such as in the early part of training. However, a reduction in the learning curve of more than 25%, as proposed in the ASGE PIVI document as a threshold for widespread adoption of their use, has yet to be demonstrated.[1,3-5,63,64] Data are sparse with regard to the impact on clinical safety and outcomes and the role of computerized simulators in teaching more advanced skills and in teaching practicing endoscopists.

Early evidence exists to support the use of mechanical part-task trainers for teaching basic skills to novice endoscopists.[3,43,57,69] Additionally, there is recent evidence supporting the integration of part-task trainers within a simulation curriculum using a progressive-learning approach, wherein simulation task complexity is progressively increased during training to closely align with participant competence.[66] There is good empiric evidence and some published evidence supporting the use of animal models (live and ex vivo) for use in teaching and assessing more advanced therapeutic skills, such as bleeding control, to both novice and advanced endoscopists.[3] No available data exist on the use of animal models for teaching basic skills. A key challenge in assessing the long-term educational and clinical benefits of simulation training is the current lack of ability to accurately and reliably collect longitudinal clinical performance data.

The usefulness of currently available virtual reality simulators in skills assessment is debatable. Most data suggest that computer generated simulator metrics cannot adequately discern between users with enough reliability or accuracy to be used as an assessment tool.[16,29-40,54,55] The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has developed a new testing scenario that uses a computerized simulator that is integrated into the board certification process for general surgery in the United States through the Fundamentals of Endoscopic Surgery (FES) program.[70] Validation data for this assessment has been limited to date, and predictive validity results are lacking. Preliminary studies suggest that scores correlate only modestly with clinical colonoscopy performance.[55,71] Research by Jirapinyo et al[57] and Thompson et al[60] examining the validity evidence of metrics derived from tasks performed on a mechanical part-task endoscopy simulator as a means to assess fundamental technical skills is promising. However, further studies are needed to establish learning curves and to correlate simulator use with improved clinical aptitude. An additional limitation of currently available metrics is their focus on technical skills.

Development of metrics with strong validity evidence would provide learning analytics to support assessment of endoscopist progress, facilitate provision of feedback, and, if automatically generated, would allow for independent training. Additionally, to determine the clinical impact of simulation training, it is essential to measure clinical "bedside" performance before and after training by using assessment metrics with strong validity evidence. Evidence of the impact of simulation on the safety and quality of care will enhance acceptance of simulation and help to facilitate its adoption, particularly by practicing endoscopists.

Research and development priorities. (1) Develop a data collection platform to enable measurement of clinical performance before and after participation in a simulation training intervention to permit evaluation of clinical impact and durability of the impact and to provide endoscopists and trainers with meaningful learning analytic data to enhance training. (2) Identify and validate simulator performance metrics that correlate with clinical outcomes and that assess not only technical skills but also cognitive and non-technical aspects of endoscopic competence. (3) Determine which metrics can be used to accurately define minimal competence to help determine whether the acquisition of competence can be accelerated by simulation training.

Lecture 2C: Simulation training of non-technical skills

Simulation can be used not only to improve competence in endoscopic technical skills but also cognitive and non-technical skills, including situation awareness and teamwork.[8,72,73] There is increasing appreciation that, in addition to technical and cognitive skills, non-technical skills play a key role in the provision of safe and effective endoscopic care. Non-technical, or integrative skills allow individuals to integrate their knowledge and technical expertise to ensure effective teamwork, communication, and adaptability, which, ultimately, contributes to enhanced patient safety.[8,23] The need to explicitly teach non-technical skills is outlined within general competency-based frameworks from accreditation bodies, such as the ACGME,[74] and is recognized as important by gastroenterology and endoscopy–focused organizations, such as the ASGE.[75] The importance of non-technical competencies has been highlighted by research in the surgical domain that has shown that well-functioning teams have fewer adverse events and are more productive.[76,77] Additionally, there is recognition that procedure-related adverse events are more likely to stem from behavioral failures, such as a communication error, as opposed to a lack of technical skill. With regard to endoscopy, the vast majority of recommendations originating from the 2004 investigation into deaths occurring within 30 days of adult therapeutic endoscopy procedures in the United Kingdom, underscored deficits in non-technical skills, such as situation awareness, rather than technical expertise. Matharoo et al[78] also found that endoscopy teams with better non-technical skills, as rated by a global rating score, had fewer safety incidents. Non-technical skills are an essential component of competent endoscopic practice and a key contributor to patient safety and clinical outcomes.

Currently, there is limited focus on training and assessment of non-technical skills within endoscopy practice.[79] *Hybrid simulation* is a term coined by Kneebone et al[61] to describe the process of attaching a simulator to a simulated patient. With regard to endoscopy, hybrid simulation involves a learner performing a procedure on an endoscopic simulator in a natural setting (ie, endoscopy suite) while interacting with an actor portraying a patient (ie, a simulated or standardized patient). Multidisciplinary team members, such as an endoscopy nurse or anesthesiologist, also can be introduced into the scenarios. In this way, aspects of non-technical skills such as role clarity, crisis management, and empathy can be taught during the simulation and discussed during the subsequent debriefing.[80] A study by Grover et al[67] supports the use of a curriculum integrating hybrid simulation as a means to improve non-technical skill acquisition in novice endoscopists and transfer of these skills to the clinical environment. A subsequent study revealed that non-technical skills acquisition is improved by applying a progressive learning strategy, wherein simulation task complexity is progressively increased during training to closely align with participant competence.[66] Additionally, a simulation-based, non-technical skills curriculum that incorporates strategies shown to be effective within the broader surgical literature, namely didactic training, use of a benchmark video, checklists, debriefing, and feedback confers benefit for non-technical skills acquisition without impacting technical or cognitive skills acquisition.[81-82] Although recent randomized controlled trials have shown that simulation-based, non-technical skills training can have an effect on early clinical performance and cost-effectiveness, and the effects on longer-term performance and clinical outcomes have not been established.

The ability to teach or coach an endoscopist is another important non-technical skill. There is increasing recognition that effective instruction is essential, and both endoscopy trainees and trainers believe that more formal instruction on how to teach endoscopy would be benficial.[67-83-84] Although research evaluating instructor training is lacking, it is increasingly recognized that, ideally, endoscopy training should be provided by individuals with the requisite skills and behaviors to teach endoscopy effectively and efficiently, including an awareness of adult education principles and best practices in procedural skills education.[85-86] Observation and experience has taught us that effective instruction is not easy or intuitive, and clinical experience is not a proxy for instructor effectiveness.[83] Endoscopy instructor courses aimed at teaching trainers essential components of an effective endoscopy training session are increasingly being implemented across jurisdictions such as Canada[87] and the United States[88] and are now mandatory for adult gastroenterology endoscopy trainers in the United Kingdom.[89-90] The World Endoscopy Organization (WEO) and the ASGE conducted an intensive 2-day program for endoscopy teachers in 2016 and have published a white paper appearing in this issue of *Gastrointestinal Endoscopy* describing key evidence-based educational principles, such as the use of performance enhancing feedback and standardized language that can be applied by trainers to enhance learning in the clinical setting.[91] Although anecdotally very effective, and there is some objective evidence to show improvement in trainer confidence and skill,[92] the short-term and long-term value and utility of these educational opportunities and their application to teaching in the simulated setting are currently unknown. Additionally, there exists a potential opportunity to integrate simulation into endoscopy *train the trainer* courses aimed at the quality and impact of endoscopy instruction. There was strong consensus among summit attendees that finding a feasible way to expand the effort to train endoscopy trainers is a high priority goal.

Research and development priorities. (1) Development and validation of an assessment tool or metrics for endoscopic non-technical skills for use within both the simulated and clinical setting to enable formative and summative assessment, aid in simulation-based debriefing and self-reflection, and facilitate research examining the effects of non-technical skills simulation–based interventions on clinical outcomes. (2) Investigation of the long-term impact of non-technical skills simulation training on patient safety and outcomes. (3) Development and evaluation of a sustainable ASGE endoscopy *train the trainer* curriculum aimed at enhancing trainer abilities regarding teaching of endoscopy. (4) Practical guidance for educators as to the optimal use of simulation for GI endoscopy trainees.

Lecture 2D: Surgical perspective on simulator training

Simulation training is part of the fabric of surgical training, both in residency and in practice. Hands-on simulation training is mandated by the ACGME during residency,[93] and it is highly encouraged as an educational platform for practicing surgeons to improve their procedure skills and acquire new proficiencies. In fact, for some new devices, the FDA mandates appropriate simulation training as part of the before-approval process.[94] Reflective of this, surgical societies and simulation centers are partnering with medical device manufacturers to develop courses that focus on teaching end-user clinicians the appropriate use of the devices, with the aim of helping practicing surgeons safely adopt new technologies.[95]

The adoption of simulation has been particularly important for training in GI endoscopy for general surgeons, given the context of limited clinical training opportunities and time constraints for surgical residents. Surgeons are important providers of endoscopic care, particularly in rural areas. In 2007 in the United States, 74% of rural surgeons performed more than 50 GI endoscopy procedures each year, with 42% of rural surgeons performing more than 200 procedures annually.[96] As such, the Society of American Gastrointestinal and Endoscopic Surgeons and the American Board of Surgery (ABS) are committed to supporting endoscopic education to ensure that surgical residents are fully trained and competent in flexible endoscopy.[70] The ABS has developed a milestone-based flexible endoscopy curriculum (FEC) for general surgery residents. This is a 5-year distributed curriculum designed to teach the fundamental knowledge and technical skills required to perform basic GI endoscopy.[6] The curriculum, which has been mandated by the ABS since July 1, 2013, incorporates hands-on simulation by using either inanimate or computer-generated models. In addition, fundamental knowledge and technical skills are assessed via a high-stakes examination by using the FES fundamentals of endoscopic surgery program.[55,97,98] The FEC program includes Web-based didactic modules, a multiple-choice question test assessing knowledge, and hands-on skills assessment by using computer-based simulation. The test components are administered at approved testing centers throughout the United States. The manual skills component of the assessment consists of 5 computer-generated simulator tasks that assess fundamental technical skills related to endoscopy. This assessment showed good test-retest reliability (intraclass correlation coefficient = 0.85), and scores correlated with endoscopy experience and performance of colonoscopy in the clinical setting as measured by unblinded assessors who used the Global Assessment of Gastrointestinal Endoscopic Skill for Colonoscopy (GAGES-C).[55,71,99,100] In addition to passing the FES, surgical residents are required to undergo clinical assessment of performance of upper and lower endoscopy by using the GAGES-C tools.[99,100]

The ABS FEC provides an example of incorporation of simulation into a milestone-based training curriculum for both formative feedback and summative assessment. However, further research is required to determine whether passing scores are a reliable and valid marker of competence in performing clinical endoscopy procedures. Notwithstanding these issues regarding predictive validity of the testing, the FEC represents an important paradigm for thoughtful construction of a comprehensive curriculum for trainees, which fully integrates simulation.

Research and development priorities. (1) Development and validation of an ASGE endoscopy skills curriculum for endoscopy trainees that incorporates simulation across the training continuum. (2) Foster partnerships with industry to help develop, validate, and support simulation training for endoscopists to learn to use new devices and technologies.

DISCUSSION

The overarching consensus at the end of the EndoVators Summit was that simulation is an important educational platform for acquiring, maintaining, and assessing skills in GI endoscopy. However, further research is required to demonstrate the long-term value of simulation and delineate best practices for its use, to ensure that its adoption is informed by evidence.

Priority needs for endoscopy trainees

Although simulation is increasingly being integrated into endoscopy training curricula, and program directors perceive it to be a valuable teaching strategy, its use is not consistent across gastroenterology training programs for a number of reasons, predominantly cost and accessability.[53] Low cost, portable simulators are needed to facilitate widespread access to simulation across training programs. An expansion of accompanying learning modules will help program directors and educators to successfully incorporate such devices into training. Additionally, simulation targeting training in areas that are infrequently encountered (eg, rare lesions) and in low volume, higher-stakes procedures will help expedite skill acquisition are promising targets for future simulation development. To help facilitate adoption and ensure successful integration of simulation-based education by training programs, further guidance is required regarding best practices on how and when to use simulation throughout training to impart technical, cognitive, and non-technical endoscopy-related skills. To help inform implementation, comparative efficacy trials assessing long-term educational and clinical outcomes are needed to help clarify which simulators are best for training specific procedures and/or tasks and the instructional design principles that optimize learning and transfer of technical, cognitive, and non-technical skill from the simulated to the clinical setting. Finally, there is a need for the development and evaluation of a sustainable endoscopy *train the trainer* curriculum to enhance trainer abilities to teach endoscopy in both the simulated and clinical setting.

Priority needs for practicing endoscopists

In 2016, the NIDDK together with the National Institute of Biomedical Imaging and Bioengineering (NIBIB) sponsored a workshop entitled "Simulation Research in Gastrointestinal and Urologic Care: Challenges and Opportunities" to examine the extent to which simulation approaches have been used by practicing clinicians caring for patients with GI and urologic diseases and to identify knowledge gaps and research needs.[101] It highlighted the need for well-designed outcomes studies to establish the role of simulation in improving the safety and quality of health care. This EndoVators Summit re-emphasized the importance of future research examining the role of simulation for practicing endoscopists, including the need to explore barriers to simulation adoption among practicing clinicians, the need to develop simulators and curricula tailored to their needs, and the requirement for research to investigate the long-term impact of simulation adoption by practicing endoscopists on the safety, quality, and outcome of their care.

The increasing recognition of preventable medical errors and focus on patient safety[102] has led health care to borrow lessons from other high-risk enterprises such as aviation and nuclear power by adopting an interest in simulation for acquiring, maintaining, and assessing skills.[103,104] Although the recognized benefits of endoscopy simulation have helped to drive its integration into training, its application for practicing endoscopists is less clear. Although practicing clinicians understand the potential value of simulation in recognizing and treating rare adverse events, in learning to use endoscopy technologies and techniques, and in the development of improved procedures, many barriers exist to its adoption. Most important is the lack of evidence that simulation adoption by practicing clinicians leads to better patient outcomes. Future research is required to delineate the value of and best practices regarding the use of simulation training for practicing endoscopists. Such research should include collection of prospective outcome data from participants in existing simulation-based educational programs. A further important area relates to evaluating the effectiveness of simulation-based educational programs for the introduction of new techniques and devices to practicing endoscopists. Namely, outcomes-based training programs that incorporate simulation in a thoughtful manner and subsequent research to demonstrate the effectiveness of such programs for new devices and technologies are required.

Priority areas for simulation development

There are a variety of currently available endoscopy simulators. Because no simulator will accomplish all tasks, the choice of simulator should be based on educational and/or assessment goals of the training program as well as on cost. Several key gaps in currently available simulator devices and technologies were highlighted at the EndoVators Summit, and needed developments are outlined in Table 1.

- Low-cost, widely available (eg, online), simulation-based cognitive learning tools to support training in lesion recognition and management decision-making skills, particularly for less frequently encountered pathological findings.
- Advances in simulators that can be used to accelerate the learning curve of more complex procedures such as EUS and ERCP, and low-volume, high-stakes therapeutic techniques.
- Low-cost, portable simulators, feasible for widespread use to facilitate uptake of simulation across endoscopy training programs.

TABLE 1. Needed developments in simulator devices and technologies

Improved visual resemblance and haptic capabilities of computerized modules
Incorporation of more complex cases to enhance the range of difficulty and increase relevance for the skilled endoscopist
Improved functional task alignment[105-106] of simulators with real-life performance (ie, similar sensory, cognitive, and/or motor processing required for the simulator as for the corresponding clinical task)
Simulator-generated performance metrics with strong validity evidence to enhance assessment capabilities and provision of feedback and increased capacity for independent practice
Improved discriminative validity, capable of distinguishing between endoscopists with small differences in skill
Inexpensive portable models to facilitate local access to simulators
Cognitive training tools targeting lesion recognition and management decision-making skills
Simulators for more complex procedures such as ERCP and EUS and low-volume, high-stakes therapeutic techniques

Priority areas for process innovation to facilitate wider uptake and improved use of simulation

Training curricula need to be created and validated in parallel to simulation development, because thoughtful integration of simulation into an overarching curriculum is known to be an essential feature of its effective use.[107] Simulation is one of several teaching strategies available to educators to help achieve learning outcomes. It is important to determine where simulation can be used most effectively within the context of a broader endoscopy curriculum by matching learning objectives to the educational method best suited to teach those objectives. Maximal learning benefit is achieved by having an organized and systematic approach to the incorporation of simulation.[12]

For endoscopy simulation, the development and validation of more robust performance metrics that assess all facets of endoscopy competence are essential both for feedback provision and to measure educational and clinical outcomes to help delineate the features of effective endoscopy simulation training. There was consensus at the summit that any effort aimed at developing competency-based training curricula and simulation-based skills assessments must be tied to clinical endoscopy performance. None of this is possible without first defining, for each procedure and technique, key cognitive, technical, and nontechnical performance metrics and subsequently delineating benchmarking standards of expert performance by using measurement tools with strong validity evidence to set standards of competence.

Currently, there are several barriers to successful integration of simulation into endoscopy training, which also represent potential areas of collaboration, research, and development.

Faculty development. A uniform endoscopy *train the trainers* curriculum would be optimal to ensure minimum standards among trainers to improve the quality of endoscopy simulation training and facilitate integration of simulation at the local level.

Engagement. Incentives, such as continuing medical education credit and allotment of professional development time for simulation, may be beneficial to effectively increase engagement and improve utilization of simulation by practicing endoscopists. Research demonstrating the effectiveness and cost savings of simulation training should be pursued because it would help to demonstrate its applicability to practice and increase buy-in from key stakeholders.

Resource requirements. Educational tools and guidance regarding optimal timing and strategies for integration of simulation into training would be beneficial for training programs to facilitate integration of simulation.

Limited local access. Development and validation of feasible, mobile simulators and accompanying simulation-based learning modules targeting specific skills would help to promote uptake of simulation across endoscopy units and training programs.

Research. Multicenter research collaborations and data management tools would facilitate collection of clinical performance data to evaluate the effects of simulation on long-term performance, safety, and quality of care. Additionally, stakeholders should work together to solicit research funding from government, industry, and foundation sources to support studies in target priority areas with optimal design and long-term follow-up.

PRIORITY AREAS FOR SIMULATION RESEARCH

Summit participants identified a number of specific research questions and general lines of investigation needed to move the field forward. The following items were considered to be the most pressing priority research areas: (1) Medium and long-term clinical outcome data collection to assess the impact of simulation-based education, targeting both trainees and practicing endoscopists, on the safety and quality of care and comparative-efficacy trials to clarify the instructional design principles required to optimize transfer of skills from the simulated to the clinical setting. (2) Evaluating predictive validity evidence of new simulation-based skills assessment tools that are developed for both diagnostic endoscopy procedures and specific therapeutic techniques as well as an analysis of learning curve data to evaluate the impact of integrated simulation-based formative assessment on learning. (3) Characterization of skills that require a periodic educational effort to be maintained by practicing endoscopists and the most cost-effective and effective ways to provide this upkeep as well as skills remediation, when required.

CONCLUSION

Moving forward, simulator development will require a combined collaborative effort by endoscopy-related societies, clinicians, researchers, engineers, programmers, and industry. There will likely never be 1 universal model that will meet the educational needs of all learners ranging from the novice to the practicing endoscopist. Tools designed to impart and assess cognitive and non-technical components of endoscopic competence are both a major current unmet need and a feasible target for near-term technological advancement. Enhanced, well-designed simulators are needed, particularity to aid in the attainment of complex procedure skills such as ERCP and EUS that require a high level of technical, cognitive, and non-technical competence. Additionally, lower cost, portable models with accompanying learning modules are required to promote integration of simulation in a distributed manner across endoscopy units and training programs. Specific engagement from professional organizations will be needed to provide guidance for established training programs on how and when to best incorporate simulation throughout training. A broad and concerted effort to train endoscopy trainers to teach effectively by using simulation will be important to the successful integration of simulation-based education. Finally, the various stakeholders will need to collaborate to design, fund, and conduct research that evaluates the effects of simulators on long-term performance and quality of care to better define the value of endoscopic simulation and to ensure its adoption is informed by evidence.

DISCLOSURES

J. Cohen is a speaker for Otsuka and Ferring Pharmaceuticals, a consultant for Olympus and Boston Scientific, and a stock holder with GI Windows and Virtual Health Partners. M. Anderson is a member of the Data Safety Monitoring Board for GlaxoSmithKline, and is an expert witness for Boehringer Ingelheim. S. Edmundowicz has stock or stock options with Beacon Medical (purchased by Covidien in 2015 then Medtronic in 2016), Endostim, Check-Cap, SynerZ Medical (purchased by Gore Medical in 2016), Motus GI, Freehold Surgical, and Elira. He is on the Medical Advisory Board for Boston Scientific Corporation, Olympus, Xlumena, and Paion as well as a paid consultant for Orchestra Medical Ventures, GI Dynamics, Elsevier Publications, Medtronic, and Gore Medical. He also receives research support (site-specific financial or equipment) from AMT Inc, Redpath, GI Dynamics, Reshape Medical, US GI, Obalon, and Medtronic. He receives society honoraria from the ASGE, American College of Gastroenterology, and American Gastroenterological Association. He has spouse/family member stock or stock options with UV Concepts Incorporated and Elira. J. Marks is a consultant for Olympus and Boston Scientific. C. Thompson is a consultant for Boston Scientific, Medtronic, USGE Medical, Olympus, Apollo Endosurgery, Fractyl, and GI Dynamics. He is a member of the Advisory Board for USGE Medical and Fractyl, and he receives research support grants from USGE Medical, Apollo Endosurgery, Aspire Bariatrics, and Spatz as well as research support (equipment loans) from Olympus. He has ownership interest in GI Windows4 and EndoTAGSS. All other authors disclosed no financial relationships relevant to this publication.

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Abbreviations: ABS, American Board of Surgery; ACGME, Accreditation Council for Graduate Medical Education; ASGE, American Society for Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration; FES, Fundamentals of Endoscopic Surgery Program; NIH, National Institutes of Health; PIVI, ASGE Preservation and Incorporation of Valuable Endoscopic Innovations; STAR, ASGE Skills, Training, Assessment and Reinforcement program.

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