



# A Systems-Based Approach to Curriculum Development and Assessment of Core Entrustable Professional Activities in Undergraduate Medical Education

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## Abstract

**Background** In 2014, the AAMC launched a pilot project with 10 institutions to test the feasibility of implementing 13 Core Entrustable Professional Activities (EPAs) for Entering Residency.

**Methods** The Curriculum and Assessment (C-A) group of the pilot has proposed using a systems-based approach (SBA) as a framework for the development and implementation of EPAs in undergraduate medical education (UME). Based on the seminal concepts of systems thinking, five process-oriented steps define the system, describe a pathway to goal accomplishment, develop connections among people responsible for implementation, prepare for work activities, and plan for continuous quality improvement.

**Results** The systems-based approach proved to be very well-suited to the specific challenges of implementing EPAs within an existing curriculum. Our results with EPA 11 provided an early indicator of a successful longitudinal and fully integrated approach to educating and assessing students in obtaining informed consent.

**Conclusions** Pilot project institutions are endorsing the SBA to develop and implement EPAs in UME to encourage scalability, replication, or adaptation, as needed locally and across institutional sites. While the work of the Core EPA pilot project is ongoing, we introduce the SBA to foster early adoption by institutions interested in incorporating EPAs into their current undergraduate medical education programs.

**Keywords** Core Entrustable Professional Activities for Entering Residency (EPAs) · Systems-based approach to assessment (SBA) · Undergraduate medical education (UME) · Informed consent · EPA 11

The emphasis on patient safety and implementation of milestones in Graduate Medical Education (GME) has re-ignited discussion on whether graduating medical students possess

the skills expected of entering residents [1]. Recently, in an ardent effort to bridge these gaps and strengthen the continuum between undergraduate medical education (UME) and

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GME, the Association of American Medical Colleges (AAMC) published 13 Core Entrustable Professional Activities (EPAs), skills and behaviors medical students should be ready to perform without direct supervision upon entering residency [2]. This framework has stimulated a call for action regarding the preparedness of medical school graduates. Medical schools are rethinking clinical experiences, their relationship to institutional competencies, and strategies for how to best guarantee appropriate training, adequate exposure, and valid assessments that will result in entrustable trainees who are prepared to function without direct supervision on day 1 of residency training.

Issues for many schools considering adoption of EPAs into the curriculum have been threefold: how best to integrate changes in teaching methods and assessments into a curriculum already well defined without major curricular overhaul; when, where, and how to assess learners when time is usually stretched to capacity within existing rotations and educational experiences; and how to garner faculty, administrator, and student support for maximum benefit and lasting effect. Without ample commitment from faculty, administrators, and students, entrustment decision-making will likely be hollow and fail to reach its potential to adequately address the present gap in student preparedness for residency training—that is, the ability to perform necessary tasks and behaviors of a physician without direct supervision on day 1.

These three aims are not easily accomplished goals, and like any change initiative, good intentions can be undermined by the unintended consequences of poor execution. Without a major overhaul of the existing curriculum, how does an institution approach a change initiative of this kind, one EPA at a time? We describe one such change initiative, small in scale, but successful in its ability to address the need for undergraduate students to learn the basics of informed consent discussions with patients and families. This article illustrates the feasibility of addressing EPAs by realizing opportunities already present in the learning environment and by making small changes that will ultimately contribute to an entrustment decision with data gathered over time. However, it is important to recognize that such small-scale change efforts begin with a big picture perspective of the learning system as a whole, along with all of its moving parts and the relationships among stakeholders.

## The History for Implementing a Systems-Based Approach

The core principles of systems thinking have been well-known in business, manufacturing, engineering, and many other disciplines for decades. They are based on four basic rules of process design and improvement to address how people actually engage in work, create a pathway for achieving goals, connect with information and ideas, and make

improvements in work processes [3]. In 2004, Armstrong et al. encouraged the use of systems thinking to tackle critical issues in clinical training within UME by recognizing medical education as a complex system, asserting that fragmented efforts at curriculum reform were likely to lead to unintended consequences and poor outcomes. Armstrong and her colleagues [4] proposed curriculum redesign and reform that addressed *systems issues* to understand the system as a whole, along with its moving parts and relationships. Recently, Bowe and Armstrong underscored the importance of systems thinking when attempting to translate large amounts of individual outcomes into “actionable intelligence” for decision-making to address continuous systems improvement, innovation, and long-term institutional planning [5]. Implementation of EPAs into an existing UME curriculum represents a systemic change in how new doctors are trained and supervised by allowing greater autonomy within the GME setting as early as the first day of residency training for learners who have been deemed entrustable [2]. To realize the potential for entrustment, however, implies better preparation of learners throughout their medical education careers. Many schools are beginning to implement or are considering implementing EPAs in their UME programs. As we begin to develop new approaches for teaching and assessment, applying systems thinking principles will encourage institutions to take a more holistic view of their programs and go beyond just developing a new checklist or a new form for faculty to complete. Rather, the use of systems thinking can help create a program that delivers clear expectations, engages appropriate stakeholders, and optimizes teaching, assessment, and feedback opportunities for students across the curriculum. It promotes a process that can anticipate and identify challenges, facilitate problem solving, and encourage continuous monitoring and improvement. Ultimately, creating a system that can achieve its intended goal and produce sustainable outcomes represents the aim of all institutions engaged in EPA implementation.

In 2014, the AAMC launched a pilot project with 10 US medical schools to foster the development of curricular materials and assessments for 13 proposed EPAs and test the feasibility of their implementation. The Curriculum and Assessment (C-A) subgroup of the pilot has proposed using a systems-based approach (SBA) based on the seminal concepts of systems thinking, for the development and implementation of EPAs in undergraduate medical education. Other scholars, including Aylward et al., have described a step-by-step process for assessing an EPA, also addressing the critical need for a systems-based approach to achieve meaningful change [6]. In a commentary to their article, Englander and Carraccio supported “not only the importance of the implementation process itself but also studying that process in disseminating educational innovations” [7].

However, Valerdi and Rouse claim that the use of *systems thinking* may not be a natural process, believing that some

people may grasp these concepts more readily than others [8]. Valerdi and Rouse define qualities of systems thinking that have implications for how we embrace the tenets of the Core EPA pilot project within individual institutions. These include the ability to “define the universe” by describing the overall system including its appropriate boundaries. Defining the universe requires examining societal needs and challenges within the current healthcare system, examining changes in how, when, and where care is delivered, and by whom. Also, key to understanding the system are the abilities to see things holistically and visualize the importance of relationships within the system, while also recognizing that relationships can yield uncertain, dynamic situations involving complexity. The final two qualities of systems thinking—the ability to communicate across disciplines and the ability to bring a broad range of concepts, principles, models, methods, and tools together to solve problems—have long been challenges in medical practice. Valerdi and Rouse believe that systems thinking represents challenges for most people because it requires changes in the way we think and act to create new mental models [8].

Although strides have been made in medical education to improve student clinical experiences, residency preparedness and patient safety are areas that continue to pose significant challenges [1]. The Accreditation Council on Graduate Medical Education (ACGME) milestone project has begun to address many of these challenges in residency training. However, Williams et al. questioned whether the new milestone requirements would lead to an end of rotation “check the box” type of reform [9]. This concern is an example of an unintended consequence that could result from Armstrong et al.’s perception of a fragmented approach to curriculum reform, a focus on the tool to guide change rather than changes that occur within the system as a whole [4]. Van der Vleuten et al.’s discussion of programmatic assessment also supports a holistic approach for curricular change [10], reiterating that “a good test is more than a random set of good quality items, a good program of assessment is more than a random set of good instruments [11].”.

### Steps for Implementing the Systems-Based Approach with EPA 11, Informed Consent

The Core EPA pilot project institutions have developed a System-Based Approach Guide to implement the EPAs based on the systems-thinking qualities outlined by Valerdi and Rouse [8]. Our guide addresses the principles of process design and improvement by translating them into a detailed, stepwise approach for implementing EPAs within UME. This approach *defines the system* (Table 1, section A), *describes a pathway* (Table 1, section B) for institutions to accomplish curricular goals,

*develops connections* (Table 1, section C) among people, *describes work activities* (Table 1, section D), and reminds us of the importance of embedding a *continuous quality improvement process* (Table 1, section E) within the curriculum. We encourage its use as a guide that can assist schools struggling with EPA implementation. We have used the SBA guide to develop the trajectory toward entrustment for EPA 11 on informed consent as an example.

EPA 11 on informed consent is an essential process in the daily practice of medicine and paramount to the patient-physician relationship. A recent *JAMA* article on the new era of informed consent described the UK Supreme court ruling on standards requiring physicians to inform patients about the risk, benefits, and alternatives of treatment as that which a reasonable patient deems important [14]. This patient-centered approach that emphasizes the patients’ perspective and shared decision-making has been adopted by nearly half the states in the USA [14]. Recent publications have emphasized concerns with patient safety issues related to informed consent and a need for improved training among providers [15–18].

While some think of informed consent narrowly, residents, even students, perform this task routinely when recommending a diagnostic test, such as HIV or PSA testing, or advising use of an antibiotic over watchful waiting. EPA 11 explicitly states that “all physicians must be able to perform patient care interventions that require informed consent. From Day 1, residents may be in a position to obtain informed consent for interventions, tests, or procedures they order or perform (e.g., immunizations, central lines, contrast and radiation exposures, blood transfusions). Of note, residents on the first day of their training should not be expected to obtain informed consent for procedures or tests for which they do not know “the indication, contraindications, alternatives, risks and benefits” [2]. EPA 11, obtaining informed consent for tests and procedures, is aligned with five relevant domains of competence from the List of General Physician Competencies by Domain found in the AAMC’s Core Entrustable Professional Activities Guide for Curriculum Developers (2014): patient care (PC), interpersonal and communication skills (ICS), professionalism (P), systems-based practice (SBP), and personal and professional development (PPD). These competencies include the ability to describe indications, risks, benefits, alternatives, and potential for complications associated with a test or procedure; communicate with the patient and family to ensure understanding and explore alternatives; create a climate that encourages the patient and family to ask questions; enlist interpretive services, if necessary; document the discussion afterwards in the health record; display an appropriate balance of confidence with knowledge and skills that put the patient and family at ease; and, most importantly, demonstrate an understanding of personal limitations and willingness to seek help when needed [2].

**Table 1** A Systems-Based Approach Guide for institutional planning in implementing EPAs into the UME curriculum (A–E)

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**A. Define the system**

Review the Core EPAs for Entering Residency Curriculum Developers' Guide [2], particularly the functions, framing competencies (competencies necessary to achieve an EPA), and the list of bulleted expected behaviors at the back of the guide for your particular EPA.

Map the EPA framing competencies to institutional competencies and/or program objectives to help align expectations, and recognize strengths and areas of weakness/gaps.

Determine where EPA curricular elements are currently taught and assessed.

Identify key stakeholders (deans, course directors, clerkship directors, residency program directors...)

Identify clinical microsystems (opportunities in clerkships, sub-internships, electives) for implementation of EPA related training and work-based assessment (WBA).

Identify drivers and barriers to successful implementation and efforts needed for sustainability.

Consider resources needed for implementation and garner leadership support.

**B. Create a pathway for goal accomplishment (what and how)**

Review EPA-related curriculum and assessment for opportunities to increase breadth, complexity, application, and integration of EPA-related content to promote learner proficiency [12].

Consider whether meeting certain pre-clerkship accomplishments or benchmarks need to precede clinical training and add opportunities for teaching these within the preclinical years.

Develop innovative methods to make the identified curricular elements and assessments in current *pre*-clerkship curriculum more relevant to the EPA's

Describe how the entrustment decision for a particular EPA will have multiple data points in assessment [10].

Use the Core EPA Curriculum Developers' Guide [2] to review the descriptions for each EPA, with particular attention to critical functions and the list of bulleted behaviors, to guide and align the development of new assessments or to identify evidence needed for entrustment decision-making

Describe the collection of "evidence" from multiple sources and contexts, such as patient logs, case write-ups, presentations, patient surveys, quality improvement projects, reflections, assessment tools, mini-CEX forms, and more [13].

Map the items on assessment tools or other evidence currently used/being developed to the related competence domains, as indicated for each EPA in the Core EPA Curriculum Developer's Guide [2] to help identify gaps or deficiencies which can be remedied. Ask the institutional implementation team if the proposed body of evidence will fulfill all competencies necessary to achieve that EPA or if gaps still remain?

Consider using a student portfolio to aggregate assessment data that will be used for entrustment decision-making by an entrustment or competency committee.

Address the need for faculty development to align expectations and develop a shared mental model for EPA implementation.

Consider the nature of a *developmental* curriculum that spans all 4 years to address all EPAs and includes fixed components (consistent across learning experiences) and variable components

**Table 1** (continued)

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(unique to a particular context or setting). Include assessments that will span the curriculum to show improvement and progression.

Determine the minimum number and mix of assessments, both granular (e.g., checklists) and holistic (e.g., global) as well as the potential for narrative assessments to create a complete picture of the learner.

Identify gateway assessments or progression points (yes, not yet), and develop plans to collate formative and gateway assessments into a summative endorsement of the entrustable learner.

**C. Develop connections**

Consider how the planning team will achieve institutional engagement and methods for continuous communication about implementation of EPAs in the UME curriculum

Develop plans for student engagement to promote and encourage students to be drivers of their own learning.

Work with the institution's faculty developers to encourage curricular changes and assessments that will result in a shared mental model for developing entrustable learners.

Ensure that the institutional planning team has designed implementation by planning progress checkpoints and a means for communicating them, as well as a plan to communicate outcomes to all stakeholders.

**D. Prepare for work activities**

Create EPA-related committees that are inclusive of appropriate stakeholders

Develop, revise, and enhance curriculum and assessment as needed

Identify champions for faculty development, consider internal surveys or focus groups to help identify or amplify training and assessment opportunities across clerkships/rotations

Develop a tool box of assessments and teaching strategies that are applicable for different levels of training, generalizable across settings, and feasible for faculty to implement without disruption to the work flow.

Ensure that all new assessment tools developed contain entrustment language or language that links their performance to level of supervision required. This will assist an entrustment committee in determining an end-point decision of readiness for residency.

Consider technology that is user friendly (at student/faculty interface), facilitates data collection and tracks performance over time

**E. Prepare for continuous quality improvement**

Evaluate the progress of the implementation team in developing new curricular components and a program of assessment across the curriculum.

Ensure that feedback to program developers, faculty developers, and others involved in implementation, including student feedback, is solicited on a regular basis and used to make changes on an ongoing basis, as needed.

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### To Define the System, Adopt a Bird's Eye View

Living deeply within its parts, we often struggle to see the system as a whole. To see the whole requires a birds' eye view, noting where in a medical school's curriculum the core EPAs and associated competencies to perform them are naturally embedded. Many may be present with the curriculum already,

although some are hidden, and others have not been well-emphasized. By mapping the competencies associated with an EPA to existing institutional goals and competencies, curriculum developers can align expectations and identify areas of opportunity. Some of the 13 EPAs are very familiar and have been well developed within the traditional medical school curriculum; others may require more work.

At Florida International University, educators began by mapping their educational program objectives to the List of General Physician Competencies (PCRS) found in the AAMC's Core Entrustable Professional Activities Guide for Curriculum Developers [2]. In doing so, they identified several areas in the current curriculum that could be improved to achieve the necessary competencies needed to successfully perform an EPA. By reviewing the four-year curriculum, they were able to identify objectives and assessments related to specific EPA 11 content. Understanding the relevant competencies needed to achieve an EPA allowed them to recognize how course content related to clinical activities, further amplifying opportunities for better integration and institutional acceptance of the EPA framework. Thus, incorporation of EPAs created a bridge between content in the preclinical years and clinical expectations for student learners.

For the first “deep dive” into the existing curriculum at FIU, educators reviewed all course objectives, teaching methods, and current assessments as they sought opportunities to link EPA 11 functions and competencies to what was already being taught. Applicable courses related to EPA 11 included first-year courses on Medical Jurisprudence and Ethical Foundations of Medicine; second-year Clinical Skills course procedure-based sessions; third-year clerkships in General Surgery, the Gastroenterology Endoscopy rotation, and Pediatrics clerkship; and two courses within the fourth year, the Professional Development Capstone course, and the Longitudinal Capstone, and End-of-Year fourth-year Clinical Medicine Simulation Capstone.

Although opportunities exist for assessing knowledge, skills, and behaviors in the preclinical years, the majority of EPA assessment will likely take place in clinical environments. While it is not feasible to assess every EPA in a single rotation, frequent data points, collected in multiple settings provide an overall depiction of learner readiness, thus providing a rich and robust picture for entrustment decision-making [19]. Clerkship experiences, as clinical microsystems [20], provide sites for EPA-related training and workplace-based assessment (WBA) for students on rotations. Educators at FIU began by identifying clinical settings with sufficient opportunity for faculty training, deliberate practice, direct observation, and feedback for students. Curriculum developers administered an in-house survey to all clerkship directors on opportunities for training and assessment of EPAs at their clinical sites. A survey was also administered to all current third- and fourth-year students asking about current

experiences with EPA-related content. Results identified the Family Medicine clerkship site as a valuable opportunity for faculty training and WBA using EPA 11 through immunization counseling. In addition, the Psychiatry clerkship was identified as an opportunity for WBA for students on this rotation to participate in discussions on informed consent in the use of psychotropic medications. A focus group session was held with all clerkship directors to discuss survey results and opportunities for embedding EPA 11 content on informed consent into the educational experience.

Since stakeholder identification is a key component in defining the system to enhance awareness of the potential for EPA-related training, curriculum developers invited key institutional leaders to take part in determining where to teach EPAs: curriculum deans, longitudinal “strand” leaders, course, and clerkship directors. Engaging stakeholders led to significant interdisciplinary faculty awareness, integration, and participation. Faculty who teach Ethics and Medical Jurisprudence in the preclinical curriculum became a close-knit group with clinical faculty after they had a better understanding of each other's perspectives, resulting in improved horizontal and vertical integration within the existing curriculum. Faculty members participated as observers or small group facilitators in each other's courses, as well.

Thoughtful discussions on EPA 11 led us to identify drivers and barriers to implementation: lack of consensus on issues related to informed consent and ambiguity of expectations for the student, including lack of clarity on who could *or should* obtain consent. Curriculum developers became aware of the lack of faculty development in teaching the behaviors associated with EPA 11, concerns about available time to evaluate learners during clerkship rotations, and the needs of clinical preceptors working in diverse settings. We identified the ambiguity associated with opportunities for students to practice informed consent skills and the reality of theory versus practice (the hidden curriculum). Drivers for implementation included patient safety initiatives, opportunities to address gaps in the curriculum, need for clarity in expectations for student learners in obtaining informed consent, and promotion of patient-centered care. In this manner, curriculum developers at FIU began to *define the system*.

### **To Travel the EPA Road, Begin by Describing the Pathway**

With a clear picture of the system, the process of carving a pathway to entrustment involves identifying key curricular and assessment elements related to each EPA that hold potential to contribute to an entrustment decision. The four-year standard medical education curriculum is often depicted as a spiral with each stage reinforcing previous concepts in a developmental trajectory that increases in complexity over time [12]. Harden proposed a four-dimensional model for

conceptualizing and planning the progression of students in terms of increased breadth of exposure to concepts, increased difficulty in knowledge acquired, increased utility and applicability to practice situations, and increased proficiency [12]. We believe that applying this model to EPA development and implementation can lead to a robust curriculum using EPAs to embrace complexity and authenticity of workplace assessment, with the ultimate goal of achieving the “does” of Miller’s pyramid [21].

To develop a pathway, curriculum developers at FIU began to review EPA-related curricular elements to help define desired breadth and complexity of a developmental approach. As they tackled these issues, key questions arose: Should we all agree to a core list of procedures for which students would be capable of obtaining informed consent? These might include immunizations, contrast radiation, blood transfusion, medications, joint injections, colposcopy with biopsy, lumbar puncture, and central line insertion. When will verbal consent be acceptable instead of written consent? What level of complexity in addressing this task is reasonable for a graduating medical student? What will student learners be responsible for in terms of addressing cultural differences, poor health literacy, religious beliefs, and situations in which there is ambiguity in risks and benefits? What will our plan be for students when the patient does not give consent, or when there is a surrogate decision-maker? What level of complexity do we expect for entrustment? For these more complex situations, is it adequate that students possess the ability to recognize a complex situation and know when to seek help? What do program directors expect on day 1 of residency regarding the ability to obtain informed consent? We are seeking consensus through the work of the pilot project member institutions on these key issues to help clarify expectations, improve training and assessment, and ensure safe patient care.

Using this stepwise process and guided by the expected behaviors explicit in the AAMC Core Entrustable Professional Activities for Entering Residency Guide [2], FIU curriculum developers were able to identify a list of pre-clerkship benchmarks that should precede teaching and assessment in the third- and fourth-year clinical experiences. For EPA 11, they focused on those that would provide the necessary foundation for informed consent. They identified 14 benchmarks for this task, including demonstrating appropriate patient-centered interviewing techniques, understanding the importance of shared decision-making, distinguishing between decisional capacity and competence, and understanding the importance of knowing one’s personal limitations. Other functions were specific to informed consent, such as identifying situations when verbal consent is appropriate in lieu of written consent and recognizing what constitutes appropriate documentation (Table 2).

Once these pre-clerkship benchmarks were identified, teaching methods and assessments were enhanced to incorporate EPA 11 content. FIU curriculum developers added EPA

**Table 2** Benchmarks as a foundation for readiness to implement EPA 11 on informed consent at Florida International University

1. List components required to obtain informed consent (PC 6, KP)
2. Recognize patient-centered vs. doctor-centered informed consent (PC 7, ICS1)
3. Demonstrates appropriate patient-centered interviewing techniques and recognizes the importance of integrating and applying these skills in the process/discussion around informed consent (PC 7, ICS1)
4. Understands the importance of shared decision-making (PC 7)
5. Uses the Ask tell Ask model when sharing information (PC 7)
6. Recognizes the importance of the use of an interpreter and knows key elements of how to use an interpreter (ICS 1, KP5)
7. Identify cases/situations when informed consent is needed (PC 6)
8. Distinguish between decisional capacity and competence (P6)
9. Identify appropriate decision-maker (P6)
10. Identify cases/scenarios when verbal vs. written consent is needed
11. Recognize appropriate documentation for informed consent (ICS 5)
12. Demonstrate obtaining informed consent for a basic scenario
13. Demonstrate documenting informed consent for a basic scenario
14. Recognizes complex scenarios that can be involved in informed consent (PPD1, PPD8)

Each pre-clerkship benchmark is mapped to the relevant competency for EPA 11<sup>2</sup>

PC patient care, KP knowledge for practice, ICS interpersonal and communication skills, P professionalism, PPD personal and professional development

11 specific objectives and developed innovative teaching methods for the year 1 Ethics course and Medical Jurisprudence course; they modified the Clinical Skills 2 course sessions on teaching procedures to include opportunities for teaching and practicing informed consent, and they also included an informed consent scenario to several year 2 case-based teaching sessions. For the end of the year 2 Objective Structured Clinical Examination (OSCE), an informed consent standardized patient station was added. As they enhanced the curriculum to address EPA 11 with appropriate assessments throughout the 4 years, they were able to define a body of evidence toward entrustment decision-making. Ultimately, multiple data points contributed to *describe the pathway* within the system.

Familiarity with the functions and expected behaviors of the pre-entrustable and entrustable learner for each competency as described in EPA Curriculum Developers’ Guide is essential to guide and align the development of assessments and identify evidence needed to help make entrustment decisions. Evidence needed for an entrustment decision can exist in many forms, including patient logs, case write-ups, OSCEs, and WBAs administered in diverse settings with multiple preceptors [13]. Assessment data may be best collected and organized within a portfolio system that compiles data points in terms of increasing sophistication, beginning with gateway assessments (yes/not yet). Holmboe et al. recommend

alignment of assessments with the construct that is being evaluated [22]. For example, when developing assessment tools for a particular setting or identifying evidence aligned with the critical functions or expected behaviors of a particular EPA, it will help to internally map the items on the assessment tool to the related competency or competency domain. This will facilitate final entrustment decisions by demonstrating whether there is an adequate body of evidence that fulfills *all* the competencies necessary for that EPA and by identifying any deficiencies in certain competencies within and *across* EPAs. We identified the body of evidence needed for an entrustment decision on EPA 11 in Table 3. Our next step is to develop a process for entrustment that will formalize decision-making. Currently, we are piloting an entrustment committee for the class of 2019 and have identified faculty who will serve as “EPA champions” and will assist in reviewing performance data. We are establishing a timeline for the appropriate entrustment committee checkpoints and are working toward aligning this process with our advising program that will provide students with feedback regarding their progress.

### For Success, Develop Connections Among People

Communication needed for successful implementation of a systems approach rests on a well-accepted and shared mental model to enhance institutional commitment, student engagement, and faculty development. Experience within the EPA pilot project confirms for us that development of a shared mental model requires time and persistent efforts of people to understand each other and respect diverse viewpoints. Most institutions have an existing organizational structure for repeated and frequent communication with stakeholders including such groups as clerkship directors, course directors, program directors, teaching faculty who attend faculty development workshops, executive leadership committees, and curriculum committees. Once these groups become champions of the change, they have the institutional clout to bring others in as innovation takes hold. We envision institutional engagement, student engagement,

**Table 3** A suggested body of evidence needed for entrustment in informed consent (EPA 11)

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End of second-year OSCE basic procedure—360 assessment
Workplace-based assessments—Family Medicine (immunizations), Psychiatry (medications)
Documentation rubric—work place documentation of informed consent
Student-driven clerkship encounters—journal
End of second-year OSCE—basic procedure
End of third-year OSCE—complexity level 1 (e.g., simple case)
Fourth-year capstone OSCE—complexity level 2 (e.g., complex case)

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and faculty development as the three pillars needed to disseminate knowledge and acceptance of EPAs for curricular changes and assessment activities within the medical school culture.

Students play a critical role in the adoption of EPAs. Clearly, they need to be aware of expectations for self-directed learning through early engagement. Holmboe et al. asserted that “learners ... must be active agents coguiding both their curricular experiences and assessment activities [22].” Students must pursue opportunities to learn, seek feedback, and demonstrate competency through shared responsibility for accomplishing EPAs with their preceptors. Residents also need to understand their role in observing and providing formative feedback to learners, with “residents-as-teachers” programs as an important driver of change. Innovative faculty development will enable development of the shared mental model so necessary for this major shift in preparation and readiness of students for internship. Chen and her colleagues are among the scholars who have created developmental scales associated with levels of supervision for EPAs, providing faculty an easy-to-use framework that changes the lens for how we assess our learners [23]. Faculty members have to now have to ask themselves a different question with each assessment decision: *Do I trust this learner to perform this activity without direct supervision?* Faculty development will also be necessary to enhance communication in transitions between clerkships and from the third to fourth year more about promoting student growth and development as students progress through clinical experiences.

To foster communication and enhance commitment and student engagement, curriculum developers at FIU developed an institutional video to promote awareness and begin the process of introducing EPAs to faculty. Students were introduced to EPAs in first-year orientation, and discussions held with the curriculum committee, clerkship directors, and during chairs’ council meetings. Selected students contributed ideas in monthly EPA committee meetings. After a detailed orientation, third- and fourth-year students have been encouraged to take an active, self-directed role in their own EPA assessments, seeking EPA 11 feedback across all clerkships. These students will be encouraged to document all encounters in which they participate in informed consent on a brief mini-clinical evaluation exercise (CEX) form developed from the functions and competencies for EPA 11 in the Core EPA Curriculum Developers Guide [2]. Over time, faculty at FIU expect that the collection of multiple student-driven assessments will provide feedback about opportunities, level of exposure within the curriculum, and how these

experiences contribute to a final entrustment decision in EPA 11. Throughout, FIU curriculum developers *built connections among the people* who were going to be responsible for implementation.

### To Prepare for Work Activities, Scaffold for Support

The fourth tier in our SBA Guide addresses the need for work experiences that improve performance among student learners and ultimately results in enhanced safety and quality in the clinical environment. Harden views this scaffolding approach as the ultimate goal of outcome-based education toward more efficient performance by the learner, with less need for direct supervision, and an increase in self-directedness [12]. As our pilot institutions work through the SBA to incorporate curricular and assessment enhancements into existing programs, we can identify areas for improvement that can be addressed by EPAs for better educational outcomes.

Work activities at FIU included creating an EPA subcommittee with relevant stakeholders that worked together to fill in curricular gaps and develop faculty to teach and assess EPA 11. The goal was to enable students to enter the clinical environment at the “shows how” level of Miller’s [21] pyramid ready to be assessed in the workplace, with the intention that they progress to an expected level of complexity and proficiency closer to the “does” level by the time of graduation. Assessment tools based on the EPA manual functions with corresponding developmental behaviors that incorporate a level of supervision scale were developed and are being implemented in the Family Medicine and Psychiatry rotations. Implementation involved faculty development sessions, multiple reminders, and brief feedback sessions during clerkship orientations to maintain student engagement and identify issues as well as a strong collaboration with technology staff to develop a feasible, easy-to-use assessment form. We will be evaluating the feasibility, validity, and reliability of this initial WBA. Our plans are to aggregate assessment data points over time to explore how these data will help define gateway and progression points, as well as final entrustment decisions.

### To Plan for Continuous Quality Improvement, Think Like an Engineer

Manufacturing organizations long ago began to adopt quality improvement initiatives, first in Japan, and then in this country in the 1980s, particularly in the automotive industry in response to overseas competition. Deming and early champions of quality improvement were engineers who encouraged organizations to appreciate the nature of systems thinking [24]. This final and critical step will remind educators to continuously ask themselves, *How does our institution, our current system, encourage the development of curricular and assessment approaches that will continue to provide program*

*feedback and quality improvement?* Bowe and Armstrong support a systems-based approach in medical education with a systems perspective that will “facilitate timely corrections”, intermittent analyses of current system performance to inform continuous quality improvement (CQI) and innovation efforts, and periodic evaluation of longitudinal system performance to determine its readiness for systemic changes needed to better prepare learners to meet the evolving needs of the healthcare system [5].

When considering how to embed continuous quality improvement for the new curricular elements and assessments at FIU, curriculum developers asked themselves whether they had developed sufficient feedback mechanisms to garner insights from teaching faculty, students, and the hospital environment as a whole, including other providers and patients. Two classes of students, those at the end of third and fourth years of medical school, participated in a mandatory, formative OSCE that was added for assessing EPA 11. All of the assessments developed for EPA 11 were mapped to the framing institutional competencies and curricular objectives. Data gathered will allow FIU to identify students’ baseline skill levels in delivering informed consent at the end of the third year and prior to graduation and compare with our pilot curriculum class of 2019. Strengths and weaknesses will allow educators to monitor for improvement over time and make additional modifications as needed. Multiple data points gathered over time that reflect student performance will be examined collectively to address overall program quality. One of Holmboe et al.’s six recommendations for improving assessments in GME that also applies to UME is to “engage local faculty in ongoing conversation about what works, for whom, why, and in what circumstances [20].” As new WBA tools are developed for EPA 11 in Family Medicine and Psychiatry rotations, curriculum developers will meet with faculty in post-rotation focus groups to discuss experiences with the new assessment tools, challenges of implementation, and overall student performance. Student-driven assessments will inform us about whether more opportunities exist across clerkships and the level of student exposure and participation needed in the clinical setting on informed consent.

### Moving Forward to Implement EPAs

The Core EPA pilot project of the AAMC has stimulated a call to action for better preparedness by students for residency training, fueled by the energy of scholars and practitioners around the globe to explore the possibilities that core EPAs hold for improving the quality of medical education. We believe that a systems-based approach for identifying opportunities and challenges within each local medical school context is both necessary and timely to ensure that piecemeal efforts



do not undermine this unique opportunity for transformational change within US medical education.

The possibility of novel solutions for implementing EPAs extends well beyond the creation of a new checklist or administration of assessments via mobile devices. What will be needed is bold, innovative, and creative thinking—a systems-based approach that considers the whole and not just the parts. Our institutions will need to engage stakeholders at multiple levels, including senior administration, faculty educators, and students in envisioning a world in which learner progress toward entrustment becomes the gold standard of a medical education. Learners will need to become self-directing in seeking out and taking advantage of opportunities to master the behaviors and skills they will need in residency on day 1. As members of the AAMC pilot project, we are invested in testing the feasibility of EPAs for developing students who are deemed ready to transition from UME to GME by their residency program directors. Our goal is for an educational experience that graduate students who know when to seek help when needed and who express justified confidence in their abilities to perform the skills and behaviors needed of every physician. The combination of variable approaches local to unique institutional contexts, and fixed, multi-institutional assessments of EPAs should ultimately result in better prepared medical students. While the work of the C-A group of the pilot project is ongoing, we have shared the Systems Based Approach Guide to foster early adoption by institutions interested in incorporating EPAs into their current medical education programs.

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