performance of the tablet or capsule when administered. During and post production, tablets and capsules undergo tests such as uniformity of content and weight to ensure that each tablet or capsule produced contains the appropriate dose and dissolution and disintegration testing to ensure that the tablet or capsule will disintegrate and drug will dissolve at an appropriate rate to produce the desired effect. The stability of the drug in the dosage form over time is also tested to ensure that the drug does not break down to inactive or toxic products.

Although there is evidence of the presence of sofosbuvir in the Egyptian tablet, there is concern regarding the increased ratio of inactive to parent drug, and many unknowns regarding safe and consistent manufacturing process. These could have more safety issues than the purported benefit, especially if the drug is effectively only a small amount, leading to potential loss of efficacy or resistance. Thus, there needs to be extreme caution with the use of drugs from unknown sources. The reason some medications are expensive is because of the extensive work involved in developing and maintaining the quality of registered medications. Use of therapeutics without any of these data is risky for patients from a number of perspectives, as discussed in this editorial.

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References

REVIEW

The ABCs of entrustable professional activities: an overview of ‘entrustable professional activities’ in medical education

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Abstract
Consultants regularly need to decide whether a trainee can be entrusted to perform a clinical activity independently. ‘Entrustable professional activities’ (EPA) provide a framework for justifying and better utilising supervisor entrustment decisions for trainee feedback and assessment in the workplace. Since being proposed by Olle ten Cate in 2005, EPA are emerging as an integral part of many international medical curricula, and are being considered by the Royal Australasian College of Physicians in the current review of physician training. EPA are defined as tasks or responsibilities that can be entrusted to a trainee once sufficient competence is reached to allow for unsupervised practice. An example might be to entrust a trainee to ‘Initiate and co‐ordinate care of the palliative patient’ with only off‐site or indirect supervision. Rather than attempting to measure directly each of the many separate competencies required to
Entrustable professional activities in medical education

During a busy clinic, Simon, your new basic physician trainee calls you. He is concerned about a deteriorating patient with advanced pulmonary fibrosis. Unfamiliar with his level of experience, you reluctantly advise him to discuss end-of-life care plans with the patient’s family. ‘After all,’ you reason – ‘…Simon has passed his exams, so he must be competent enough to complete this task…’

Introduction

Current approaches to assessment suggest that a coordinated programme of multiple types of complementary assessments may produce a more meaningful result than simply the sum of its parts. This acknowledges that no one method of assessment can cover all the required knowledge, skills and attitudes required of medical experts. The Royal Australasian College of Physicians (RACP) training programme includes written and clinical examinations with a workplace-based assessment component known as Physician Readiness for Expert Practice. ‘Entrustable professional activities’ (EPA) have emerged internationally as tools for assessing on-the-job performance and may play an important role in revising the workplace component of RACP curricula. However, given their recent development, many clinicians and educators are unfamiliar with this educational tool.

The concept of EPA was introduced by ten Cate in 2005 as a novel method of assessment in medical education. The aim was to ‘help supervisors in their determination of competence of trainees’. EPA are essentially units of significant clinical work. They are defined as tasks or responsibilities to be entrusted to a trainee once sufficient competence is reached to allow for unsupervised practice.

What does ‘entrustable’ mean?

Trust plays a central role in the daily interactions of supervisors and trainees. Supervisors regularly need to decide what level of trainee supervision is needed for safe patient care. Assessment using EPA formalises these daily clinical entrustment decisions, by providing a framework to collect evidence and document what clinical supervisors are already doing – using their expert judgement based on their observations of the trainee’s proficiency.

When dealing with EPA it is important to highlight the relationship between ‘activities’ and ‘competencies’. Competencies are general attributes of a doctor – for example, ‘The ability to apply interpersonal and communication skills’. In contrast, activities are elements of professional work – for example, ‘Discuss end of life care with a patient and family’.

Tasks appropriate for an EPA must be: observable, measurable, executable within a given timeframe and suitable for entrustment decisions. An EPA grading system has been developed based on the amount of trust a supervisor has in a trainee. There are five levels of trainee proficiency:

1. has knowledge
2. may act under full supervision
3. may act under moderate supervision
4. may act independently (with ‘supervision at a distance’)3
5. may act as a supervisor and instructor

So how do supervisors make ‘entrustment decisions’? Unsurprisingly, the literature suggests that this is a complex multifactorial process. In a survey-based study of supervisors and trainees, four main domains of ‘entrusting factors’ were identified: trainee factors (e.g. confidence), supervisor factors, task factors and systems factors. Furthermore in a qualitative study, Dijksterhuis et al. found significant variability in how obstetrics and gynaecology supervisors make entrustment decisions. Reported methods included direct observation, discussions with colleagues and even ‘blind faith’.

Given the complexity of an entrustment decision, it has been argued that sustained observation of the trainee performing clinical work over time allows supervisors to make better decisions. The success of using trust as the basis for assessment therefore hinges on effective implementation in the real world context of clinical training.

The case for EPA

With the advent of competency-based education (CBE), traditional assessment techniques attempted to measure
directly a trainee’s ‘competence’. However, the literature suggests that this is neither a practical nor useful exercise, highlighting the need for a new approach to assessment.

The first problem with measuring competencies, rather than focussing on activities, is that competence does not necessarily predict performance. A trainee may appear to be ‘competent’ in an examination setting, but exhibit poor performance in daily clinical work. Most clinical supervisors can give examples of trainees who perform exceptionally in written examinations and simulated tests of clinical skills, but poorly in daily clinical work, and vice versa. Consider the introductory scenario – if Simon was deemed able to apply interpersonal and communication skills, it does not necessarily mean that he can be trusted to discuss end of life care with a patient.

Furthermore, it may not even be possible actually to measure competencies in the workplace environment. In 2009 Lurie et al. systematically reviewed published evidence that the Accreditation Council for Graduate Medical Education’s six general competencies can be measured in a reliable way. They found that current measurement tools were not able to measure competencies independently of one another. For example items on global rating forms tended to cluster into one or perhaps two domains, rather than the six competencies on which they were based. The authors resolved that these competencies may ‘exist in a realm outside of measurement’. These problems paved the way for a novel approach to assessment in CBE. According to Miller’s well-known framework for clinical assessment (‘Miller’s pyramid’), trainees typically progress through four stages of development:10

1. Knows (knowledge)
2. Knows how (competence)
3. Shows how (performance)
4. Does (action)

Instead of attempting to measure directly ‘competence’, EPA assess trainees at the ‘Does’ level in the context of daily clinical practice. Descriptors of a typical EPA are shown in Table 1. For a more detailed sample EPA, refer to the worked example published by ten Cate using the task of completing a patient handover.3

Developing EPA for post-graduate training

The rapid international uptake of EPA into education and training programmes has been remarkable and perhaps reflects an underlying need for better assessment methods in CBE.

EPA are being incorporated into numerous post-graduate training curricula, including paediatrics, internal medicine, family medicine, psychiatry, obstetrics and gynaecology, and nursing.11-13 Full-scale implementation has been undertaken in Australia and New Zealand (psychiatry training) and the Netherlands (obstetrics and gynaecology training).11 Another notable example is the Association of American Medical Colleges’ list of EPA describing a core set of behaviours to be expected from all medical graduates entering residency.14

The suggested number of EPA for a full postgraduate programme is 20–30.15 The selected EPA should be ‘critical activities that constitute a specialty’, which can be unique to the practice setting or context where the assessment occurs.4 By definition, each EPA will require multiple competencies which can be mapped in a two-dimensional grid. EPA can also specify the stage of training, so as a trainee progresses through terms, a portfolio of completed EPA can develop. Indeed, the concept of using a digital portfolio to track EPA through a learner’s lifetime was recently proposed.15

However, there remain important questions on EPA development and implementation. How should EPA be selected? How should educators decide on the content, or the ‘Required knowledge and skills’ of EPA? What are appropriate ‘Assessment methods’?

ten Cate has suggested ‘...there is no single correct mode of description and application of EPAs…’.16 Accordingly, multiple approaches to EPA design have emerged recently highlighting both potential benefits and pitfalls of this educational tool.

The Royal Australian and New Zealand College of Psychiatrists provide a model example of how to select EPA and schedule them over the course of training.17 EPA were chosen through a college-wide consultative process using surveys and expert panels. Respondents provided feedback on whether trainees should be entrusted with a specific list of EPA by the first stage of training. The result was the selection of four EPA from a list of 30.

Building on such work, Aylward, Nixon and Gladding proposed a model for EPA assessment development using ‘resident handoff’ as an example.18 A nine-step process was used to create the EPA, which can be adopted by other institutions. Their rigorous methodology seems appropriate given that only a limited number of EPA form the defining activities for a particular specialty. Key aspects of their approach were wide consultation and an iterative process allowing for multiple revisions. Sources used for EPA development included literature reviews, curriculum material from medical boards and expert opinion. Behavioural descriptors for each level of entrustment were written.

Other approaches have included using a modified Delphi technique and more recently a sequential qualitative and quantitative mixed methods approach.19,20
However, such heterogeneity in the design process has led to significant variation in developed EPA. One potentially significant pitfall is producing an exhaustive list of detailed tasks resembling a checklist, losing the holistic value of EPA-based assessment. For example, a published list of 76 EPA for ambulatory practice in family medicine carries this risk. Further research in the area of EPA design is needed to inform this process.

Finally, the potential role of EPA in undergraduate medical education and internship has recently emerged. This could perhaps improve continuity between undergraduate and post-graduate medical training, as EPA are benchmarked against different levels of clinician supervision, which can be applied across clinical settings.

**Table 1** Descriptors of an EPA

<table>
<thead>
<tr>
<th>Title</th>
<th>A succinct title clearly describing the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Description of the activity – with inclusions and exclusions</td>
</tr>
<tr>
<td>Required competencies</td>
<td>Linking the EPA with a competency framework</td>
</tr>
<tr>
<td>Required knowledge, skills and attitudes (KSA)</td>
<td>A clear explanation of expectations for trainees regarding the required KSA. May refer to resources which reflect standards</td>
</tr>
<tr>
<td>Information sources to assess progress</td>
<td>Describe the sources of information used to make entrustment decisions.</td>
</tr>
<tr>
<td>Estimated stage of training when unsupervised practice may be reached (or supervision at a distance)</td>
<td>This will vary depending on the nature of the EPA and the training programme</td>
</tr>
<tr>
<td>Basis for formal entrustment decisions</td>
<td>Define who will assess the trainee, criteria for formal entrustment</td>
</tr>
</tbody>
</table>

The EPA includes (a) recognition of the dying patient, (b) participation in end-of-life discussions with the patient and family, (c) communicating with interdisciplinary health professionals, (d) written documentation and (e) prescribing appropriate pharmacotherapy.

Relevant domains of competence include: Communication Skills, Professionalism and Scholarship/Medical knowledge.

The trainee must have satisfactory knowledge to understand the overall medical condition of the patient, including: active medical problems, co-morbidities, required investigations, treatment options and prognosis. The Australian Palliative Care Therapeutic Guidelines provide a framework for the standards expected of trainees. A high level of communication skills is required to sensitively and professionally discuss end-of-life issues with the patient, family members and interdisciplinary healthcare professionals.

The trainee must be directly observed in caring for palliative patients, including reviewing documentation and prescribed medications. Feedback must be received from nursing staff and other relevant health professionals caring for the patient. The supervisor must be satisfied the trainee has provided safe, compassionate care and communicated effectively as a member of the treating team.

| Information sources to assess progress | Direct observation of trainee interactions with the patient, family members and healthcare professionals. Structured feedback from interdisciplinary health professionals caring for the patient |
| Estimated stage of training when unsupervised practice may be reached (or supervision at a distance) | Second year of basic physician training |

†More recent EPA examples have included behavioural descriptors at each level of entrustment to guide the observer and learner. EPA, Entrustable Professional Activity.

However, such heterogeneity in the design process has led to significant variation in developed EPA. One potentially significant pitfall is producing an exhaustive list of detailed tasks resembling a checklist, losing the holistic value of EPA-based assessment. For example, a published list of 76 EPA for ambulatory practice in family medicine carries this risk. Further research in the area of EPA design is needed to inform this process.

Finally, the potential role of EPA in undergraduate medical education and internship has recently emerged. This could perhaps improve continuity between undergraduate and post-graduate medical training, as EPA are benchmarked against different levels of clinician supervision, which can be applied across clinical settings.

**Is the workplace ready for EPA?**

Significant concerns have been raised regarding the application of EPA into constrained hospital-based training programmes. In a feasibility study evaluating implementation of internal medicine EPA, Hauer et al. identified multiple barriers, including limited trainee-supervisor contact and interns prioritising immediate work duties over learning activities.

EPA-based assessment hinges on trust, and trust takes time – a precious resource for both supervisors and trainees. Furthermore, trainee rotations may need to be adjusted to accommodate EPA-based training programmes. Factors such as this have led some authors to conclude that the ‘...flexibility of current workplaces is insufficient for EPA’. Given that evaluation studies of EPA-based curricula are still pending, one would be forgiven for maintaining status quo for the time being.

**Conclusion**

Let us return to the opening scenario. Can EPA help this supervisor? Perhaps the more important question is whether EPA can improve the quality and safety of care this patient receives. To quote Buhyan et al., ‘Ultimately, the EPA should be a list of what the public can expect from their family physicians’. In theory, an EPA-based
training programme can equip Simon’s supervisor to make an informed, safe entrustment decision. However, this assumes rigorous design and application of this educational tool in a supportive learning environment. We keenly await the progress and evaluation of EPA implementation to shed light on this question.

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