Implementing Entrustable Professional Activities as Outcomes in a German Undergraduate Medical Curriculum

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Abstract

How can we best prepare medical trainees for patient care? What makes a good doctor? These questions have guided curricular reforms in medical education for decades. A novel approach is represented by the integration of entrustable professional activities (EPAs), which are medical activities in the workplace that can be gradually entrusted to qualified personnel (ten Cate, 2005). Defined sets of EPAs are increasingly integrated as outcomes in medical curricula to structure learning, teaching and assessment. This thesis describes the process of defining and implementing a set of Core EPAs as outcomes for the undergraduate curriculum at the Charité - Universitätsmedizin Berlin (Charité).

The definition and content validation of Core EPAs is covered in the first three articles. The first article addressed the question of how a set of Core EPAs can be defined as outcomes for an undergraduate curriculum and reported on a three-round Delphi study conducted with physicians at the Charité. The relevance of defining EPAs that are adapted to a specific context was emphasized. The second article focused on the question of which EPAs beginning residents are expected to perform under distant supervision in the first days of residency, and it reported on the results of the Delphi study. A set of 12 Core EPAs was defined for the Charité context, including, for each EPA, a detailed description with a title; specification/limitations; conditions and implications of entrustment decisions; knowledge, skills, and attitudes; and links to competencies and assessment sources. The third article covered the content validation of the developed Core EPAs by means of a survey of graduates at the Charité. It studied the question of whether the defined Core EPAs represent realistic workplace expectations for beginning residents. The results found further evidence for the validity of the previously defined set of Core EPAs but mixed results with respect to the included medical procedures, which initiated discussion to reduce the list of procedures.

The first steps of implementing the Core EPAs in the medical curriculum are addressed in two additional articles. The fourth article focused on the question of whether an entrustment-supervision scale could be integrated into a standard objective structured clinical examination (OSCE) at the Charité. The entrustment-supervision rating was added to the assessment scheme, and assessors were surveyed on the inclusion of the scale. The findings supported arguments favouring the inclusion of entrustment ratings in an existing OSCE setting but also indicated some potential problems related to the usefulness of the scales in all OSCE stations and some doubts among assessors.

The fifth article aimed to build a basis for understanding the underlying question of how supervising physicians make the decision to entrust a trainee with an EPA. A conceptual model of the entrustment decision-making process was developed, which provides an overview of the potential interaction of different factors influencing the entrustment decision.

The results of this thesis contribute to the national and international movement of integrating EPAs as outcomes in undergraduate medical curricula. The defined Core EPAs serve as a foundation of the recently developed German Graduate Profile EPAs, which all German medical faculties are called upon to set as outcomes to better prepare students for the demands of the workplace.

Zusammenfassung

Wie können Studierende am besten auf die Patientenversorgung vorbereitet werden? Was macht einen guten Arzt oder eine gute Ärztin aus? Seit Jahrzehnten prägen diese Fragen die curriculare Weitentwicklung von medizinischer Aus- und Weiterbildung. Das Konzept der „Entrustable Professional Activities“ (EPAs) wird vermehrt als übergeordnetes Lernziel in medizinischen Curricula eingesetzt, um die Lehre und das Lernen und Prüfen von Studierenden zu strukturieren. EPAs sind ärztliche Tätigkeiten, die schrittweise an qualifiziertes Personal anvertraut (entrusted) werden können (ten Cate, 2005). Diese Dissertation begleitete den Prozess, Core EPAs als outcomes für den Medizinstudiengang der Charité-Universitätsmedizin zu definieren und zu implementieren.

Die Definition und inhaltliche Validierung von Core EPAs wird in den ersten drei Artikeln behandelt. Der erste Artikel beschäftigte sich mit der Frage, wie ein Set von EPAs als outcomes für einen Medizinstudiengang definiert werden kann und berichtete über die an der Charité durchgeführte Delphi Studie mit drei Runden. Es wurde hervorgehoben, dass es vor allem wichtig ist, spezifisch an den Kontext angepasste EPAs zu entwickeln. Der zweite Artikel fokussierte sich auf die Frage, welche EPAs von Assistenzärzten*innen in den ersten Tagen der Weiterbildung unter entfernter Supervision durchgeführt werden. Es wurden die Ergebnisse der Delphi Studie an der Charité berichtet, in der 12 Core EPAs ausgearbeitet wurden. Jede EPA enthält eine detaillierte Beschreibung, inklusive eines Titels, Spezifikationen/Limitationen, Bedeutung der Entrustment-Entscheidung, Kenntnisse, Fertigkeiten und Haltungen, Kompetenzbereiche und Assessment.

Der dritte Artikel berichtet über die inhaltliche Validierung der Core EPAs anhand einer Befragung von Absolventen*innen der Charité. Es wurde der Frage nachgegangen, ob die definierten Core EPAs realistische Erwartungen für beginnende Assistenzärzte*innen darstellen. Die Ergebnisse lieferten zum einen weitere Anzeichen dafür, dass die Core EPAs die Erwartungen widerspiegeln. Auf der anderen Seite fanden sich durchmischte Ergebnisse bezüglich der enthaltenden ärztlichen Prozeduren.

Zwei weitere Artikel befassten sich mit den ersten Schritten die notwendig sind, die Core EPAs im Medizinstudiengang zu implementieren. Der vierte Artikel untersuchte, ob eine entrustment-supervision Skala der objective structured clinical examination (OSCE) an der Charité hinzugefügt werden kann. Die entrustment-supervision Skala wurde dem Bewertungsbogen hinzugefügt und Prüfer*innen evaluierten die Integration der zusätzlichen Skala. Die Ergebnisse unterstützten zum einen Argumente für den Einsatz der Skala in einem bestehenden OSCE, lieferten jedoch auch Hinweis auf Probleme im Zusammenhang mit der Nutzbarkeit der Skala in allen OSCE Stationen und Zweifeln von Prüfer*innen.

Der fünfte Artikel zielte darauf ab eine Basis für unser Verständnis zu schaffen, wie Ärzte*innen die Entscheidung treffen, einem Studierenden eine EPA anzuvertrauen. Ein

konzeptuelles Model des „entrustment decision-making“ process wurde entwickelt, welches eine Übersicht der potentiellen Einflussfaktoren und deren Interaktionen liefert.

Die Ergebnisse dieser Dissertation trugen zu der nationalen und internationalen Bewegung bei, EPAs als outcomes in Medizinstudiengänge zu implementieren. Die definierten Core EPAs bildeten eine Grundlage für die kürzlich entwickelten EPAs des deutschen Absolventenprofils. Alle deutschen medizinischen Fakultäten sind angehalten, diese als outcomes zu integrieren, um Studierende besser auf die Anforderungen am Arbeitsplatz vorzubereiten.

Chapter 1

Introduction

Introduction

Imagine being a patient entering a hospital to get treatment for severe abdominal pain. The physician taking your medical history and performing the physical examination is a first-year resident who received his medical degree one month ago. How much do you trust this resident to take good care of you? Does he have the right knowledge? Is he equipped with the right skills to detect the relevant clinical signs? His qualification largely depends on the medical education he received during his undergraduate medical training, which is subject to a process of continuous advancement. In the last century, the focus in undergraduate medical education was mainly on the transfer of knowledge (Norman, 2012). Currently, medical graduates need more than a broad knowledge base, for instance, the skills of communication and interaction with patients and colleagues as well as the application of the right diagnostic tests, and calls have been made to shift from knowledge-based to competency-based curricula (ten Cate & Billett, 2014). Several frameworks for the competencies a “good physician” should possess have been defined and implemented in undergraduate medical curricula (Harris et al., 2010). The most recent advancement in competency-based curricula is likely the definition and integration of “entrustable professional activities” (EPAs), which can be gradually entrusted to medical trainees in the workplace (Meyer et al., 2019; ten Cate, 2005). The concept of EPAs bridges the gap between the theoretical consideration of necessary competencies and the actual work that needs to be done in the workplace. Taking a history and performing a physical examination is an example of an EPA, which requires a trainee to demonstrate a range of necessary competencies. EPA-based medical curricula aim to prepare trainees for the activities they are expected to perform without direct supervision at the end of a training phase.

The focus of this thesis is the definition of a set of Core EPAs to serve as overarching outcomes for the context of the competency-based undergraduate curriculum at the Charité - Universitätsmedizin Berlin (henceforth, Charité) and some first steps in their implementation. Chapter one provides background information on the medical education system in Germany, the EPA concept, the necessary steps of implementing an EPA-based undergraduate curriculum and the setting at the Charité. Chapters two, three and four cover the content validation of end-of-undergraduate training EPAs for the Charité context. Chapters two and three describe the approach to defining the content of a set of EPAs in a three-round Delphi study with domain experts (physicians) at the Charité. Chapter four describes a survey that was conducted to elicit empirical data from graduates of the Charité on their workplace involvement in the first months of residency based on the defined EPAs. The results allow further refinement of the EPAs to increase their content validity for the Charité context.

The definition of outcomes is key to the curriculum development process in competency-based education; however, the implementation of these outcomes is achieved when students´ teaching, learning and assessment are aligned with them. Outcome

implementation is a multistep process, and two essential elements regarding the assessment of EPAs are covered in this thesis. Chapter five explores the introduction of an entrustment rating scale in the regular practical examinations of students. Chapter six introduces a conceptual framework for how physicians make the decision to entrust trainees to perform professional activities under a certain level of supervision. Chapter seven discusses the results, limitations and practical implications of the presented studies, as well as directions for future research in light of the current literature.

Medical education in Germany

In the last century, the face of medicine and the training of physicians changed remarkably due to the changing demands on the health care system. The amount of medical knowledge rose exponentially, and new methods, techniques, and approaches have been discovered and developed in combatting diseases. Medical training in industrialized countries is normally divided into under- and postgraduate education (Wijnen-Meijer et al., 2013), and both phases have undergone severe transformations to optimize the qualifications of physicians for patient care. The leading question remains: What makes a good doctor?

In the beginning of the 20th century, medical education was characterized by knowledge-based curricula. Undergraduate education in Germany was situated in universities and was built around scientific knowledge and findings (Bonner, 2006). For that time, this system was exemplary and served as an inspiration for the Flexner report, which proposed changes to enhance the quality of undergraduate curricula in North America and shaped medical undergraduate curricula sustainably (Flexner, 1910). In 1927, the novella of the examination regulations (Novella der Prüfungsordnung) officially constituted the division of undergraduate curricula into a preclinical and a clinical phase (Schleicher, 1997). In the preclinical phase, students were taught natural sciences to gain an understanding of the normal functioning of the human body. In the clinical phase, students learned in theory about different clinical subjects and their diseases. Until today, the majority of undergraduate curricula in Germany have retained this subdivision, even though several innovations and improvements have been implemented over time. In 1970, the Medical Licensing Regulations for Physicians (Approbationsordnung für Ärzte, ÄApprO) were established, which are published by the Federal Ministry of Health with the consent of the Upper House of Parliament. This set of regulations defines the legal framework of undergraduate medical curricula by specifying the number of required training hours, learning content, required internships and examinations. Additionally, it provides recommendations for the improvement of medical education. Since its introduction, various new editions have been published, and several changes to the traditional curriculum have been proposed, among others, to strengthen the practical training of students, to integrate clinical subjects, to include learning formats other

than lectures, to define learning outcomes and to train relevant medical competencies (Schleicher, 1997). However, some propositions of the ÄApprO have only been implemented hesitantly. At the turn of the century, medical students and experts voiced their concerns with the quality of undergraduate medical education, as the curricula did not adequately prepare students for the start of postgraduate education or ultimately for patient care (Begenau & Kiessling, 2019; Robert Bosch Stiftung, 1995). As a consequence, a "model" clause has been implemented in the ÄApprO, allowing medical faculties to develop and implement new forms of curricula that have some greater freedom in comparison to the restrictions of the traditional curriculum (§41 ÄApprO, 2002). Today, 14 out of 36 medical faculties have developed and implemented a reformed curriculum, a number that is increasing (Kiessling et al., 2019). Inspired by innovative curricula reforms worldwide, reformed curricula in Germany are characterized by their competence orientation, new learning and teaching formats, the integration of learning content, early patient contact and emphasis on scientific elements (Wissenschaftsrat, 2014). However, although reformed curricula have some freedom regarding the regulations of the ÄApprO, they still have to adhere to the principal regulations (§1 ÄApprO, 2002). Both traditional and reformed curricula schedule 5500 training hours, which results in six years and three months of training. In the course of study, students have to complete a first-aid course, a three-month nursing internship and four months of internships in medical specialities. The last year is a long-term clerkship called the practical year, where students spend four months in each of three different specialities (internal medicine, surgery, and an elective subject). Two state examinations have to be passed to complete the undergraduate study and to receive the approbation. One written examination takes place before the final year, and one practical examination is held after it. Only if students receive the approbation can they officially have a licence to practise medicine and start postgraduate medical training.

Residency training is a completely separate training phase lasting 5-6 years that takes place in hospitals and medical centres. Beginning residents are involved in the care of patients from day one. In Germany, the trend towards specializing in a field started in the 19th century, even though "specialization" at that time meant gathering some experience in a field (Hoppe, 1997). In 1968, the first version of the exemplar of training regulations (Musterweiterbildungsordnung, MWBO) was published by the German Federal Chamber of Physicians, which defined the relevant specialties, a time frame and a general proposal of learning objectives. The MWBO represents the basis for the training regulations issued by the Regional Chambers of Physicians for each federal state. The education of residents is principally a federal state matter and is not as rigorously regulated as undergraduate education. German postgraduate education is scarcely structured by detailed curricula but is guided by the philosophy of learning by doing (van den Bussche et al., 2017; van den Bussche

et al., 2018). This is in full contrast to postgraduate education in other industrialized countries, where it is often attached to academic centres and increasingly structured by competency frameworks (Weggemans et al., 2017).

Competency-based medical education

The concept of competency-based medical education has received repeated interest from the medical education community. In 1978, the WHO published a book on "Competency-Based Curriculum Development in Medical Education" (McGaghie et al.), emphasizing the advantages of reforming traditional curricula. The overarching idea is to define the competencies that constitute a good physician, such as communication with patients or collaboration with team members. However, to date, different understandings of how to define competencies have been proposed. In an attempt to create a common understanding, Frank and colleagues defined competency as "an observable ability of a health professional related to a specific activity that integrates knowledge, skills, values, and attitudes. Since competencies are observable, they can be measured and assessed to ensure their acquisition. (…)" (2010a, p. 641). Based on a literature review, Frank and colleagues further defined competency-based medical education as "an approach to preparing physicians for practice that is fundamentally oriented to graduate outcome abilities and organized around competencies derived from an analysis of societal and patient needs. It deemphasizes time-based training and promises greater accountability, flexibility, and learner centeredness" (2010b, p. 636). Around the turn of the century, medical schools in Western societies developed the first competency-based frameworks for both post- and undergraduate curricula. These frameworks are united in their attempt to define the competencies that trainees are expected to acquire during a specific training phase. The "Outcomes for graduates" Initiative of the UK and the Netherlands' National Undergraduate Framework are examples of competency frameworks for undergraduate education (General Medical Council, 2018; Laan et al., 2010). Well-known examples of postgraduate education are the Canadian CanMEDS model and the American ACGME outcome project (Edgar et al., 2020; Frank et al., 2015). The most influential framework is the CanMEDS model, as it sustainably shaped the competency frameworks for both under- and postgraduate curricula around the world (van der Lee et al., 2013). The CanMEDS framework attributes several roles to a physician, which are all linked to specific competencies. First, physicians need to be *medical experts* who adequately apply medical knowledge and abilities. They need to be able to talk to the patients in an appropriate manner (*communicator*) and to collaborate with other physicians and other professions (*collaborator*). Physicians are required to take on the role of a *leader* to guide others in the decision-making process and the role of a *health advocate* to improve the health of patients. Additionally, physicians need to engage in lifelong learning to ensure optimal patient care

(*scholar*) and are encouraged to act professionally (*professional*). The framework defines, for each of the seven roles, the key competencies (28 in total) and enabling competencies (88 in total), which describe in more detail the expectations for physicians (Frank et al., 2015). The role of the communicator includes, for example, five key competencies and 17 enabling competencies specifying adequate communication during patient encounters.

The CanMEDS framework and other available frameworks have significantly influenced the content of undergraduate competency-based curricula in Germany. In contrast to other countries, competency-based medical education is primarily found in German undergraduate curricula, as postgraduate training is scarcely structured by a curriculum (Kadmon et al., 2017; Nikendei et al., 2009). Medical schools, which have already implemented a reformed curriculum, most often create their own set of competencies as outcomes, resulting in a multitude of different outcome catalogues. The Association of Medical Faculties in Germany (Medizinischer Fakultätentag, MFT) set out to develop a “National Competence Based Catalogues of Learning Objectives for Undergraduate Medical Education” (NKLM) that aims to function as a guideline for medical faculties implementing competencies as outcomes for their curricula (Fischer et al., 2015). The first version of the NKLM was published in 2015, and there was a revised version in 2021 (MFT, 2021). The importance of the acquisition of competencies, at best in practical training, was also emphasized by the “Masterplan Medical Studies 2020”, which outlines the steps all undergraduate medical curricula should take to enhance their quality (BMBF, 2017).

The promise of competency-based medical education is to better prepare physicians for practice by imparting the required competencies and by ensuring that all graduates have acquired them. This is in contrast to former curricula, which are also referred to as a tea bag model: If a trainee stays in a curriculum for a sufficient time, it is assumed that the graduate possesses all relevant competencies (Snell & Frank, 2010). However, competency-based curricula are complex to develop and challenging to implement, as competencies need to be defined, trained and assessed (Carraccio & Englander, 2013). The selection of competencies as outcomes of a curriculum is the first critical step. Critics point out that some competencies are formulated abstractly and that the developed frameworks tend to be too detailed (Huddle & Heudebert, 2007). For example, to capture the relevant communication competencies of a physician, one can differentiate between all possible person groups with whom the physician needs to communicate (patients, family members of patients, other physicians, colleagues from other professions) and all the specific situations in which the physician needs to interact with them. To capture all facets of a competent physician, too many elements that are too specific tend to be included in competency frameworks, making them overly detailed and too broad to implement. However, if the defined competencies are difficult to capture or if too many competencies are defined as outcomes, it will become difficult if not impossible to teach and

assess them in an appropriate manner (ten Cate & Scheele, 2007). Competencies are best trained and assessed in the workplace, a notion that is supported by the theory of situated learning (Lave et al., 1991). This theory postulates that learning should occur in the context in which learners will apply the competencies and that learners need to become a part of the workplace community. A high quality of workplace learning and assessment is a precondition for competency-based curricula (ten Cate et al., 2015).

Entrustable professional activities

In 2005, Olle ten Cate first described the concept of EPAs. As a professor of medical education and program director of undergraduate medical education at University Medical Centre Utrecht, he experienced the difficulties physicians have with the assessment of competencies and thought of a way to bridge the gap between the theoretical framework and clinical practice. He proposed a shift in focus away from the description of a competent physician and towards the work that needs to be done in the workplace. EPAs are tasks that can be found in professional working life that can gradually be entrusted to a trainee (ten Cate, 2005). EPAs possess the following characteristics. “They:

1) are part of essential professional work in a given context;
2) must require adequate knowledge, skill and attitude, generally acquired through training;
3) must lead to recognised output of professional labour;
4) should usually be confined to qualified personnel;
5) should be independently executable;
6) should be executable within a time frame;
7) should be observable and measurable in their process and their outcome, leading to a conclusion (‘well done’ or ‘not well done’); and
8) should reflect one or more of the competencies to be acquired.”
   (ten Cate, 2005, p. 1177).

Taking a medical history and performing a physical examination on a patient is an essential professional activity students learn to perform in undergraduate medical education. While a student with little experience might only be allowed to observe a physician performing this activity, a graduating student is often able to carry out this task without a physician being present in the room. Over the course of training, the students gain increasing competence and are gradually entrusted to perform the activity under decreasing levels of supervision.

Gradually entrusting the trainee to take over more responsibility and to engage more and more in daily workplace activities can be found quite commonly in the training of different occupations, whether the trainee is becoming a baker, a lawyer, a gardener, an architect, or any other profession. The Dreyfus model of skill acquisition (Dreyfus & Dreyfus, 1986)

describes how learners acquire skills or competence during training by passing through five stages: 1) Novice; 2) Advanced beginner; 3) Competent; 4) Proficient; 5) Expert. Carraccio and colleagues applied this model to the acquisition of clinical skills (2008). As novices, medical trainees begin with no experience and need to follow rules and apply analytic reasoning to a patient's case. Advanced beginners still have to follow the rules but have gained some experience and recognize familiar situations. Competent trainees have developed a sense of responsibility and can manage most situations, as they know all the rules and recognize patterns. Once trainees are proficient, they have gathered so much experience that they primarily rely on pattern recognition and feel comfortable with unfamiliar situations. As experts, they solve clinical problems intuitively and focus foremost on features deviating from the standard. The more competently medical trainees act, the more independent they can be in performing professional activities. If a trainee is deemed competent, he or she can be entrusted to perform an EPA unsupervised (ten Cate et al., 2010). A supervising physician determines, on a daily basis for numerous trainees and professional activities, the necessary level of supervision to facilitate the trainees' learning while ensuring patient safety.

The introduction of the EPA concepts thus builds on two core elements of medical training, professional activities and supervision levels, which are also referred to as entrustment-supervision levels (ten Cate et al., 2020). Table 1 displays the entrustment-supervision scales that have been defined for under- and postgraduate education (Peters et al., 2017). Five entrustment-supervision levels have been defined for postgraduate education, ranging from not being allowed to perform the EPA to supervising others in practice (ten Cate et al., 2010). In the process of adapting the levels to the undergraduate setting, Chen and colleagues (2015) added more granular levels to the original scale to better depict the developmental progression of the learners.

EPAs and competencies

The distinction between EPAs and competencies has led to some confusion amongst physicians in the workplace. Is communication with patients a competency or an EPA? And what about taking a blood sample? The distinction becomes very important when a set of EPAs is being developed for a curriculum. To guide this process, one general rule is that competencies are attributes of a person, and EPAs describe the tasks that must be done in the workplace that can be entrusted to qualified personnel (ten Cate, 2013). The EPA concept does not replace the competency approach but merely extends it, as each EPA integrates a multitude of competencies (ten Cate & Scheele, 2007). For example, to take a history and perform a physical examination safely (that is, perform an EPA), the trainee needs to possess a wide range of competencies. Among other important aspects, he or she requires the necessary medical knowledge, needs to be able to evaluate the overall impression of a patient,

and needs to talk to the patient in an adequate manner (open, respectful and patient-centred communication; verbal and non-verbal communication; attention to diversity). Thus, by assessing the trainee's ability to take the medical history and to perform the physical examination, one simultaneously assesses whether the trainee possesses the required competencies. In entrusting a trainee to perform an EPA without supervision, he or she is said to have mastered all of the required competencies.

Table 1

Entrustment-supervision scales

Entrustment-supervision scale for postgraduate education	**Entrustment-supervision scale for undergraduate education**
1. Not allowed to practise EPA	1) Not allowed to practise EPA a) Inadequate knowledge/skill (e.g., does not know how to preserve sterile field); not allowed to observe b) Adequate knowledge, some skill; allowed to observe
2. Allowed to practise EPA only under proactive, full supervision	2) Allowed to practise EPA only under proactive, full supervision a) As coactivity with supervisor b) With supervisor in room ready to step in as needed
3. Allowed to practise EPA only under reactive/on-demand supervision	3) Allowed to practise EPA only under reactive/on-demand supervision a) With supervisor immediately available, all findings and decisions double checked b) With supervisor immediately available, key findings and decisions double checked c) With supervisor distantly available (e.g., by phone), findings and decisions promptly reviewed
4. Allowed to practise EPA unsupervised	4) Allowed to practise EPA unsupervised a) With remote monitoring (e.g., next day check-in for learner questions) b) Without monitoring
5. Allowed to supervise others in practice of EPA	5) Allowed to supervise others in practice of EPA

Note: Table adapted from Peters et al., 2017

Spread of the EPA concept

Since the EPA concept was first proposed in 2005, it quickly received the attention of the medical education community. Originally, it was proposed to complement postgraduate education curricula, as residents are directly involved in patient care and perform professional activities on a daily basis. EPAs convert this daily work into a structured form to make it transparent to both learners and supervisors. In 2019, a literature review by O'Dowd and colleagues identified 15 specialities for which EPAs have been defined, including internal medicine (Hauer et al., 2013), family medicine (Shaughnessy et al., 2013), psychiatry (Boyce et al., 2011) and anaesthesiology (Wisman-Zwarter et al., 2016).

As competency-based medical education is also found in undergraduate education, the question arose of whether EPAs can also be applied in this earlier stage of training (Chen et al., 2015). On the one hand, students are not as routinely involved in patient care and are not legally authorized to perform any activity without the supervision of physicians. Additionally, EPAs should be assessed in the workplace, and students most often have only short-term internships, where opportunities for workplace-based assessments are rare. On the other hand, complaints were voiced repeatedly, both nationally (Gartmeier et al., 2017; Ochsmann et al., 2010; Ochsmann et al., 2011) and internationally (Monrouxe et al., 2017; Young, 2011), that graduates are not well prepared for practice. Beginning residents are paradoxically expected to perform various professional activities (Raymond et al., 2011), and it would only be logical to prepare graduates for these expectations through undergraduate curricula (Englander et al., 2016). The first approach to defining EPAs for undergraduate curricula was conducted by the Association of American Medical Colleges (AAMC), which published a set of Core Entrustable Professional Activities for Entering Residency (CEPAER) that graduates should be able to perform without supervision within the first days of residency (AAMC, 2014). The published materials included detailed guides for curriculum developers and for faculty and learners, describing in detail the components of the EPA framework and providing suggestions for its integration into undergraduate curricula. Worldwide, these materials inspired medical faculties to implement EPAs in undergraduate education, and various Core EPA frameworks have since been developed (AFMC, 2016; Michaud et al., 2016; Meyer et al., 2019; ten Cate et al., 2018).

Core EPAs have the potential to enrich undergraduate curricula, as they could provide both students and supervising physicians with an understanding of learning expectations, could enable performance feedback for students and could provide a basis for students to self-direct their learning (ten Cate et al., 2015). They might foster students' development of practical competence and might better prepare them for patient care (Sterkenburg et al., 2010). Both supervising physicians and trainees rated an EPA-based evaluation tool positively, with students praising its usefulness in establishing performance goals and an impression of their

readiness for practice (Bramley et al., 2020; Marshall et al. 2020). This could not only lead to enhanced patient safety and reduced health care costs but could also result in a better experience of the course of study. Self-determination theory assumes that people have an inherent growth tendency and that three factors (competence, relatedness and autonomy) influence intrinsic motivation, self-regulation and well-being (Ryan & Deci, 2000). The effective involvement of students in the workplace could satisfy these three basic psychological needs (Jonker et al., 2018). Working with the care team could enhance their feeling of “relatedness”, the training of professional activities their feeling of “competence” and the increasing levels of responsibility their feeling of “autonomy”.

Concerns have been voiced regarding the lack of objectivity of assessments with entrustment-supervision scales (Kane & Lorant, 2018; Krupat, 2018). The performance of an examinee should be assessed without any influence of personal preferences, interests or opinions (de Groot, 1961; van der Vleuten et al., 1991), but entrustment-supervision scales partly build on the intuition of assessors (Krupat, 2018). A counterargument is that workplace-based assessments in the clinical context are all subjective in nature and that it would be advantageous to embrace this subjectivity and to make it explicit (ten Cate & Regehr, 2019; ten Cate et al., 2020).

Building an EPA-based undergraduate curriculum

Faculties that find the idea of Core EPAs as outcomes appealing have to undertake numerous steps to implement an EPA-based curriculum (Obeso et al., 2018; ten Cate et al., 2018). Following the definition of the Core EPAs, aspects concerning education, learning and assessment need to be aligned with these outcomes. In what follows, the key steps are described in more detail.

Step 1: Identifying EPAs

The identification of Core EPAs that the faculty would want to implement as outcomes is the beginning. This is commonly performed by gathering the opinions of stakeholders, for example, via group discussions, surveys or structured group consensus procedures such as Delphi studies or the nominal group technique (O’Dowd et al., 2019; ten Cate et al., 2015). Each defined EPA should include several categories to provide a comprehensive understanding of the activity for both the faculty and the learner (Chen et al., 2016; ten Cate, 2013). First, a ‘title’ is needed to indicate the task at hand. Second, the ‘specification/limitations’ should describe in detail which elements are included in the EPA and which are not. This category is guided by the questions of which steps need to be taken to perform the activity and which patient groups or clinical presentations should be treated by the trainee and which should be excluded. Third, the relevant ‘knowledge, skills and attitudes’ (KSA) should be listed, as well as, fourth, the

‘most relevant domains of competence’ that link the EPAs to a relevant competency framework. Fifth, the relevant ‘assessment sources’ should list which sources could be used as the basis for an entrustment decision. Finally, one defines the ‘expected supervision level at the stage of training’, indicating at which point in the training the trainee should reach which level of supervision.

The EPA concept builds upon the pragmatic assessment of professional activities that are routinely part of the work. The identification of too many potentially relevant EPAs would not be likely to lead to an improvement of the situation but would only add more work. The identification of relevant EPAs for a curriculum is thus a critical step. The framework should not include too many or too few activities, and they should not be too small or too large (ten Cate, 2018). As a rule of thumb, it has been proposed to limit the number of EPAs to 20-40 for an entire curriculum (ten Cate, 2018). Whether an activity qualifies as an EPA also depends on the possibility of entrusting it. Only if the decision to entrust a trainee to perform the activity without supervision is meaningful and represents a developmental step in the progression toward becoming a physician should the activity be included in an EPA framework (ten Cate et al., 2015).

Step 2: Integration of EPAs into the curriculum

As complex as the definition of an EPA framework is, it is only the beginning of the endeavour (Mulder et al., 2010; ten Cate et al., 2015). The EPAs need to be integrated into the curriculum in a meaningful way, by linking the EPAs to the learning content and by creating and pointing out learning and assessment opportunities. One helpful approach to achieving this is the concept of “nested" EPAs. The first time medical students are involved in patient care and are in fact performing medical activities on patients is challenging, even if the first tasks are small in nature, involve few responsibilities and bear minimal or no risks for the patients. Examples include taking blood pressure and checking in on a stable patient. The more experience and training students gain, the broader and more complex the activities become, and the more responsibilities are involved. However, smaller activities are still relevant, as they represent the building blocks of broader activities. Figure 1 provides an example of how smaller EPAs might be “nested” within larger EPAs. The concept of nested EPAs reflects and illustrates the continuity of the medical profession (Chen et al., 2015). The professional activities in which students are trained form the basis for the activities residents carry out, which in turn form the basis for the practice of a specialist (AAMC, 2014).

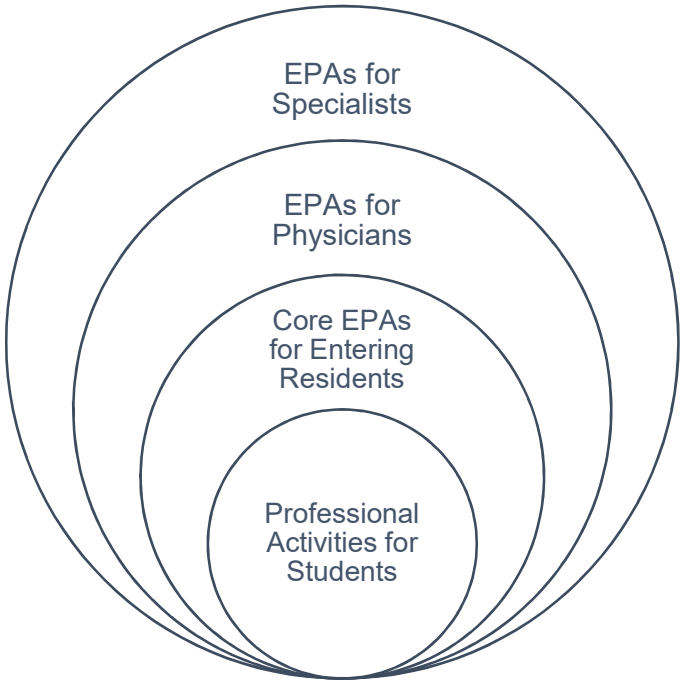

Figure 1. Nesting of EPAs in Medical Training

To integrate a set of Core EPAs as outcomes in a curriculum, one could identify the smaller activities that build the basis for the broader Core EPAs and structure students' learning experiences accordingly. However, nested EPAs also show the potential danger of breaking down every professional activity into too many smaller activities to gain a "complete" overview of all possible activities physicians might encounter during training (ten Cate et al., 2015). Therefore, it is important to keep in mind that the complete EPA framework should not add more workload to the faculty and learner but should mainly build on the activities that naturally occur. In the end, the defined EPAs need to be trained and assessed in the curriculum.

Step 3: Development of an assessment system

The development of an integrated and coherent assessment system builds on the alignment of EPA assessments with traditional assessments. The assessment of EPAs is different, as the focus is not on the comparison of students' performance against a defined standard but on the decision of whether the students' performance is good enough that they can take care of patients (ten Cate, 2017). It has been proposed to define the expected level on the entrustment-supervision scales that a student should reach at a given point in the curriculum for the defined Core EPAs and to ensure that students receive the respective "summative entrustment decisions" (ten Cate et al., 2015). Summative entrustment decisions are structural, as they grant trainees the permission to perform a specific EPA under a decreased level of supervision. These decisions should not be made by a single supervising physician but by a

group of supervising physicians, which makes this decision based on sufficient evidence (Brown et al., 2017). In contrast, ad hoc entrustment decisions are formed on a daily basis when supervising physicians decide whether a trainee can perform a specific EPA under the given circumstances on a particular patient (ten Cate, 2013). Ad hoc entrustment decisions are thus made in the moment and are limited in time.

The basis for both ad hoc and summative entrustment decisions could be different kinds of assessments, covering all levels of Miller's pyramid of clinical skills/competence/performance assessment (Miller, 1990). The four levels, starting from the bottom, are as follows: Knows (Knowledge), Knows How (Competence), Shows How (Performance) and Does (Action). The higher the level, the more complex the assessment, which leads to measurement inaccuracy (Miller, 1990). Whether students know important medical facts can be assessed rather reliably and robustly via written examinations, such as multiple-choice questions, which are commonly used in undergraduate education (Yudkowsky et al., 2019). The next level is "knows how", where students need to demonstrate that they can apply their knowledge to solve theoretical clinical problems. This could be assessed via essays or via case-based discussions, where the supervising physicians question a student about a patient case, including its risks and potential complications, as well as about the implications of theoretical alterations of the patients' symptoms or unexpected findings (Peters et al., 2017). The "shows how level" could be assessed, for example, via simulations or objective structured clinical examinations (OSCEs), where students have to prove their competence in artificial situations with or without simulation patients. The "does" level is assessed in the workplace, where students actually perform professional tasks, e.g., EPAs. Various forms of naturally occurring workplace-based assessments can be utilized (Peters et al., 2017). Directly observing the trainee performing an EPA and then providing detailed feedback for improvement, as well as longitudinal observation of the trainee's performance over a timespan, are optimal to gain an impression of his or her professional development. Another way to assess students' competence is by evaluating their work products, such as their entries in health records or their reports (Peters et al., 2017).

To base the entrustment decision on the available performance indicators, the assessment results and previous entrustment decisions should ideally be summarized in an electronic portfolio documenting the student's learning trajectory (ten Cate et al., 2015; van der Schaaf et al., 2016). This is of help for the supervising physician, but the student could also use the accumulated data on his or her own professional development to reflect on his or her own strengths and weaknesses to foster self-directed learning and learner ownership (Peters et al., 2017).

Step 4: Faculty development on EPAs

The implementation of any curricular reform should be accompanied by faculty development to heighten the acceptance among the faculty and the chance of successful reform (Snell, 2014). The key stakeholders that have been identified for the process of implementing EPAs in an undergraduate curriculum are students, didactic faculty, residents, supervisors, portfolio coaches, curriculum deans, resource managers and faculty developers (Lupi et al., 2018). The stakeholders need to see how they and all faculty benefit from this reform and the potentially associated work (Lupi et al., 2018). They all should have a common understanding of the EPA concepts and their implementation in the curriculum to foster communication among them. Workshops, trainings and information material on EPAs and the related concepts should be provided.

Especially students and physicians involved in education need to have an overview of the expected outcomes for students in order to organize and structure the learning and training accordingly. They also need to get accustomed to making the entrustment decisions explicit and transparent and should have an understanding of the role of trust and the impacting factors on the entrustment decision. The literature, for example, differentiates between three forms of trust: presumptive trust, initial trust, and grounded trust (Peters et al., 2017). The reputation of a student or the knowledge that he or she is in the fifth study year results in presumptive trust. When the student has performed a few activities and provided some insight into his or her competence, initial trust emerges. However, only if a supervising physician can gather a certain amount of information on a student, for example, by means of an e-portfolio, can grounded trust emerge. Needless to say, grounded trust is the best basis for an entrustment decision, but ad hoc entrustment decisions are commonly based on presumptive or initial trust as well (Peters et al., 2017). Supervising physicians should therefore be trained in reflecting on the reasons why they feel unsafe or safe in letting a student take care of a patient. It is thereby also helpful to be aware of the factors that have been described as influencing the entrustment decision (ten Cate et al., 2016). These can be grouped into the following categories: factors related to the trainee, the supervising physician, the context and circumstances, the professional activity and the relationship between the trainee and the supervising physician (ten Cate et al., 2016). Some of these factors, such as the competence of the trainee, the experience of the supervising physician and the risk involved for the patient, are probably factors that students and physicians expect to exert an influence. However, students, for example, should be mindful that their honesty and reliability are also relevant and that supervising physicians pay attention to whether one is able to recognize one’s limitations (ten Cate et al., 2016). Physicians should be aware that their own general propensity to trust other people may have an influence on their willingness to entrust students with activities (ten Cate et al., 2016).

Medical students are used to being competitive and to striving for the best performance. However, the entrustment concept implies the growth of competence over time by starting with not being allowed to perform an activity (ten Cate et al., 2010). The student is measured against a standard that he or she needs to reach at a future point on the professional path, and feedback along the way is meant to direct their learning. Concerns have been voiced that students might struggle with this approach, as they, at some level, assume that they somehow fail when they are not able to perform an activity with a certain level of autonomy and are reluctant to ask for help when needed (Branfield et al., 2020; Karp et al., 2019; Martin et al., 2020; Watling and Ginsburg, 2019;). It is thus important that students and supervising physicians develop a profound understanding of the new concepts and the implications that are associated with them as they share the responsibilities of the upcoming modifications (Sohrmann et al., 2020). The process of implementing these profound changes to the curriculum and training students and supervising physicians is very complex and requires both time and financial resources (Hauer, 2019; Obeso et al., 2018).

Implementing EPAs as outcomes in the undergraduate curriculum at the Charité

The research conducted in the framework of this dissertation accompanied the implementation of Core EPAs in the undergraduate curriculum at the Charité - Universitätsmedizin Berlin. The Charité is one of the largest university hospitals in Europe, offering 11 different study programmes to over 8000 students at four different campuses (Charité - Universitätsmedizin Berlin, 2021a). The Charité was the first German medical faculty to offer a reformed curriculum to a subgroup of students, in 1999 (Begenau & Kiessling, 2019; Burger, 2006), and was one of a few to implement a completely new integrated, competency-based Modular Curriculum of Medicine (MCM). Between 2010 and 2016, the MCM was designed and implemented in a complex, faculty-wide process and successively replaced the traditional curriculum (Hitzblech et al., 2019; Maaz et al., 2018). The team that managed the curriculum development process was located at the Dieter Scheffner Centre for Medical Education and Educational Research (DSFZ) under the leadership of the Dean's Office of Study Affairs. Today, approximately 300 medical students are enrolled each semester in the MCM, and 200 professors and 2000 faculty members from approximately 100 departments are involved in teaching (Maaz et al., 2018).

Structure of the modular curriculum of medicine

The MCM is an outcome-oriented modular curriculum lasting six years, with the sixth year being the practical year. The curriculum is characterized by early patient contact, a focus on clinical competence, a scientific orientation, the inclusion of interdisciplinary teaching formats and the consideration of gender and diversity aspects (Guse & Kuhlmey, 2018; Hitzblech et al., 2019; Maaz et al., 2018). Basic science teaching and clinical and patient-based teaching

are integrated over the whole curriculum, which is represented by learning spirals covering the modules up to the 10th semester. Lectures and small group courses are complemented by practical courses such as bedside teaching, short-term clerkships, and examinations, as well as interactive simulations (Studienordnung des Modellstudiengangs Medizin der Charité – Universitätsmedizin Berlin, 2018, StO MSM, 2018). The modules are additionally linked by longitudinal courses such as problem-based learning courses, communication skills, teamwork training and scientific skills training (Hitzblech et al., 2019; StO MSM, 2018). As required by the ÄApprO, students have to complete a first-aid course and a three-month nursing internship in the first two years of study (§1 Abs. 2 ÄApprO, 2002). Between the third and fifth years, students have to spend four months in medical clerkships during their lecture-free time (§1 Abs. 2 ÄApprO, 2002; StO MSM, 2018). They need to spend one month in an outpatient clinic, two months in a hospital or a rehabilitation centre and one month at a family practice. To complete their degree, students spend their last year in the tripartite practical year (§3 ÄApprO, 2002).

Competency framework and learning objectives

Table 2 displays the underlying competency framework of the MCM, which was derived from a faculty-wide Delphi study and was inspired by international competency frameworks (Charité - Universitätsmedizin Berlin, 2007; Maaz et al., 2018). It includes nine domains of competence and four content domains (Hitzblech et al., 2019). The competency framework builds the basis for the general and specific learning objectives assigned to the courses. The general learning objectives describe the superordinate competence the student should acquire, whereas the specific learning objectives describe the specific knowledge, skills and attitudes, as well as small professional activities that are taught, that students are expected to learn. For each module, a handbook is available that provides an overview of the general theme of the module, the courses that will be given and the general and specific learning objectives of each course. In the curriculum development process of the MCM, many resources were allocated to ensure that the learning will spiral for students. The modules and learning objectives build on one another and increase in difficulty (Hitzblech et al., 2019).

Assessments

The acquisition of the learning objectives is checked via multiple forms of summative assessment, which are all explained in the examination regulations of the Charité (Prüfungsordnung des Modellstudiengangs Medizin der Charité – Universitätsmedizin Berlin, PrO MSM). At the end of each semester, a multiple-choice examination tests the conveyed knowledge of the respective modules (§3, section I PrO MSM, 2015). At the end of the second and fourth semesters, oral-practical examinations covering multiple modules assess the

knowledge and practical skills by means of oral and practical exams (§3, section III PrO MSM, 2015). An OSCE with six stations assesses the practical skills at the end of the ninth semester (§3, section IV PrO MSM, 2015).

Table 2

Competency framework of the Charité

Competence domains	Content domains
A. Diagnoses, therapy and care B. Health promotion and prevention C. Working in the societal context D. Scientific thinking and working E. Teaching others F. Life-long learning G. Medical decision-making H. Self-evaluation, professional development and self-care I. Communication skills and teamwork	1. Principles of longitudinal and basic science areas 2. Complaints, symptoms and findings 3. Diagnoses and clinical presentations 4. Practical skills

Note: Table derived from Hitzblech et al., 2019

The short-term clerkships also include an oral-practical examination (§3, section II PrO MSM, 2015), and the scientific working course requires the writing of a scientific paper (§3, section V PrO MSM, 2015). In addition to these summative assessments, the formative progress test of medicine (PTM) is applied at the beginning of each semester and provides students with a longitudinal impression of their increase in medical knowledge (Nouns & George, 2010; §4 PrO MSM, 2015). In the practical year, students are obliged to keep a logbook on a range of predefined activities and are expected to have regular feedback sessions with their supervising physicians on their professional development (Charité - Universitätsmedizin Berlin, 2021b). The current assessment system of the MCM does not include workplace-based assessments in short-term clerkships or the practical year. To ensure the comparability of all German medical curricula, medical students have to pass the medical state examination, which is divided into three parts (§1 Abs. 3 ÄApprO, 2002). Students of the MCM are certified to have successfully completed the first part when they have passed all examinations from the first six semesters. The second part is a nationwide written examination at the end of the 10th semester, which is followed by an oral-practical examination at the end of the practical year. Only after passing all parts of the medical state examination do students receive their licence to practise medicine.

EPAs in the medical curriculum at the Charité

When the MCM was being developed, the EPA concept was relatively new to the medical education community and was mainly implemented in postgraduate medical curricula (ten Cate, 2005; ten Cate & Scheele, 2007). However, the project management team presented the idea of EPAs to the faculty, and it was decided to include mini professional activities as learning objectives (Maaz et al., 2018). EPAs are thereby included as a longitudinal curricular structure, as the defined tasks increase in complexity and difficulty with the course of the study (Maaz et al., 2018). As an example, students learn in the first year to take a medical history and perform a physical examination and to recognize whether the patient is healthy. In the second year, students encounter prototypical diseases related to the module themes, and they learn to recognize these by taking the medical history and by performing the physical examination. They are expected to be able to describe the pathogenesis and pathophysiology and to derive the diagnosis, treatment and management (Maaz et al., 2018). In years three to five, they take medical histories and perform physical examinations on patients in the bedside-teaching course, and they are expected to derive a differential diagnosis related to the module theme. They are expected to propose, discuss, and interpret the diagnostics and to propose and discuss therapy for uncomplicated cases (Maaz et al., 2018).

The application of professional activities as learning objectives in the curriculum is a good starting point, as it provides both students and faculty members with an overview of the expected professional development over the course of studies. However, the professional activities included as learning objectives were determined in the module planning sessions and were not structurally validated. Since its implementation, the MCM has been continuously developed and refined, and one focus has been on the identification and implementation of Core EPAs as outcomes for the curriculum.

Dissertation project

This thesis focuses on the definition of a set of Core EPAs as outcomes for the MCM at the Charité and on the first steps of its implementation. The research questions of the chapters are as follows:

Chapter 2: How can a set of Core EPAs be defined for an undergraduate curriculum?

Chapter 3: Which EPAs are beginning residents expected to perform under distant supervision in the first days of residency?

Chapter 4: Do the defined Core EPAs represent realistic workplace expectations for beginning residents?

Chapter 5: Can the entrustment-supervision scale be integrated into an existing objective structured clinical examination?

Chapter 6: How do supervising physicians make the decision to entrust a trainee with an EPA?

All of the described projects were embedded in a rapidly developing field of research, where new findings and insights are constantly published. The projects' aims are described in more detail in what follows.

Definition and content validation of a set of Core EPAs

A Delphi study with members of the faculty was conducted to define a set of Core EPAs as an outcome for the MCM. As there was scarcely any work on EPAs in the German context at that time, the international literature available was utilized to prepare for and guide the study (AAMC, 2014; Hauer et al., 2013). Forty-five physicians from different specialities at the Charité were invited to participate in the Delphi study, and 36, 35 and 34 participated in the three rounds. In the iterative process, participants provided both qualitative feedback and quantitative ratings on a list of EPAs. The qualitative feedback was used by a writing team to refine the EPAs, and the quantitative ratings were summarized by descriptive statistics. In the course of the study, complete descriptions were given of 12 Core EPAs that graduates are expected to perform with distant supervision at the beginning of residency. Chapter two describes in detail every step of the Delphi study to provide support and guidance for other institutions interested in implementing EPAs in their curriculum. The results of the Delphi study, the complete list of EPAs and the ratings of the faculty members are shown in Chapter three. They were published separately in a German journal, as this content is of higher interest for the national medical community.

The development of Core EPAs by means of medical experts using consensus finding procedures is prevalent in the medical education field (AAMC, 2014; AFMC, 2016; Michaud et

al., 2016; ten Cate et al., 2018). To find further evidence for the content validity of the defined Core EPAs, the workplace involvement of beginning residents was studied. A regular postgraduate survey was sent out to ask recent graduates of the Charité how often they had performed the EPAs since the start of residency and under which level of supervision. In total, 720 graduates received the postgraduate questionnaire, and 131 could be included in the data analysis. The results were summarized by descriptive statistics and provided valuable insight into the actual workplace involvement of beginning residents (Chapter four).

Integrating entrustment ratings into the regular examinations at the Charité

Medical students at the Charité are assessed by means of various forms of examinations. This project sought to explore how the entrustment-supervision scale could be integrated into existing examinations to keep the changes to the assessment program as few as possible. The OSCE in the ninth semester requires students to perform professional activities in a simulated setting while being assessed by physicians. The introduction of the entrustment-supervision scale as an additional rating to the standard assessment sheet of the regular OSCE was explored (Chapter five). The resulting entrustment ratings were brought into connection with the standard ratings, and the assessors evaluated the introduction of this new form of rating. A total of 227 students and 54 assessors participated in this study. Descriptive and inferential statistics were applied.

The formation of an entrustment decision

With the introduction of EPAs into the undergraduate curriculum, the faculty have to make entrustment decisions explicit. In the long run, these entrustment decisions are intended to represent assessment points for students, and the faculty, supervising physicians and students should understand the nature of entrustment decisions. In Chapter 6, occupational and organizational theory was applied to develop a conceptual model of the entrustment decision-making process, outlining the factors influencing these entrustment decisions and the way entrustment decisions are made.

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Chapter 2

How to define core entrustable professional activities for entry into residency?

Holzhausen, Y., Maaz, A., Renz, A., Bosch, J., & Peters, H. (2018). How to define core entrustable professional activities for entry into residency? *BMC Medical Education, 18*(1), 87. https://doi.org/10.1186/s12909-018-1159-5 [1]

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Abstract

Background: Institutions considering to employ core Entrustable Professional Activities (EPAs) for entry into postgraduate training as outcomes for their undergraduate medical programs can partly build on published examples, but also have to undergo their own content validation process to take their specific context into consideration. This process involves several challenges and is not well-described in the literature. Here, we report in detail on a systematic, literature-based approach we recently utilised at our institution to define core EPAs for entry into residency.

Main body: Central to the process was a modified Delphi consent procedure. It involved a multistep interaction between a writing team and a multidisciplinary panel of experienced physicians. Panel members provided both quantitative ratings and qualitative feedback on the EPA categories title, specification/limitations, conditions and implications of entrustment decision, knowledge, skills, and attitude. Consent was achieved when a Content Validity Index (CVI) of ≥80% was reached. The writing team adjusted the EPA category descriptions on the basis of panel members´ ratings and comments, and specified the EPA categories' link to competencies and assessment sources. This process produced a description and definition of a full set of core EPAs for entry into residency adapted to our context.

Conclusions: This process description for locally adapted core EPAs for entry into residency may support and guide other medical schools in the development and implementation of EPAs into their programs.

Keywords: Entrustable Professional Activities, Curriculum development, Undergraduate medical education, Consensus methods

Background

The definition of core Entrustable Professional Activities (EPAs) for entry into postgraduate training has become an active field of development. Many institutions are currently considering the use of EPAs as outcomes for their undergraduate medical programs [1]. These institutions can build in part on EPAs which have been reported at a national level [2–4] and at a local level [5], but will be required to undertake their own content validation process to adapt these EPAs to their specific context. However, available reports do not include a fully detailed description of the EPA development process which could guide other institutions. In this article, we report in detail on a systematic, literature-based approach we employed to define core EPAs for entry into residency as outcomes for the undergraduate medical curriculum at Charité - Universitaetsmedizin Berlin, Germany (Charité).

We chose a modified Delphi study procedure, an established method for anonymised, non-hierarchical content validation, including EPA development in medical education [1, 6]. As a modification of the Delphi process, panel members received a predefined list of EPAs in the first round. Our goal was the definition of a full set of core EPAs with a seven-category description for each EPA according to current recommendations in the literature (1, 7, 8]. The definition of educational outcomes by EPAs is generally achieved in an iterative process, beginning with the identification of authentic professional tasks, followed by the elaboration of its characteristics, and finally validation of the content by a group of experts [1, 7]. Figure 1 provides an overview of our Delphi study process which involved a multistep interaction between a writing team of educationalists and a panel of experienced physicians.

Delphi study process

Panel selection and writing team

A total of 45 panel members were purposely selected from the Charité faculty body. All panel members had long-time supervision experience in both undergraduate and postgraduate medical training and were actively involved in the curriculum development process for the current undergraduate program. The EPA writing team, consisting of the authors of this article, were members of both the curriculum development group for the undergraduate medical program and educational researchers in the field of EPAs.

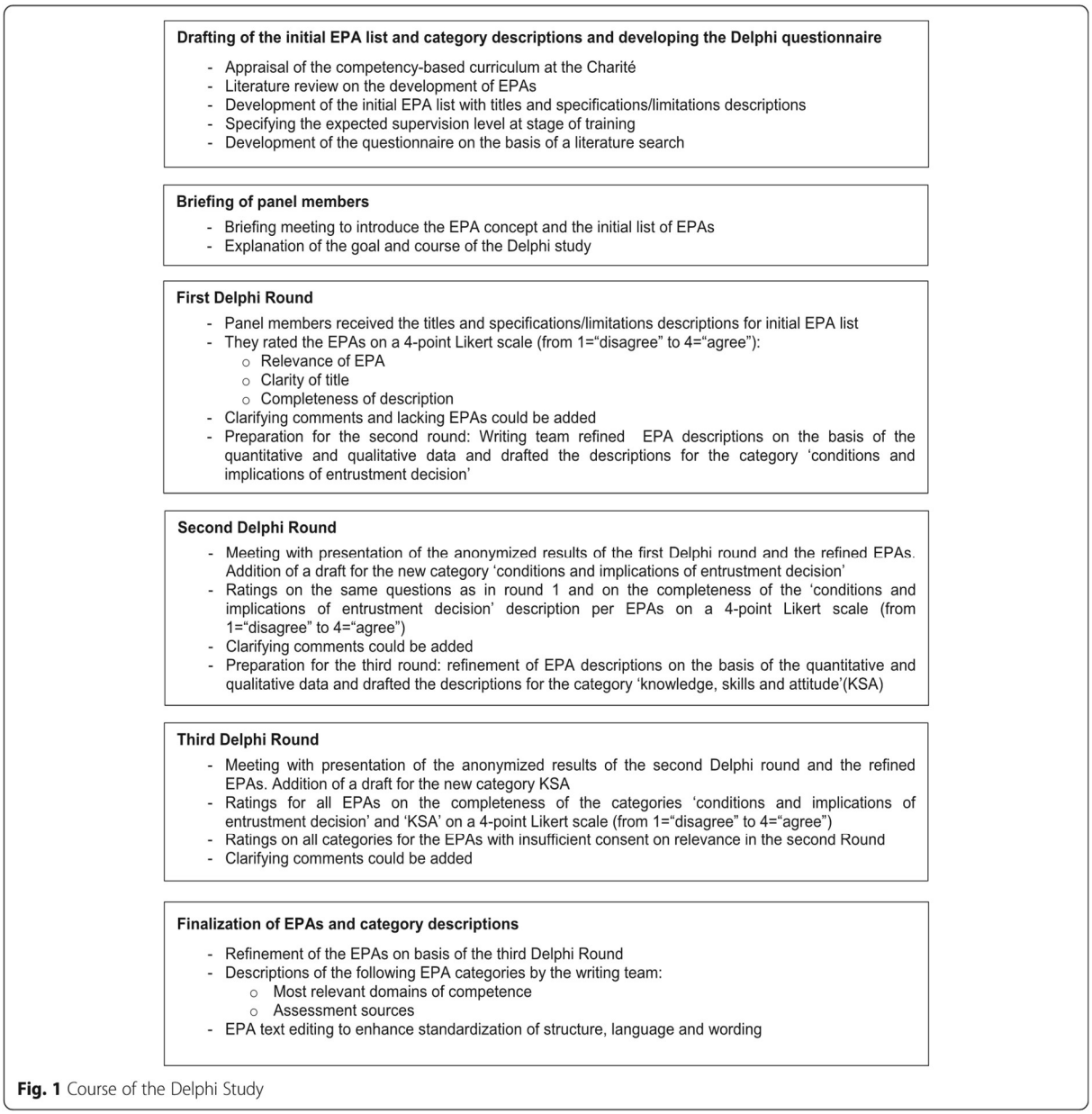

Fig. 1 Course of the Delphi Study

Guiding principles for EPA content definition

The following guiding principles were formulated for EPA content definition: 1) They should comply with the recommendations for EPA definition [8], i.e. represent independently executable tasks which are observable, measurable, confined to qualified personal and suitable for an entrustment decision. 2) The EPAs should consist of full, seven-category descriptions, including the following categories: 'title', 'specification/ limitations', 'knowledge, skills and attitudes' (KSA), 'conditions and implications of entrustment decision', 'most relevant domains of competence', 'assessment sources', and the 'expected supervision level at the stage of training'. 3) The EPA content elaboration should use clear language describing tasks and workplace context and avoid educational jargon. This includes a short brief title, succinct descriptions as well as an alignment of structure, language and wording within the set of EPAs.

4) The EPAs for entry into residency constitute the core, this is the full set of professional activities expected from a graduating physician. 5) The breadth and level of difficulty of the EPAs should be manageable for graduating physicians, align with the workflow and the supervision routines in the clinical setting, and 6) the supervision level is defined by the time it takes for the supervisor to be physical available as well as the degree of subsequent work verification.

Drafting of the initial EPA list and category description

In an iterative process, the writing team drafted the initial list of tasks to be considered as EPAs for entry into residency according to the specific context. This involved mapping these tasks to the Charité competency framework, a search and appraisal of the literature, along with continuous discussions and developments within the Charité curriculum development group. The AAMC core EPAs were used as a starting point [2]. In addition, the writing team consulted articles on the EPAs concept in general [8–12] and articles covering the development of EPAs for postgraduate training [13–16]. The draft of the initial EPA list included tasks which graduating physicians should be able to perform under a granular operationalised level of supervision [17]. The following categories were elaborated for each EPA: ‘title’, ‘specification/limitations’, and ‘expected supervision level at stage of training’. These categories are thought of as those representing the quintessence of an EPA description, upon which the other categories subsequently build.

Questionnaire development

The writing team developed the questionnaire for the Delphi process based on the literature on EPA development. For EPA identification and content validation, panel members were asked to rate the relevance of professional tasks for new residents, the clarity of each EPA title and the completeness of the EPA category descriptions on a 4point scale. The questionnaire was administered online using EvaSys (Electric Paper Evaluationssysteme GmbH, Lüneburg, Germany), a software for survey based research.

Establishing consensus among panellists’ ratings

Content validity indices (CVI) were calculated to establish consensus among the ratings of panel members [18].This included the relevance ratings of the EPAs, the ratings of the ‘clarity of the title’ and the completeness of the EPA categories ‘specification/limitations’, ‘conditions and implications of entrustment decision’ and ‘KSA’. The CVI describes the percentage of respondents who rated the relevance of the EPAs or the categories with ‘agree’ or ‘somewhat agree’. A CVI of at least 80% was set as the predefined consensus level. If this level was reached, consensus was assumed and no further validation was deemed necessary.

Panel member invitation and briefing

The panel members were invited to a formal meeting at the beginning of the Delphi study to prepare them for their participation. During the meeting, they were informed about the EPA concept and the aim and structure of the Delphi process. Similar panel meetings were held again before the second and third Delphi rounds. Here, panel members were provided with an anonymised summary of the previous round's results, the refined EPA content descriptions, and information on subsequent tasks. The meetings were audio-recorded, screencasted, and sent out to panel members as podcasts along with other material shown in the panel meeting.

Round 1 Panel members received the initial draft of EPAs relevant for entering residency including titles and specification/limitations. Panel members provided ratings and could add narrative text for explanations or suggestions for refinement. They were also asked to propose relevant tasks which they felt were missing for entry into residency. The EPA writing team summarised the quantitative and qualitative information provided and refined the EPAs accordingly. The qualitative feedback was clustered inductively and allocated to the corresponding EPA text passages. The proposed changes were then discussed within the writing team until a consensus was reached on the EPA description refinement. The topics for additional EPAs were discussed within the writing team and reviewed on the basis of the abovedescribed guiding principles for EPA content definition.

Round 2 Panel members received the anonymised, summarised panel rating results of the first round along with the refined EPA titles and specification/limitations descriptions. Changes made following the first round were highlighted. The panel members received the same questions as in Delphi Round 1. In addition, they were asked to rate a description drafted by the writing team on the EPA category 'conditions and implication of entrustment decision' which specifies how the supervision level is operationalised into the workplace. Again, all quantitative ratings could be supplemented with narrative feedback. The EPA writing team summarised the quantitative and qualitative information and adjusted the EPA descriptions as described above for Round 1.

Round 3 The panel members were given the anonymised, summarised panel rating results of Round 2. They also received the refined EPA titles and descriptions of the categories 'specification/limitations' and 'conditions and implications of entrustment decision' with an indication of changes made following feedback in the previous round. Panel members were asked to rate again on the content of the refined categories in those EPAs which had not received sufficient consensus on the relevance rating in the previous round. For the third Delphi

round, the writing team drafted the EPA category ‘KSA’ for each EPA. The panel members rated the completeness of the categories ‘conditions and implication of entrustment decision’ and ‘KSA’ in all EPAs. The ratings could be supplemented by narrative comments. In the final round, a CVI of over 80% was reached in the panellists’ ratings on the EPA category descriptions.

Finalisation of EPA list and category descriptions

The writing team made final changes to the content of the EPA categories on the basis of panel member ratings and comments from Round 3. EPA categories ‘most relevant domains of competence’ and ‘assessment sources’ were defined in an iterative consensus process with the Charité curriculum development group. Furthermore, special attention was paid to harmonising structure, language and wording in the EPA descriptions.

Conclusions

This article reports in detail on the process of defining a full set of core EPAs for entry into residency. Our process description may provide support and guidance to other medical schools for the development and implementation of EPAs for their own programs according to their specific contexts.

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Chapter 3

Development of Entrustable Professional Activities for entry into residency at the Charité Berlin

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Abstract

Background: Entrustable Professional Activities (EPAs) have emerged as a new approach to operationalise the workplace performance expectations for the transition from under- to postgraduate medical training. However, the transferability of such EPAs from one context to another appears limited. In this article, we report on the results of our approach to define a full set of core EPAs for entry into residency with the expectation to be performed under distant supervision.

Methods: The EPA development involved a modified, three round Delphi study, conducted at the Charité - Universitätsmedizin Berlin. The supervision level was operationalised as supervisor being distantly available and findings being reviewed. The threshold for consent was reaching a content validity index of a least 80%. The Delphi study involved experienced physicians (n=45) and resulted in a set of core EPAs with the descriptions of the categories: title, specification/limitations, conditions and implications of entrustment decision, knowledge, skills, and attitude, link to competencies and assessment sources.

Results: The response rates were 76-80% in the Delphi rounds. Key to the content validation process for the performance expectation was deciding on "to act under distant supervision". The results are full descriptions of 12 core EPAs, organised into 5 overarching EPA domains.

Conclusions: Our systematic approach yielded the definition of 12 core EPAs for entry into residency at the level of "act with distant supervision" according to the practice in our context. This report may support other medical schools who plan to implement EPAs into their curricula.

Keywords: Entrustable Professional Activities; consensus methods; curriculum development; undergraduate medical education.

1. Background

The progress from undergraduate to postgraduate training represents an important and critical transition in medical education. This holds true for the institutions and educators involved, as well as for the individual trainee and future medical doctor. Competency-based medical education (CBME) has provided a shared conceptual framework for both undergraduate and postgraduate programs, and has thereby led to a better alignment of the two training periods [1], [2]. However, CBME does not translate well into real-world clinical practice [3]. There is nevertheless a need for a tangible operationalisation that defines the workplace performance expectations for residents when entering the postgraduate training, which in turn would represent the overarching outcomes that should be reached by graduates at the end of undergraduate education. The concept of Entrustable Professional Activities (EPAs) has emerged as a meaningful approach to specify educational outcomes in postgraduate medical training in several countries [4]. In Germany, the EPA has received an increasing amount of attention in postgraduate medical education [5], [6], [7]. Its application to the transition from undergraduate to postgraduate medical education is currently an active field of development and research [8], [9], [10], [11], [12], [13], [14]. Although examples of such core EPAs for entry into residency have become available, their application to other contexts and countries is limited. Many medical schools who consider the implementation of EPAs into their programs have to undergo their own EPA development process according to their context. Key to this process is specifying the supervision level at entry into residency. In this article, we report on the results of our approach to define a full set of core EPAs for entry into residency at the Charité – Universitätsmedizin Berlin (Charité) according to the medical practice of our educational setting.

The specification of educational outcomes by the EPA concept builds on two of its key elements:

1. professional activities which represent authentic workplace tasks characteristic of a profession, and
2. levels of supervisions, i.e. the degree of supervision a trainee needs to carry out a professional activity [3], [4].

The professional activities can range from smaller tasks for junior trainees to the full range of all tasks characteristic of a discipline being envisaged for senior physicians when completing their postgraduate medical training [4]. Over the course of medical training, the supervision levels gradually decrease from “allowed to observe only” (level 1) and “act under direct observation” (level 2) in early training, over “act under indirect supervision” (e.g. being available on request, level 3) to “act unsupervised” in later training stages (level 4) [15]. The combination of these two components – i.e. professional activities and supervision levels – can be employed to operationalise the performance-based outcomes in medical education. A further strength of

this approach is that it builds on real-world workplace practices and uses a language that communicates well with medical supervisors, trainees and program directors.

The content definition of educational outcomes by EPAs is generally achieved through a step-by-step consent process among content experts. It begins with the identification of authentic professional tasks, secondly the elaboration of its characteristics, followed by the content validation procedure [4], [16]. Key to the definition of EPAs for entry into residency is choosing and specifying a supervision level which reflects the supervision practice for graduating physicians in a particular context. Chen at al. have introduced a more granular operationalisation of supervision levels, especially for “act under indirect supervision” [8]. Closer or less close supervision will have an impact on the breadth and depth elaboration of entry into residency EPAs, for instance the spectrum of patient and disease complexity to be included. According to the current literature, an EPA definition should yield a seven-category description to fully define its content [4], [16], [17].

So far, core EPAs for entry into residency have been reported at a national level for the USA [9], Canada [10] and Switzerland [11]. While these sets of EPAs have several features in common, there are also tangible differences in the tasks which constitute the core of activities expected from all entering residents and the level of task difficulty to ensure they are manageable for entering residents. These differences likely reflect differences in the medical practice of these countries and indicate that one set of core EPAs for entry into residency cannot automatically be transferred from one context to another. All three EPA sets do not clearly specify the expected level of supervision at entry into residency. For the USA, the goal is without direct supervision (> level 2), for Canada it is with indirect supervision (supervisor not in the room but available to provide assistance) and for Switzerland it is distant, on-demand supervision (both level 3). The supervision levels leave open the temporal availability of the supervisor and how the findings and approaches of the resident are checked afterwards. We think this step is critical for the further content elaboration and validation of the breadth and depth of core EPAs for entry into residency in any context. The benefits of using a more granular supervisions levels as introduced by Chen at al. have shown in a recent article reporting on the definition of EPAs for the undergraduate medical curriculum in Utrecht, the Netherlands [12].

At the Charité, we have recently undergone a curricular reform of the undergraduate medical program [18]. The new curriculum was developed and implemented semester-by-semester in a faculty-wide approach on basis of a pre-defined outcome catalogue comparable to the Nationaler Kompetenzbasierter Lernzielkatalog (NKLM) and the CanMEDS framework [19], [20]. The result was a competency-based, vertically and horizontally integrated undergraduate medical curriculum with the first graduates entering postgraduate training in 2016. As professional activities served as the main longitudinal curriculum structure, there was

a need to define EPAs as overarching outcomes for the program and for entry into residency [18]. In our context, the vast majority of graduating physicians start their postgraduate training in a hospital setting, where they mainly take care of adult patients. The general expectation is that the graduating physicians are in charge of adult patients on the ward during the day shift under distant supervision. The typical workflow of supervision encompasses daily routine meetings between trainee and supervising physician where new patients are presented and key medical decisions on all ward patients are coordinated. In addition, the trainee and supervisor jointly undertake full ward rounds twice a week. This aligns with supervision level 3c (supervisor distantly available and findings are reviewed) according to Chen at al. [8].

The aim of this article is to report on the results of a Delphi study defining a set of core EPAs delineated as full, seven-category descriptions. According to our context, they operationalise the clinical performance expectation for medical graduates entering residency, when acting under distant supervision. This is operationalised as the supervisor is not on the ward and findings are reviewed afterwards.

2. Methods

Setting

The study was conducted from January 2014 to November 2015 at the Charité. Its undergraduate medical program has an intake of more than 600 students per year, spans over six years and 5500 teaching hours in total. The Charité data protection office and ethics board approved the study (No EA2/091/14, Ethics Board Charité, Campus Mitte).

Delphi study

The approach was based on a modified, 3 round online Delphi consensus procedure. This process has been reported in detail elsewhere [21]. To summarise, it involved a step-by-step interaction between a writing team and a multidisciplinary panel of 45 purposely selected physicians from the Charité faculty body with long-time clinical supervision experience and active involvement in the curriculum development process of the current undergraduate medical program (e.g. as module board members or department teaching coordinators).

The starting point was the identification of core tasks expected from all graduating physicians when entering into residency to be performed under distant supervision. During the course of the Delphi study, participants received the description of various EPAs and had to rate the relevance and the specific content of the presented categories on a 4-point Likert scale (disagree / somewhat disagree/ somewhat agree / agree) [21]. The threshold for consent was reaching a content validity index (CVI) of ≥80% [22]. CVI represents the percentage of respondents who agreed or somewhat agreed to the description of a certain EPA category. Descriptive statistics were calculated using IBM SPSS statistics 23 following each Delphi

round, including mean (M) and standard deviation (SD). In Delphi round 1, panel members could propose EPAs not included in the initial list provided. During the Delphi procedure, panel members provided both quantitative ratings and qualitative narratives on the EPA categories until consent was achieved: title (round 1-2), specification/limitations (round 1-3), conditions and implications of entrustment decision (round 2-3), and knowledge, skills, and attitude (round 3). It has recently been described in detail how we decided on which categories to include in the respective Delphi rounds [21].

The writing team adjusted the EPA category descriptions on the basis of panel members´ ratings and comments. The EPAs were finally arranged according to the five overarching EPA domains to provide a more coherent picture [12].

3. Results

Delphi response rate and panel members

The response rates were 80, 78 and 76 % in the three Delphi rounds with 36, 35 and 34 faculty members participating in each respectively. Thirty-two participants completed all three rounds. Participants' demographics and characteristics are depicted in table 1.

Table 1: Participants' demographics and characteristics

Sex (%)	
Men	62
Women	38
Age (years)	
Mean	46
STD	8
Working experience as a physician (years)	
Mean	19
STD	8
Experience in supervising trainees (years)	
Mean	15
STD	7
Medical Discipline (n=)	
internal medicine	16
anaesthesiology/ intensive care	6
neurology	4
surgery	3
psychiatry	2
otolaryngology	2
dermatology	2
paediatrics	1
general medicine	1
orthopaedics	1
Curriculum Development Experience (n=)	
Involved in planning of modules	32
Involved in planning of the study program	6

Identification of core EPAs for entry into residency

The panel members reached consensus on a total of 12 core activities with clinical performance expectations for entry into residency at the Charité. Table 2 displays the titles of the 12 core EPAs as grouped within 5 EPA domains. The panel members proposed an additional 20 topics for EPAs not listed in the initial list circulated in Delphi Round 1. A number of these suggestions could be integrated into the 12 EPAs, for instance “to document in the patient file” or “demonstrate sufficient understanding of basic science”. Others were of general nature, such as “show good time management”, or “recognise communication in stressful situations as a challenge”. The writing team decided that none of the proposed topics qualified as a separate EPA.

Table 2: Titles and Content Validity Indexes (CVI) on the relevance of 12 core EPAs for entry into residency, grouped into 5 EPA

EPA		Round 1 CVI (Mean)	Round 2 CVI (Mean)	Round 3 CVI (Mean)
1. Along the clinical encounter				
1.1	Gather a medical history, perform a physical exam and provide a structured summary of the results	92% (3.7)	100% (3.8)	/
1.2	Compile a diagnostic work plan and initiate implementation	89% (3.4)	97% (3.8)	/
1.3	Interpret test results and initiate further steps	75% (3.2)	89% (3.4)	/
1.4	Compile a treatment plan and initiate implementation	72% (3.1)	91% (3.6)	/
2. General medical procedures				
2.1	Perform general procedures of a physician	78% (3.3)	71% (3.3)	94% (3.7)
3. Communication with patients				
3.1	Seek consent for medical examinations and procedures	86% (3.5)	86% (3.5)	/
3.2	Inform and advise a patient	56% (2.9)	77% (3.4)	88% (3.6)
4. Communication and collaboration with colleagues				
4.1	Present a patient history	89% (3.7)	100% (3.9)	/
4.2	Give or receive a patient handover	92% (3.6)	94% (3.9)	/
4.3	Write and distribute a patient report	86% (3.4)	100% (3.9)	/
5. Patient care in special situations				
5.1	Recognize an emergency situation and act upon it	75% (3.3)	97% (3.9)	/
5.2	Undertake an evidence-based patient case presentation and initiate patient-specific implementation	61% (2.8)	86% (3.3)	/

Note: Panel member rated from 1 (disagree) to 4 (agree). Shown are the content validity index (percentage) and ratings (mean) of the relevance for each EPA.

Content elaboration and validation of core EPAs for entry into residency

During the Delphi process, the panel members reached consensus on the relevance ratings of the EPAs. Table 2 provides an overview of the ratings during the three Delphi rounds. The relevance rating indicates the match between the descriptions of an EPA with the expectation for entry into residency. In the case of a low CVI for an EPA, the EPA description was refined on the basis of the panel members´ narrative comments. In most cases the EPA specifications were perceived as too difficult, for entering residents to be able to perform them under distant supervision. In Delphi round 1, six EPA descriptions reached a CVI of 80% and higher, in round 2 a total of 10 EPA descriptions, and in round 3 all 12 EPA descriptions. Table 3 provides an overview of the panel member ratings during the Delphi process for the EPA category descriptions “title”, “specification/limitations”, “conditions and implications of entrustment decisions” and “knowledge, skills and attitude”.

Key to the content validation process was the elaboration and definition of “to act under distant supervision” in the EPA category “conditions and implications of entrustment decision”. This was operationalised as the trainee acting autonomously and his or her findings and decisions being reviewed by the supervisor during the next regular meeting or ward round. In the subsequent process, this level of autonomy led to a specification of the patients as adults, presenting with typical clinical presentations or common diseases and no major difficulties involved. In an attempt not to exclude some patient groups and medical disciplines, the limitation section of each EPA emphasises that a closer level of supervision is required and a lesser degree of autonomy is granted in the case of unstable or critically ill patients, new-borns, infants, children, pregnant women and discipline-specific clinical presentations or diseases.

Table 4 provides the description of EPA 1 “Gather a medical history, perform a physical exam and provide a structured summary of the results”. The article appendix includes the full description of all 12 EPAs as developed in this Delphi study. In addition to information on the context, smaller tasks were incorporated to describe what is included in an EPA. This led to two types of nested EPAs: one, in which the EPA is specified by a chronological order of all activities included (EPA 1.1-1.4, 3.1, 4.2 and 5.2), and another, in which the EPA forms a collection of tasks from the same group (EPA 2, 3.2, 4.1, 4.3 and 5.1) (see attachment 1).

Table 3: Results of panel member ratings in Delphi round 1 to 3 (R 1 to R 3) on the category descriptions of 12 core EPAs for entry into residency

EPA	Clearness of title			Completeness of specifications and limitations			Completeness of conditions and implications of entrustment decision		Completeness of KSA*
	R 1 CVI (Mean)	**R 2** CVI (Mean)	**R 3** CVI (Mean)	**R 1** CVI (Mean)	**R 2** CVI (Mean)	**R 3** CVI (Mean)	**R 2** CVI (Mean)	**R 3** CVI (Mean)	**R 3** CVI (Mean)
1.1	86 (3.5)	100 (3.8)	/	83 (3.5)	94 (3.7)	/	97 (3.8)	97 (3.6)	91 (3.6)
1.2	83 (3.4)	97 (3.8)	/	81 (3.5)	94 (3.7)	/	100 (3.9)	91 (3.6)	85 (3.5)
1.3	92 (3.6)	94 (3.8)	/	86 (3.4)	86 (3.4)	/	83 (3.5)	94 (3.7)	91 (3.7)
1.4	92 (3.6)	97 (3.9)	/	75 (3.4)	91 (3.7)	/	83 (3.5)	97 (3.6)	91 (3.6)
2	89 (3.7)	94 (3.9)	91 (3.8)	72 (3.2)	71 (3.3)	91 (3.6)	83 (3.6)	91 (3.8)	85 (3.7)
3.1	100 (3.8)	100 (3.9)	/	92 (3.6)	89 (3.6)	/	91 (3.7)	88 (3.5)	94 (3.7)
3.2	86 (3.7)	94 (3.9)	94 (3.9)	75 (3.5)	83 (3.5)	94 (3.5)	83 (3.7)	85 (3.5)	91 (3.7)
4.1	97 (3.9)	97 (3.9)	/	94 (3.7)	97 (3.8)	/	91 (3.9)	91 (3.7)	88 (3.6)
4.2	97 (3.9)	100 (4.0)	/	94 (3.7)	91 (3.8)	/	94 (3.8)	91 (3.6)	91 (3.8)
4.3	100 (3.9)	100 (4.0)	/	92 (3.7)	94 (3.8)	/	94 (3.9)	97 (3.8)	100 (3.8)
5.1	97 (3.9)	100 (4.0)	/	86 (3.6)	91 (3.5)	/	100 (3.9)	100 (3.8)	100 (3.9)
5.2	92 (3.6)	83 (3.5)	/	92 (3.6)	91 (3.6)	/	77 (3.2)	91 (3.6)	94 (3.7)

Note: Ratings ranged from 1 (disagree) to 4 (agree). Shown are the content validity indices (percentage) and ratings (mean) of the EPA categories.

*KSA = knowledge, skills and attitude

Table 4: Gather a medical history, perform a physical exam and provide a structured summary of the results.

Title	**Gather a medical history, perform a physical exam and provide a structured summary of the results (EPA 1.1)**
Specification	At the beginning of postgraduate training, the resident is able to autonomously gather a medical history, perform a physical exam and provide a structured summary of results for adult patients who present with typical clinical presentations or common diseases. The execution of the EPA includes: 1) active search for typical symptoms and clinical signs of disease and disorders to be considered (differential diagnosis "with the patient"), 2) collation of previous reports and documents relevant to the patient's medical history, previous medication and if necessary the consultation of the patient's family members or co-treating physicians, 3) complete or focused medical history and physical exam, according to the situational requirements, 4) structured summary, for example in terms of chief and additional complaints, relevant differential diagnoses and suspected or preliminary diagnoses, current or previous medical history, 5) presentation to the supervising physician, 6) sharing information with the wider care team (e.g. physicians, nurses), 7) documentation in patient file.
Limitations	A closer supervision level than "act with distant supervision" is required for: a) unstable or critically ill patients (e.g. patients in intensive care or emergency units), b) newborns, infants, children, adolescents and pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology).
Knowledge, skills and attitude	Knowledge: Structure and function of the human body; presentation and pathophysiology of typical clinical symptoms and common diseases; principles and technique of physician-patient communication, verbal, non-verbal and paraverbal aspects of communication; course and structure of a medical history (current complaints, medical history, personal, vegetative, family, social and medication history, intolerances) and of a physical exam (head- and neck region, thorax, abdomen and extremities by means of inspection, auscultation and percussion, basic neurological, musculoskeletal and dermatological examination); hygiene standards and infection prevention; concepts and techniques of differential diagnoses, step-wise differential diagnoses for common complaints and medical results; communication with patient, relatives and the care team. Skills: Evaluation of the overall patients´ impression; patient-centred communication, establishing a trustful hysician-patient relationship; taking a structured medical history; performing a structured physical exam, recognizing typical and common clinical symptoms, differentiating between "normal" and "non-normal" in case of special discipline-specific findings; case presentation to the supervising physician with a summary of findings, mentioning inconclusive findings or those with ought to be checked again; differential diagnostic considerations; development of a working diagnosis; entry of findings into the patient file. Attitudes: Open and respectful communication; attention to diversity (gender, age, culture); use of patient-friendly language; attention to hygiene standards; compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The collected and collated findings and diagnoses by the resident form the basis of further decision making regarding the diagnostics, treatment and management of the patient without an immediate or detailed check by the supervising physician. The medical history, findings and file entries will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, () Collaborator, () Manager, () Health Advocate, (X) Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements), case-based discussions and patient charts reviews.
Expected supervision level at stage of training	Distant supervision for entry into residency.

4. Discussion

The present study reports on the results of a process of defining 12 core EPAs for entry into residency at the level of “act with distant supervision”. The EPA content was established in a step-by-step process based on a modified Delphi procedure and a systematic interaction between a multidisciplinary faculty expert panel and a writing team of educational experts [21]. The results of this process are full, seven-category descriptions of 12 EPAs which operationalise the performance expectations of graduating physicians according to the workplace practice and the new competency-based undergraduate medical program in our context at the Charité. In the following sections, we will discuss the results and implications of our study in the light of current literature.

In a modified Delphi study, content experts from our medical school were intentionally involved to make the EPAs as relevant as possible to our setting and to gain the support of those who will eventually work with them. Decisive for our EPA definition process was the designation of a supervision level for entry into residency. According to the practice in our context, we chose “to act with distant supervision” as an anchor to define the content description of our 12 core EPAs by our panel members. This designated supervision level was subsequently operationalised during the Delphi process when the panel members expressed uncertainty during the panel meetings and in their narrative feedbacks as to how this level of autonomy would actually translate into the supervision practice. Their uncertainty connects to literature on trust and EPAs noting that entrustment decisions require the specification of exactly what has been decided [23], [24], [25]. Entrustment relates to the acceptance that the trustee is permitted to act in circumstances where risks are present but still manageable [23]. To approach the panel members´ uncertainty, we specified for each EPA in detail when and to which degree the findings and decisions by the trainee are to be checked by the supervisor in the EPA category “conditions and implications of entrustment decision”. Our operationalisation aligns well with supervision level 3c by Chen and colleagues (supervisor not immediately available, findings are reviewed), which had not been published when we defined our supervision level [8].

Next, with “distant supervision” being set as the leading expectation, it became apparent that the difficulty of the tasks needed more specification to be manageable for graduating physicians. For this, we anchored the task complexity by referring to patients as adults with typical presentations, common diseases and typical courses of a disease. We can envision that in a specific clinical setting, this context can be further clarified according to the actual workplace practice. For instance, this could involve the 10-15 most common clinical presentations, diseases, drugs and procedures for which the distant supervision level is granted. To further curtail the EPA difficulty, we generally assigned a closer than distant

supervision level for high-risk patients requiring urgent care, new-borns, children, pregnant woman and patients with special discipline-specific complaints and diseases.

The result of our modified Delphi study were 12 core EPAs, i.e. authentic units of work which we arranged for a more logical listing into 5 EPA domains as proposed by ten Cate et al. [12]. For instance, the four EPAs within the EPA domain “along the clinical encounter” can be seen as one workflow, but they represent separate EPAs, because a check by the supervisor is needed before the next EPA can be carried out. We identified 12 core EPAs, which is in the range of 9 to 13 EPAs identified by others [9], [10], [11], [12]. In addition, there is an overlap in the breadth and scope of these sets of core EPAs. However, there are also several differences. First, there are differences in splitting and arrangement of the tasks. For example, others have defined the EPA to “prioritize a differential diagnosis” [9], [11]. In our study, this task is integrated into EPA 1.1 “Gather a medical history, perform a physical exam and provide a structured summary of the results” and 1.2. “Compile a diagnostic work plan and initiate implementation” according to the workplace practice in our setting. Second, there are differences in the actual tasks chosen. For example, others have included an EPA for system improvements [9], [10], [11]. In our setting, there is no such activity in the workplace for entering residents, and thus this task is not part of our 12 EPAs. There are also differences in the number of medical procedures to be carried out by a graduating physician. According to practice in our setting, we incorporated 15 medical procedures, while others included only four [9]. Finally, we decided to organise our EPAs in such a manner that the specifications of the EPAs are described as nested tasks to make them observable and suitable for assessment purposes in early semesters.

Our report holds several implications which go beyond the study itself. First, this study adds further example to the current search on how to define EPAs for entry into residency. It may serve as a stimulus and contribution for the definition of EPAs at a national level in Germany and the intended future development of the NKLM. Second, our Delphi study produced relevant faculty developments and ownership at our institution on how to translate CBME into practice by using the concepts of EPAs. Furthermore, the set of EPAs will be implemented as overarching outcomes for our undergraduate medical program with the intention to better prepare medical students for the workplace requirements in residency training. In order to reach this goal, the set of core EPAs should be employed to identify gaps, align learning sequences in a meaningful manner, adjust the assessment program and connect classroom and workplace learning in the undergraduate curriculum. Finally, the 12 core EPAs for entry into residency provide a blueprint for future educational research, for instance on the level of preparedness of graduates of our program on those core professional activities.

This work has limitations. With regard to the content expert panel, there may have been a selection bias as only a subgroup of the faculty was invited to take part. In addition, first year

residents were not included but could have been an important source for content validation. Moreover, we did not operationalise the performance expectations for the closer supervision level in special patient groups. The generalizability of the resulting EPAs to settings with differences in workplace practice is limited.

5. Conclusions

In conclusion, this study reports on the results of defining 12 core EPAs for entry into residency at the level of “act with distant supervision” by Charité faculty members. This report aims to provide support and encouragement to other medical schools considering the implementation of EPAs in their curricula.

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Attachment 1

English Version

Entrustable Professional Activities for entry into residency

1.	**Along the clinical encounter**
1.1	Gather a medical history, perform a physical exam and provide a structured summary of the results
1.2	Compile a diagnostic work plan and initiate implementation
1.3	Interpret test results and initiate further steps
1.4	Compile a treatment plan and initiate implementation
2.	**General medical procedures**
2.1	Perform general procedures of a physician
3.	**Communication with patients**
3.1	Seek consent for medical examinations and procedures
3.2	Inform and advise a patient
4.	**Communication and collaboration with colleagues**
4.1	Present a patient history
4.2	Give or receive a patient handover
4.3	Write and distribute a patient report
5.	**Patient care in special situations**
5.1	Recognize an emergency situation and act upon it
5.2	Undertake an evidence-based patient case presentation and initiate patient-specific implementation

EPA domain 1 – Along the clinical encounter

Title	**Gather a medical history, perform a physical exam and provide a structured summary of the results (EPA 1.1)**
Specification	At the beginning of postgraduate training, the resident is able to autonomously gather a medical history, perform a physical exam and provide a structured summary of results for adult patients who present with typical clinical presentations or common diseases. The execution of the EPA includes: 1) active search for typical symptoms and clinical signs of disease and disorders to be considered (differential diagnosis "with the patient"), 2) collation of previous reports and documents relevant to the patient's medical history, previous medication and if necessary the consultation of the patient's family members or co-treating physicians, 3) complete or focused medical history and physical exam, according to the situational requirements, 4) structured summary, for example in terms of chief and additional complaints, relevant differential diagnoses and suspected or preliminary diagnoses, current or previous medical history, 5) presentation to the supervising physician, 6) sharing information with the wider care team (e.g. physicians, nurses), 7) documentation in patient file.
Limitations	A closer supervision level than "act with distant supervision" is required for: a) unstable or critically ill patients (e.g. patients in intensive care or emergency units), b) newborns, infants, children, adolescents and pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology).
Knowledge, skills and attitude	Knowledge: Structure and function of the human body; presentation and pathophysiology of typical clinical symptoms and common diseases; principles and technique of physicianpatient communication, verbal, non-verbal and paraverbal aspects of communication; course and structure of a medical history (current complaints, medical history, personal, vegetative, family, social and medication history, intolerances) and of a physical exam (head- and neck region, thorax, abdomen and extremities by means of inspection, auscultation and percussion, basic neurological, musculoskeletal and dermatological examination); hygiene standards and infection prevention; concepts and techniques of differential diagnoses, step-wise differential diagnoses for common complaints and medical results; communication with patient, relatives and the care team. Skills: Evaluation of the overall patients´ impression; patient-centred communication, establishing a trustful physician-patient relationship; taking a structured medical history; performing a structured physical exam, recognizing typical and common clinical symptoms, differentiating between "normal" and "non-normal" in case of special discipline-specific findings; case presentation to the supervising physician with a summary of findings, mentioning inconclusive findings or those with ought to be checked again; differential diagnostic considerations; development of a working diagnosis; entry of findings into the patient file. Attitudes: Open and respectful communication; attention to diversity (gender, age, culture); use of patient-friendly language; attention to hygiene standards; compliance to confidentiality standards, respecting patient privacy.

Conditions and implications of entrustment decision	The collected and collated findings and diagnoses by the resident form the basis of further decision making regarding the diagnostics, treatment and management of the patient without an immediate or detailed check by the supervising physician. The medical history, findings and file entries will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, () Collaborator, () Manager, () Health Advocate, (X) Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Compile a diagnostic work plan and initiate implementation (EPA 1.2)**
	At the beginning of postgraduate training, the resident is able to autonomously compile a step-wise diagnostic work-up plan for adult patients with typical clinical presentations, medical results or common diseases and to initiate its implementation following coordination with the supervising physician.
Specification	The execution of the EPA includes: 1) requesting basic diagnostic tests (i.e. monitoring weight, balances, blood pressure and pulse, basic blood readings, ECG, and thorax x-ray), 2) compiling a differential diagnostic work-up plan according to the symptoms, disease manifestation, medical results and patient preferences, 3) presenting the plan to the supervising physician and achieving agreement. Following the coordination with the supervising physician: 4) requesting patient-specific diagnostics, 5) completing diagnostic order request forms, 6) sharing information with the patient and, where appropriate, with family members. 7) sharing information with the wider care team (e.g. physicians, nursing).
Limitations	A closer supervision level than “act with distant supervision” is required for: a) unstable or critically ill patients (e.g. patients in intensive care or emergency units), b) newborns, infants, children, adolescents and pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology).
Knowledge, skills and attitude	Knowledge: Pathophysiology of typical clinical symptoms and common diseases; concepts and techniques of differential diagnoses, step-wise differential diagnoses for common complaints and medical results; standards for basic diagnostic testing; standards or established diagnostic work-up for typical clinical symptoms and common diseases; course, benefits, risks, indications and contraindications of common diagnostic procedures (laboratory, imaging techniques with or without ionising radiation or radionuclides, endoscopic and electrophysiological procedures, pathology). Skills: Compiling a patient-specific, differential diagnostic work-up plan; consultation with supervisor; implementation of the patient-specific diagnostic work-up plan; rational medical decision-making; sharing information with the patient and care team. Attitudes: Attention to diversity (gender, age, culture); balancing effort, expense and risks of diagnostics with benefits and results; dealing with uncertainty.
Conditions and implications of entrustment decision	The resident autonomously requests basic and patient-specific diagnostics following coordination with the supervising physician. He/ she initiates the implementation without an immediate or detailed check by the supervising physician. The implementation of the diagnostic work-up plan will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, () Communicator, (X) Collaborator, (X) Manager, () Health Advocate, (X) Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Interpret test results and initiate further steps (EPA1.3)**
Specification	At the beginning of the postgraduate training, the resident is autonomously able to interpret results of common tests and to classify them generally for adult patients, recognizing common emergencies. He/ she initiates further steps following coordination with the supervising physician. The execution of the EPA includes: 1) reviewing and interpreting findings of basic diagnostic tests (e.g. monitoring weight, balances, blood pressure and pulse, pulse oximetry, standard laboratory parameters, 12-lead ECG, chest X-ray), 2) reviewing and interpreting findings of common further examination methods (e.g. general laboratory parameters, microbiology, virology, endoscopy, radiological imaging), 3) recognising common emergency situations and acting upon them, (in accordance with EPA 12 “recognising emergencies and acting upon them”), 4) reporting to the supervising physician, and if necessary coordinating of subsequent diagnostic and therapeutic steps, 5) requesting and initialising further diagnostic tests and treatments, 6) sharing information with the patient and, where appropriate, with family members, 7) sharing information with the wider care team (e.g. physicians, nursing).
Limitations	A closer supervision level than “act with distant supervision” is required for: a) unstable or critically ill patients (e.g. patients in intensive care or emergency units), b) newborns, babies, children, adolescents, pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology).
Knowledge, skills and attitude	Knowledge: Parameters to evaluate the significance of diagnostic results; implication of results from basic diagnostics and common further examination methods, including emergency situations. Skills: Reviewing and interpreting patient test results; adjusting, consultation with the supervising physician; implementation of the patient-specific diagnostic or treatment plan; rational medical decision-making; informing patients and the care team. Attitudes: Attention to diversity (gender, age, culture); balancing effort, expense and risks of diagnostics against benefits and results; dealing with diagnostic uncertainty.
Conditions and implications of entrustment decision	The resident’s report on the basic diagnostics and common tests form the basis for the further diagnostic and treatment steps without an immediate or detailed check by the supervising physician. Test and examination results are being reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, () Communicator, () Collaborator, (X) Manager, () Health Advocate, () Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Compile a treatment plan and initiate implementation (EPA 1.4)**
	At the beginning of the postgraduate training, the resident is autonomously able to compile a structured treatment plan for adult patients with common diseases and typical cours of disease. Following coordination with the supervising physician, the resident initiates the implementation of the treatment plan.
Specification	The execution of the EPA includes: 1) requesting generic therapies (e.g. diet, fluid intake, regulating bowl activity, sleeping aides, simple pain medication), 2) compiling a treatment plan according to the test results, diagnoses and medication requirements of the patient, 3) presenting the plan to the supervising physician and achieving agreement. Following the coordination with the supervising physician: 4) requesting patient-specific medication and therapy, 5) requesting basic therapy (e.g. physiotherapy, respiratory exercise), 6) sharing information with the patient and, where appropriate, family members, 7) sharing information with the wider care team (e.g. physicians, nurses).
Limitations	A closer supervision level than “act with distant supervision” is required for: a) unstable or critically ill patients (e.g. patients in intensive care or emergency units), b) new-borns, babies, children, adolescents or pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology).
Knowledge, skills and attitude	Knowledge: Pathophysiology of common diseases and their typical course; principles of prevention and therapy; standards of generic therapies; standards of established specific therapies for typical diseases; course, benefits, indications, contraindications and risks of common therapies (diet, substitution, physio- and ergotherapy, drugs, interventions, anesthesiology, surgery, radiation- and nucleotidtherapy); common drug interactions. Skills: Compiling a patient-specific, therapeutic plan; safe medication prescibing; consultation with the supervising physician; initiating patient-specific therapies; rational medical-decision making; informing patients and the care team. Attitudes: Attention to diversity (gender, age, culture); balancing effort, expense and risks of treatments against their benefits and results; dealing with uncertainty.
Conditions and implications of entrustment decision	The resident autonomously compiles a treatment plan. Following coordination with the supervising physician, he/ she requests common and/or patient-specific therapies. The resident initiates implementation without an immediate or detailed check by the supervising physician. Implementation of the treatment plan will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, () Communicator, (X) Collaborator, (X) Manager, () Health Advocate, (X) Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

EPA domain 2 – General medical procedures

Title	**Perform general procedures of a physician (EPA 2)**
Specification	At the beginning of the postgraduate training, the resident is able to autonomously perform a defined set of general medical procedures. The execution of this EPA includes: 1) explaining the procedure to the patient, 2) venous and capillary blood sampling (EPA 2.1 and 2.2), 3) inserting a peripheral catheter (EPA 2.3), 4) taking a blood culture (EPA 2.4), 5) taking a smear (oral, nasal, wound, anal, urogenital or cervical) (EPA 2.5), 6) giving an intracutaneous, subcutaneous or intramuscular injection (M. deltoideus) (EPA 2.6, 2.7 and 2.8), 7) giving an infusion (EPA 2.9), 8) placing a nasogastric tube (EPA 2.10), 9) performing a bed-site test to determine the blood group (EPA 2.11), 10) giving a blood product (e.g. erythrocytes, thrombocytes) (EPA 2.12), 11) putting on or changing a simple bandage (EPA 2.13), 12) taking an ECG (EPA 2.14), 13) writing a prescription (EPA 2.15).
Limitations	A closer supervision level than “act with distant supervision” is required for: a) patients unable to give consent, b) unstable or critically ill patients (i.e. patients in intensive care or emergency units), c) newborns, babies, children, adolescents and pregnant women.
Knowledge, skills and attitude	<u>Knowledge:</u> Structure and function of the human body relevant to the medical procedure; legal basis for performing the medical procedure; hygiene and infectious disease prevention; course, aims, indications, contraindications and potential risks of the medical procedure, prescribing medication. <u>Skills:</u> Preparing the procedure; securely identifying the patient; performing the medical procedure; post processing, including organising or excecuting the packing and distribution of patient-related materials; completing the requisition slip; writing a prescription. <u>Attitudes:</u> Putting the patient at ease; awareness of the risks involved for both the patient and oneself; use of language which is understandable to patients; attention to hygiene standards.
Conditions and implications of entrustment decision	The resident is able to perform the medical procedures autonomously with no immediately available supervising physician to assist. Results of the procedure will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, (X) Collaborator, (X) Manager, () Health Advocate, () Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve manikin-based simulation, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

EPA domain 3 – Communication with patients

Title	**Seek consent for medical examinations and procedures (EPA 3.1)**
Specification	At the beginning of the postgraduate training, the resident is able to autonomously inform patients about the course, benefits, risks and possible alternatives of a defined set of medical examinations and procedures and to seek patient consent. The execution of this EPA includes: 1) explaining the medical examination and procedure to the patient, 2) filling in and completing the patient information sheet, obtaining the patient's signature and signing documents for the administration of erthocytes, thrombocytes or preparations of plasma, 3) Seeking oral patient consent for medical examinations and procedures which do not require written consent (i.e. taking blood, urinary catheter, feeding tubes, x-rays).
Limitations	A closer supervision level than "act with distant supervision" is required for: a) patients unable to give consent, b) medical examinations and procedures the resident is not familiar with, c) unstable or critically ill patients (i.e. patients in intensive care or emergency units), d) newborns, babies, children, adolescents and pregnant women, e) surgical procedures, anaesthetics, and non-surgical interventions (e.g. angiography, angioplasty, stenting, fibrinolysis).
Knowledge, skills and attitude	Knowledge: Legal basis for performing medical examinations, procedures and interventions; patients' capacity to consent; course, aims, indications, contraindications and potential risks of medical examinations and medical procedures; principles and techniques of physician-patient communication and decision-making processes, risk communication as well as shared decision-making. Skills: Assessing capacity to consent; structuring the decision-making process; informing patients about the planned medical examination and procedure; communicating risks; seeking oral or written consent. Attitudes: Open and respectful communication; attention to diversity (gender, age, culture); use of language which is understandable to patients; dealing with uncertaintenty, compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The patients´ consent sought by the resident forms the basis for the implementation of the medical examination or procedure without an immediate or detailed check by the supervising physician. The consent will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	() Medical Expert, (X) Communicator, () Collaborator, (X) Manager, () Health Advocate, () Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Inform and advise a patient (EPA 3.2)**
Specification	At the beginning of the postgraduate training, the resident is able autonomously to inform and advise adult patients who present with common diseases or counselling reasons. The execution of this EPA includes: 1) gathering information concerning type of complaint and diagnosis of the patient, 2) providing general information about diagnostics, therapies and management, 3) following the consultation with the supervising physician, sharing and explaining information regarding the diagnostic and therapeutic steps to the patients, as well as the estimated duration of the treatment and hospital stay, 4) general advice on lifestyle changes (healthy diet, exercise, stress management), 5) general advice on alcohol and nicotine abuse, 6) general advice on sexually transmitted diseases.
Limitations	A closer supervision level than “act with distant supervision” is required for: a) unstable or critically ill patients (i.e. patients in intensive care or emergency units), b) breaking bad news (e.g. infuast prognosis), c) domestic violence or emotionally challenging situations, d) patients who are acute psychiatric or suicidal, e) patients unable to give consent, f) children and parents.
Knowledge, skills and attitude	Knowledge Principles of physician-patient communication, including active listening styles, considering content and relational aspects, the verbal and nonverbal level, as well as cognitive, emotional and motivational influencing factors; models and variables of health and illness, as well as prevention and health promotion; pathophysiology, standard diagnostic and therapy of typical clinical presentation medical results or common diseases. Skills Creating a trustful physician-patient relationship; realisation of a patient-centred conversation, consideration of the specific types, phases and purpose of the conversation; capture patients’ health and lifestyle and working towards their improvement. Attitudes Empathy; open and respectful communication; attention to diversity (gender, age, culture); use of language which is understandable to patients; compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The counselling carried out by the resident forms the basis for the diagnostic, therapy and management of the patient without an immediate or detailed check by the supervising physician. Results of the patient counselling will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	() Medical Expert, (X) Communicator, () Collaborator, () Manager, (X) Health Advocate, () Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, objective structured clinical examinations (including simulated patients), observations with patients in various clinical contexts (courses and clinical placements) and case-based discussions.
Expected supervision level at stage of training	Distant supervision for entry into residency.

EPA domain 4 – Communication and collaboration with colleagues

Title	**Present a patient history (EPA 4.1)**
	At the beginning of the postgraduate training, the resident is able to autonomously provide an oral report of a patient case in a structured manner, appropriate to the target audience and the situational requirements.
Specification	The execution of the EPA includes: 1) typical clinical presentations and common diseases with typical course, 2) non-typical clinical presentations and/or disease course and less common diseases following the consultation with the supervising physician, 3) a complete and focused presentation of the patient history according to the situational requirements, including current status and steps next to be taken, 4) presentation during ward rounds and patient-case discussions (e.g. clinical conference, x-ray demonstration, pathology conference, team meeting).
Limitations	A closer supervision level than "act with distant supervision" is required for: a) unstable or critically ill patients (i.e. patients in intensive care or emergency unit), b) newborns, babies, children, adolescents and pregnant women, c) discipline-specific clinical presentations or diseases (for example ophthalmology). d) presentations for surgery or invasive procedures, e) histories of patients the resident does not personally care for.
Knowledge, skills and attitude	Knowledge: Clinical presentations, pathophysiology and test results of typical clinical presentations or common diseases; structure of a complete or focussed presentation of a patient history; aims and course of ward rounds and patient-specific case discussions. Skills: Presenting a patient history appropriate to the audience and the context, including differentiation between main and additional findings, diagnoses, suspected or working diagnoses; addressing open questions and if necessary seeking advice or decisions on the further management of the patient. Attitudes: Open communication; attention to diversity (gender, age, culture); attention to hygiene standards; compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The presentation of the patient history through the resident forms the basis for the further management of the patient within the care team without an immediate or detailed check by the supervising physician. Patient history, test results and entries into the patient file will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, (X) Collaborator, () Manager, () Health Advocate, () Scholar, (X) Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve objective structured clinical examinations (including simulated patients) and observations in various clinical contexts (courses and clinical placements).
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Give or receive a patient handover (EPA 4.2)**
	At the beginning of the postgraduate training, the resident is able to autonomously give or receive a structured patient handover for adult patients to and from other medical personnel or departments, appropriate to the target audience and the situational requirements.
Specification	The execution of the EPA includes: 1) common diseases with typical course, 2) less common diseases and/or disease courses following the consultation with the supervising physician, 3) a complete and focused handover of the patient history according to the situational requirements including current status and steps next to be taken 4) shift change or patient handover to/ from physicians in the same clinical department, 5) patient handover to/from non-medical staff (e.g. nursing, other caregivers, patient transport).
Limitations	A closer supervision level than “act with distant supervision” is required for: a) unstable or critically ill patients (i.e. patients in intensive care or emergency units), b) handovers to/from surgery and invasive interventions, c) handovers to/from intensive care and emergency units, d) newborns, babies, children, adolescents and pregnant women, e) discipline-specific clinical presentations or diseases (for example ophthalmology), f) patients the resident does not personally care for.
Knowledge, skills and attitude	Knowledge: Clinical presentation, pathophysiology and findings of typical clinical presentations or common diseases; structure of the patient history according to the aim and course of the handover; principles of oral, written and electronic communication, as well as medical confidentiality and data protection. Skills: Presentation of a patient history according to the aim and setting of the handover, including differentiation of main and additional findings, diagnoses and suspected diagnosis; addressing open questions, as well as problems or tasks which may arise after the handover. Attitudes: Open communication; attention to diversity (gender, age, culture); compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The patient handover carried out by the resident forms the basis of further diagnostics, therapies and management of the patient without an immediate or detailed check by the supervising physician. Outcome of the patient handover will be reviewed and possibly checked by the supervising physician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, (X) Collaborator, (X) Manager, () Health Advocate, () Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve objective structured clinical examinations (including simulated patients) and observations in various clinical contexts (courses and clinical placements).
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Write and distribute a patient report (EPA 4.3)**
Specification	At the beginning of the postgraduate training, the resident is able to autonomously write a structured patient report and distribute to it to appropriate personnel or departments. The execution of the EPA includes: 1) writing and signing of preliminary discharge, transfer or interim reports based on the consultation with the supervising physician on the further management of the patient, 2) submitting, revising and counter-signing of the final report by the supervising physician, 3) structuring the report in line with local specifications (i.e. departmental letter head, patient identifikation, list of diagnoses, medical history and examination, results, summary and patients´course, medication at discharge, 4) distributing the report to the appropriate personnel and departments, if necessary initiate accordingly.
Limitations	A closer supervision level than “act with distant supervision” is required for: a) transfer to the intensive care unit, b) patients the resident does not personally care for.
Knowledge, skills and attitude	Knowledge: Clinical presentation, pathophysiology and findings of typical clinical presentations and common diseases; structure of a written patient report tailored to the target group; principles of oral, written and electronic communication, as well as medical confidentiality and data protection. Skills: Preparation of a written patient case in form of a discharge, transfer, and interim report; transmission in provisional form; coordination with the supervising physician; preparation and transmission of the final report. Attitudes: Communication targeted to the audience; attention to diversity (gender, age, culture); compliance to confidentiality standards, respecting patient privacy.
Conditions and implications of entrustment decision	The interim report prepared by the resident forms the basis for the further diagnostic, therapy and management of the patient without an immediate or detailed check by the supervising physician. The final report will be prepared in coordination with the supervising physician. The transmission of the final report to the appropriate personnel or departments will be carried out by the resident without an immediate or detailed check by the supervising physician.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, (X) Collaborator, (X) Manager, () Health Advocate, () Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve objective structured clinical examinations (including simulated patients) and observations in various clinical contexts (courses and clinical placements).
Expected supervision level at stage of training	Distant supervision for entry into residency.

EPA domain 5 – Patient care in special situations

Title	**Recognise an emergency situation and act upon it (EPA 5.1)**
	At the beginning of the postgraduate training, the resident is able to autonomously recognise an emergency situation and to broadly assess its scope. The resident is able to autonomously provide emergency aid and to call for help for the further management of the patient.
Specification	The execution of the EPA includes: 1) calling for help according to the local circumstances (e.g. emergency team), 2) beginning basic-life support without technical resources in patients of any age showing loss of vital functions, 3) beginning reanimation with technical resources (e.g. ambu breathing bag; defibrillator) in adult patients showing loss of vital functions, 4) recognising situations of imminent vital threat and start managing the patient (sign for shortness of breath or hypoxia, chest pain, increasing impairment of consciousness, high temperature, arterial hypo- and hypertension, tachy- and bradycardia, hypo- and hyperglycaemia, anuria, internal and external bleeding, trauma and injury), 5) immediately informing the supervising physician and requesting support.
Limitations	A closer supervision level than “act with distant supervision” is required for: a) reanimation of non-adult patients with technical resources, b) performing the continuing management in conditions of vital threat.
Knowledge, skills and attitude	Knowledge: Rescue chain in and outside the hospital; manifestation, pathophysiology, standard diagnostic and therapy in conditions of imminent vital threat; basic and advanced life support; airway management, trauma management. Skills: Recognising and acting on conditions of imminent vital threat; initiation of a rescue chain; performing basic and advanced life support; handling the defibrillator; positioning of emergency patients; working in a team to manage an emergency patient. Attitudes: Recognising the role as first aider; preserving the safety of the patient and one’s own.
Conditions and implications of entrustment decision	The resident immediately requests support for patients with loss of vital functions and conditions of vital threat. He/ she provides emergency aid until the arrival of the emergency team or the supervising physician. The emergency situation and the procedure will be discussed in retrospect with the supervising physician.
Most relevant domains of competence	(X) Medical Expert, (X) Communicator, (X) Collaborator, (X) Manager, () Health Advocate, () Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing, manikin-based simulation and objective structured clinical examinations (including simulated patients).
Expected supervision level at stage of training	Distant supervision for entry into residency.

Title	**Undertake an evidence-based patient case presentation and initiate patientspecific implementation (EPA 5.2)**
	At the beginning of the postgraduate training, the resident is able to autonomously collate best available evidence concerning a medical problem of an individual patient and to present it in a structured manner. The resident is able to initiate adjustments to the management of the patient following coordination with the supervising physician or physician team.
Specification	The execution of this EPA includes: 1) medical problems which can be handled by the resident, 2) searching for best available evidence (using data bases and scientific journals), including guidelines and clinical reviews, 3) checking the clinical relevance and applicability for the individual patient, 4) delivering a structured patient case presentation (i.e. departmental discussion, inhouse training session), 5) seeking agreement with the supervising physician in terms of what changes should be applied to the management of the patient, 6) requesting changes according in line with EPA 1.2 ”diagnostic plan” and EPA 1.4 “treatment plan”.
Limitations	A closer supervision level than “act with distant supervision” is required for: a) presentations of a medical problem which are too complex, b) presentations of a medical problem with little clinical evidence, c) evidence which primarily relies on basic research.
Knowledge, skills and attitude	Knowledge: Principles of medical problem definition and evidence-based medicine; methodology, use and limitations of evidence-based medicine, including formulation of the search question, literature search and appraisal as well as judging its patient-specific applicability, course and structure of a patient case presentation. Skills: Searching for and grading evidence-based literature for an individual patient case and medical problem; presenting the case to the team; making adjustments, seeking agreement with the supervising physician and initiate implementation of a patientspecific management plan; rational medical decision-making; informing patients and care team. Attitudes: Attention to diversity (gender, age, and culture); balancing effort, expense and risks of diagnostics and therapies against benefits and results; dealing with diagnostic uncertainty.
Conditions and implications of entrustment decision	The resident presents the results of the evidence search and its application to the individual patient to the physicians’ team. Following coordination with the supervising physician, he/ she adjusts the management plan of the patient and initiates implementation without an immediate or detailed check by the supervising physician. Implementation of the adjusted management plan will be reviewed and possibly checked by the supervising clinician during the next regular meeting with the resident or ward round.
Most relevant domains of competence	(X) Medical Expert, () Communicator, () Collaborator, (X) Manager () Health Advocate, (X) Scholar, () Professional
Assessment sources	Passing the assessment of the undergraduate medical programm and the final state examination. The assessment should involve knowledge testing as well as evidencebased case elaboration and presentations in various clinical contexts (courses and clinical placements).
Expected supervision level at stage of training	Distant supervision for entry into residency.

Chapter 4

What can we expect from medical graduates? Empirical survey on the performance of Core EPAs in the first days of residency

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[3] The original publication is available via https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-020-02376-y

Abstract

Background: Core Entrustable Professional Activities (EPAs) have been defined to specify the performance expectations for entering residents worldwide. The content of these EPAs was elaborated and validated primarily via medical expert consent approaches. The present study aims to collect empirical information on the actual task performance and supervision level of entering residents as a complementary methodological approach to enhance the content validity of a set of institutional EPAs.

Methods: In the summers of 2017 and 2018, Charité medical graduates ($n = 720$) received a post-graduation survey by mail. The questionnaire covered the performance of Core EPAs, Core procedures and more advanced EPAs. Graduates were asked how frequently they had performed the respective EPAs since the start of residency and under what level of supervision. We expected the large majority of graduates (> 75%) to have performed the Core EPAs and procedures under at least indirect supervision.

Results: In total, 215 graduates (30%) returned the questionnaire, and 131 (18%) surveys could be included in the data analysis. The majority of participants were female (63%) and worked in hospitals (50%) or in university medical centres (30%) across various medical disciplines. Among the Core EPAs, 10 out of 11 tasks had been performed by more than 75% of graduates since the start of residency, 9 under indirect supervision. Regarding the Core procedures, only 3 out of 13 procedures had been performed by the large majority of graduates under indirect supervision, and 10 procedures had not been carried out by at least one-third of participants. Among the 5 advanced EPAs, none of 5 had been performed by more than 75% of the participants since the start of residency, and 4 had been carried out by 50% under indirect supervision.

Conclusions: The results of this study largely and complementarily confirm the validity of the defined Core EPAs representing realistic expectations for entry into residence at our institution. The low actual performance rate of Core procedures serves to stimulate an institutional discussion on their adjustment to better match the workplace reality.

Keywords: Entrustable professional activities, Undergraduate education, Medical graduates, Residents

Background

Entry into residency is characterized by a sudden and often overwhelming increase in responsibilities for graduating physicians with respect to the care of patients. To ease this critical transition, medical education experts have developed Core Entrustable Professional Activities (EPAs) for entry into residency [1-5]. The content elaboration and validation of such Core EPAs did not involve explicit empirical data or research on the tasks entering residents actually perform. However, such real-world data from clinical workplaces could be used for triangulation of the performance expectations with experts' opinions by providing complementary evidence of their content validity or, in the case of divergence, an opportunity for the re-adjustment of the Core EPAs.

The EPA concept builds on authentic tasks that trainees perform in the workplace under varying levels of supervision [6, 7]. Depending on the level of competence of the trainees, professional activities can be gradually entrusted to them. The idea behind the EPA concept is to define those tasks trainees are commonly expected to perform at the end of a training phase without supervision and to implement these as outcomes for the curriculum.

The beginning of residency is educationally very dynamic, as the responsibilities of entering residents increase markedly in a short period, from smaller units of work, such as history taking and the physical examination of new patients, to conducting and managing the complete admission of a patient or even conducting a night shift with complete responsibility for the care of patients. Core EPAs for entry into residency aim to define the performance expectations for beginning residents, irrespective of the discipline chosen, and are implemented as outcomes in undergraduate medical curricula. The content of the developed Core EPA frameworks was generally defined by various expert groups, i.e., medical educators or experienced physicians, using iterative group discussions and various consent-finding methods [1-5]. Overall, the Core EPAs have much in common; however, they also involve relevant differences in content. These differences are related to the kind and number of professional tasks, their specifications and limitations, and the respective levels of supervision [5]. These differences may reflect variations in workplace practices in different contexts or disciplines but may also be indicative of a need to further adjust the content. Notably, the existing Core EPAs were generally defined by majority voting procedures. Thus, there were possibly several experts in the groups who did not agree that the defined EPAs reflect the expectations for entering residency. In addition, others have argued that the breadth and depth of the Core EPAs are too narrow to reflect the expectations and workflows in clinical settings, calling for more aspirational and less granular EPAs [8, 9].

The Core EPA concept implies that the professional activities included, and the supervision levels assigned reflect the requirements and practices in the real-life work context for entering residents. Gaining insights into and empirical information on the workplace reality

of entering residents could provide additional validating evidence for the Core EPAs and could be used to adjust them. To date, there is only sparse, insufficiently detailed information and research available on what entering residents actually do in the first weeks and months of residency. Existing studies on the experiences of beginning residents have assessed the needed supervision level or residents' preparedness to perform the Core EPAs without direct supervision [10, 11]. The results show that the majority of residents show high confidence, identifying only a few EPAs that the majority do not feel safe to perform without direct supervision. Other studies assessed residents' general confidence or preparedness to perform the AAMC Core EPAs, without specifying the level of needed supervision [12, 13].

The aim of this study was to explore the actual workplace involvement of entering residents on the basis of a set of Core EPAs for entering into residency recently defined at our institution, the Charité – Universitätsmedizin Berlin (Charité). A section of questions regarding the professional tasks performed, how frequently and under what level of supervision was incorporated into the regular post-graduation survey. We further explored the degree to which the EPA variables are interrelated.

Method

Previous work

At the Charité, institutional Core EPAs were defined from 2014 to 2015 in a modified, three-round Delphi procedure with an expert group consisting of 45 experienced clinicians from various disciplines. Panel members were asked to rate the relevance of professional tasks for entering residents at the indirect supervision level as measures for Core EPA identification and validation. Consent was achieved when a content validity index (CVI) of ≥80% was reached. The process resulted in a set of Core EPAs and Core medical procedures [5, 14].

Participants

In the summers of 2017 and 2018, Charité medical graduates (n = 720) received a regular post-graduation evaluation questionnaire by mail within 9 months after graduation. They were asked to answer the questionnaire and send it back to the research team at the Charité. Contacting graduates via e-mail was not possible as their institutional e-mail addresses expired 3 months after graduation. The study protocol received approval from the Charité data protection office (No. 567/16) and ethics board (No. EA4/051/20).

Questionnaire

The questionnaire was developed by an institutional working group with colleagues from the department of Quality Management (QM) Teaching and Learning, the Dieter Scheffner Centre for Medical Education and Educational Research, the Institute of Medical Sociology and

Rehabilitation Science and with medical students from the Charité. It comprised a broad spectrum of questions covering person-related data, the evaluation of the medical curriculum and the respondents' experiences as graduates. The development of the questionnaire was distributed among the working group members according to their field of expertise. The questions were partly derived from previous questionnaires and partly newly created.

One section entailed questions regarding the Charité EPAs expected to be performed in the first days of residency (Additional File 1). Table 1 provides an overview of the 11 Core EPAs and 13 Core medical procedures that were asked about in the questionnaire and the corresponding terms used in this manuscript. The questionnaire also included five broader, less granular EPAs representing more advanced expectations for medical graduates. The questions about the EPAs were developed by the authors to characterize the real-life workplace involvement of graduates.

Participants were asked:

1) how many times they performed the activities (frequency of performing EPAs) and
2) to indicate the highest level of supervision under which they performed an EPA at least three times (experienced supervision level).

The frequency was captured by the following response categories: 0; 1–5; 6–10; 11–25; 26–100; > 100; and > 500. For data analysis, these seven categories were summarized into four categories (Fig. 1). In the results section, we will especially refer to those tasks performed at least one and more than ten times since graduation. Supervision levels were captured on the basis of the levels of supervision established for postgraduate medical education [15]. The study participants indicated the following: I observed the activity but did not perform it; I performed the activity under direct supervision (supervising physician in the room); I performed the activity autonomously under indirect supervision (supervising physician on the ward, readily available); and I performed the activity autonomously under distant supervision (supervising physician not in the hospital, not readily available).

We expected the large majority of beginning residents to have performed the activities within the first months of residency at least under level 3, or indirect supervision [5]. As our study is explorative in nature, we decided to take > 75% as the threshold for operationalizing the large majority. In addition, we report the study results for the plain majority (> 50%).

Statistical analysis

Analyses were carried out using SPSS 25 [16]. The frequency distribution of the EPA variables is displayed by means of valid percentages, excluding the randomly occurring missing values. Spearman's Rho correlations were used to determine the relation among the EPA variables. Due to the explorative nature of the analyses, no corrections for multiple testing were applied [17].

Table 1 Overview of EPAs used in the questionnaire

	Terms used in the manuscript	EPA descriptions used in the questionnaire
Core EPAs	History, physical and synthesis	Take a medical history, perform a physical examination and summarize the results in a structured manner (typical presentation, common disease pattern)
	Diagnostic plan	Compile a diagnostic plan and initiate implementation (typical presentation, common disease pattern, typical course of disease; tiered diagnostics)
	Interpret test results	Interpret test results and initiate further steps (common diagnostic methods)
	Treatment plan	Compile a treatment plan and initiate implementation (common disease pattern, typical course of disease)
	Obtain Informed consent	Seek consent for medical procedures and diagnostics (inform patient about course, benefits, risks and alternatives)
	Inform and advise a patient	Inform and advise patients (common consolations, reasons and diseases)
	Present patient history	Present a patient history (structured; according to the target audience and situational requirements)
	Patient handover	Give or receive a patient handover (structured; according to the target audience and situational requirements)
	Patient report	Write and transmit a patient report (structured; transmit oneself or delegate)
	Act in emergency situations	Recognize an emergency situation and act upon it (estimate the degree of severity, provide on-the-spot aid, call for help)
	Evidence-based case presentation	Undertake an evidence-based patient case and initiate patient-specific implementation
Core Procedures	Venous blood sampling	Venous blood sampling
	Capillary blood sampling	Capillary blood sampling
	Peripheral catheter	Inserting a peripheral catheter
	Blood culture	Taking a blood culture
	Taking a smear	Taking a smear (oral, nasal, wound, anal, urogenital)
	Intracutaneous injection	Giving an intracutaneous injection
	Subcutaneous injection	Giving a subcutaneous injection
	Intramuscular injection	Giving an intramuscular injection
	Infusion	Giving an infusion
	Nasogastric tube	Placing a nasogastric tube
	ECG	Taking an ECG
	Bandage	Putting on or changing a bandage
	Prescription	Writing a prescription
Advanced EPAs	Complete patient admission	Manage an in-patient admission
	Ward round	Conduct a ward round in the hospital
	Complete patient discharge	Manage an in-patient discharge
	Weekend ward round	Conduct a weekend ward round in the hospital
	Late/night shift	Take a late/night shift (supervising physician available via telephone)

Results

Participants

In total, 215 graduates returned the questionnaire (return rate = 30%). Of those, 84 were not yet working as physicians or reported insufficiently on the EPA section of the survey. Accordingly, data from 131 graduates were included in this study (response rate = 18%). The graduates were on average 29 years old (SD = 4), and 63% were female. The majority worked in hospitals (50%) or in university medical centres (30%). They were situated in various medical

disciplines: internal medicine (n = 23), paediatrics (n = 15), gynaecology and obstetrics (n = 14), anaesthesiology (n = 14), general medicine (n = 12), surgery (n = 12), neurology (n = 8), radiology (n = 8), psychiatry (n = 6), and dermatology (n = 5).

Frequency of performing the EPAs

Figure 1 displays how frequently the participants performed the EPAs since the start of residency. The results are separately depicted for the Core EPAs, the Core medical procedures and the more advanced EPAs.

Among the Core EPAs, 10 out of 11 had been performed at least once by more than 75% of the graduates since the start of residency. The Core EPA “Case presentation” had been carried out by approximately two-thirds of the graduates. Eight out of 11 EPAs had been performed more than 10 times by at least 75% of the graduates. The Core EPAs “Act in emergency situations” and “Case presentation” had been carried out by approximately one-third of the graduates more than 10 times.

Regarding the Core medical procedures, a greater variation was seen in the frequency with which they had been performed by the entering residents. Three out of 13 Core medical procedures had been performed at least once by more than 75% of the graduates since the start of residency. Eight procedures had been performed by at least 50% of the graduates. Seven of the 13 Core medical procedures had been performed by less than 25% of the entering graduates more than 10 times. The lowest performance rate (34%) was seen for the Core medical procedure “Nasogastric tube”. Ten procedures had not been performed by at least one-third of the participants.

Among the more advanced EPAs, none of the 5 professional activities had been carried out at least once by more than 75% of the graduates. All the tasks had been carried out by at least 50% of the graduates, three more than 10 times.

Experienced supervision level

Figure 2 depicts the supervision levels under which participants performed the EPAs, including the percentage of participants who had not performed the activities and had only observed them. Among the Core EPAs, 9 of the 11 had been performed by more than 75% of respondents, i.e., the large majority of graduates, under the expected level of supervision. The exceptions were again the EPAs “Act in emergency situations” and “Evidence-based case presentation”, which had been carried out by 64 and 53% of participants under indirect or distant supervision, respectively.

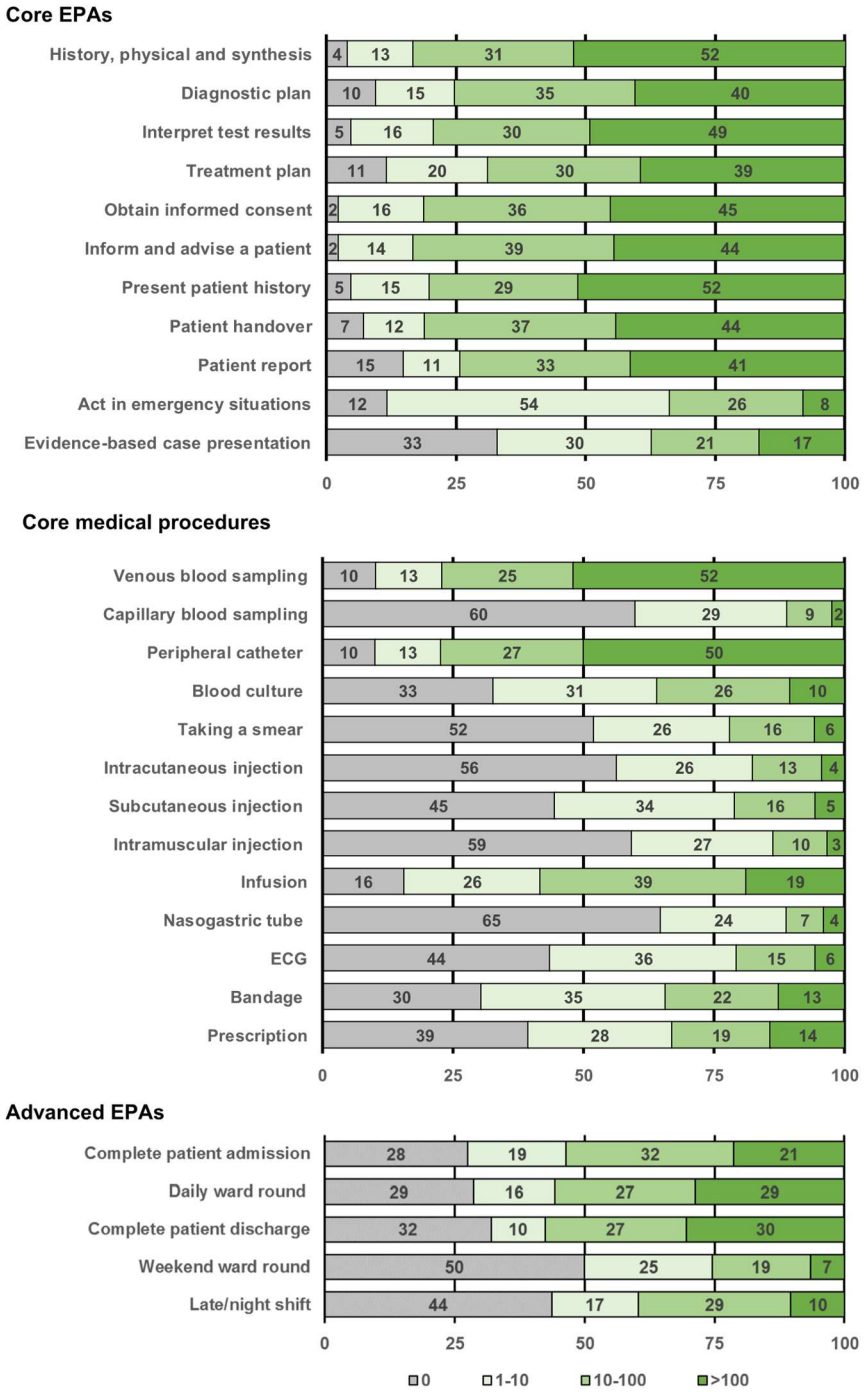

Fig. 1 Frequency of performing EPAs. The figure depicts the valid percentage of participants performing the EPAs

Regarding the Core medical procedures, greater variability in workplace practice was again observed. Three out of the 13 Core medical procedures had been performed under at least indirect supervision by more than 75% of the graduates since the start of the residency and 5 procedures by at least 50% of the graduates.

Regarding the more advanced EPAs, none of the tasks had been carried out by more than 75% of the graduates under at least indirect supervision. For 4 out of 5, this supervision level was reached by at least 50% of the graduates.

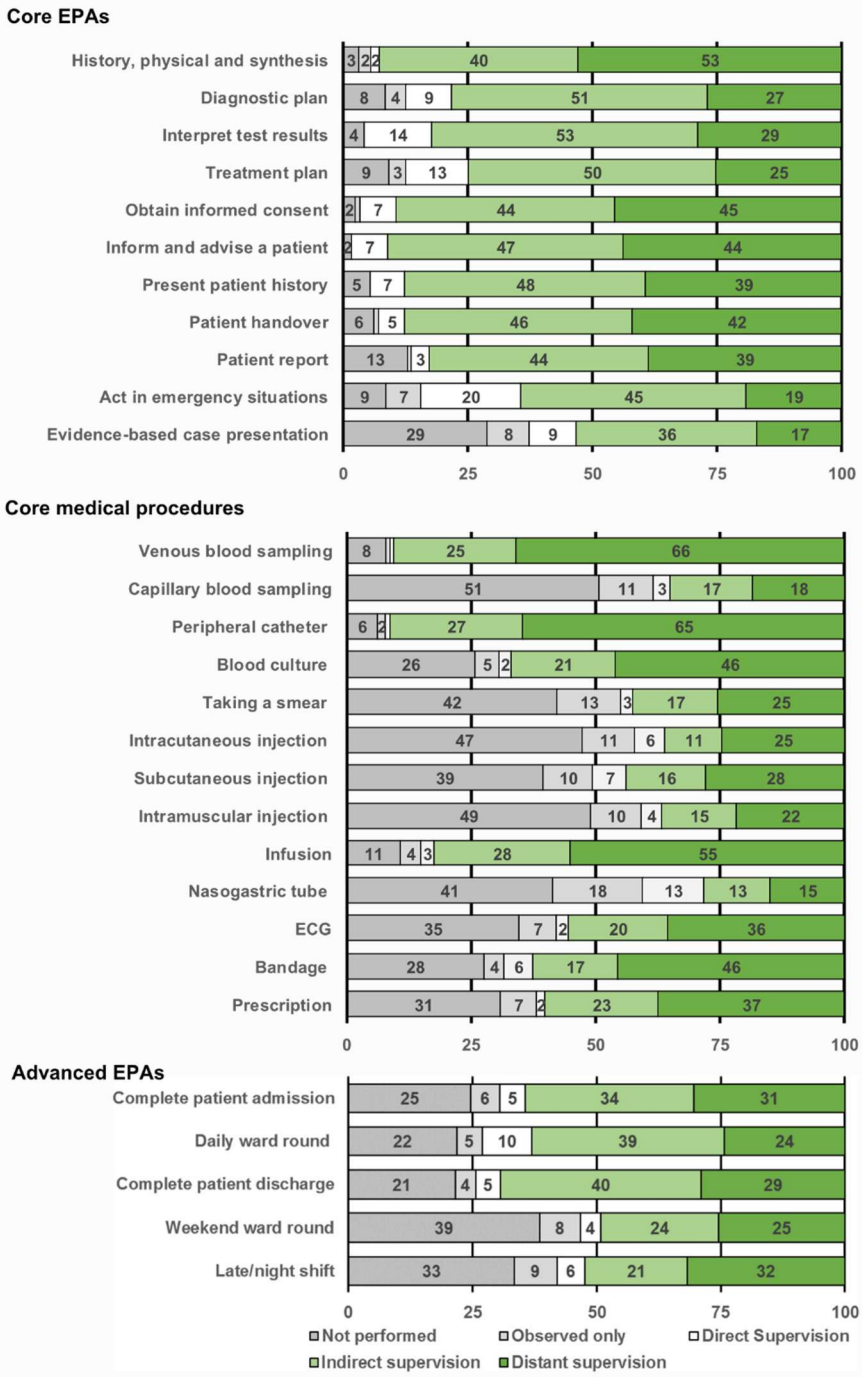

Fig. 2 Experienced supervision level. The figure depicts the valid percentage of participants performing the EPAs under the respective supervision levels

Exploratory analyses

The statistical analyses revealed that the history of performing the activities correlated positively with the experienced supervision level for all activities. The correlation coefficients ranged between 0.211 and 0.77 (Additional file 2).

Discussion

The purpose of this study was to gather empirical information on beginning residents' actual task performance and supervision level using a regular post-graduation survey. In the following, we will exemplarily triangulate the results of this survey to the expert expectations, both from the same institution, thereby combining several methods to reflect on the content of our Core EPAs from an empirical angle.

It was among the Core EPAs that we found the best fit between the expectations of the medical experts and the actual workplace performance of the beginning residents. For nine of the 11 Core EPAs, the tasks were performed by more than 75% of the graduates under at least indirect supervision. This supports the content validity of these tasks and their granularity and further indicates that these tasks are relevant to many if not all covered medical disciplines. The Core EPAs "Act in emergency situations" and "Evidence-based case presentation" were performed more infrequently and under a closer level of supervision by the majority of graduates. However, there are still valid reasons to include both activities in the set of Core EPAs for our institution. In the clinical workplace, graduating physicians can at any time be exposed to patients who suddenly develop life-threating conditions at a time when no supervisor is in the room or on the ward. Graduates must be able to recognize these situations and provide appropriate patient care until the emergency team or the supervisor has arrived. The Core EPA "Evidence-based case presentation" might not be as essential as the EPA "Act in emergency situations". However, in our context, all the medical experts contributing to the EPA content definition were working in an academic setting. It was important to them to include at least one EPA that explicitly applies science, i.e., evidence-based medicine, to patient care, both to reflect the practice in their clinical context and to impact the future clinical practice of Charité graduates in other settings [5, 14].

Among the Core medical procedures, we found only a marginal fit between the medical experts' expectations and the actual practice of graduating physicians in our workplace context. Three of the 13 Core medical procedures had been carried out by more than 75% of the graduates under at least indirect supervision. Furthermore, 10 of the 13 procedures had not been carried out by more than one-third of the graduates. This may reflect the fact that most of the tasks included are rarely performed at all and may be performed by other professionals and with variable frequency in the various disciplines. This raises a question regarding whether all the identified procedures qualify as Core medical procedures expected of all graduates at our institution. Internationally, the number of Core medical procedures varies between 6 and 22; thus, there are evidently some differences in the number and kind of medical procedures considered to be important [1, 3]. The empirical results of this study serve as an important stimulus for our institution to consider a substantial reduction in the number of Core medical procedures expected to be performed by its graduates under indirect

supervision. This does not mean these tasks should not be further trained and assessed during undergraduate medical training. In many cases, it could lead to the adjustment of the supervision level being expected for entry into residency. In disciplines and contexts in which the procedures are not part of general practice, co-performance or direct supervision may be a more reasonable starting point. The present study did not allow to compare how often and under what level of supervision the procedures are conducted in the different disciplines due to the rather low overall sample size. To address these issues in future studies, we have now permanently included the EPA section in the post-graduation survey and will use the accumulating data for such comparative analysis. In combination with information from different sources and studies, these results will be used to discuss and decide on the refinement of Core EPA for entry into residency in our context.

Among the advanced EPAs, 4 out of 5 had been performed by more than 50% of the graduates. For the interpretation of these results, several factors should be considered. The more advanced EPAs included in this study were not defined as outcomes for the undergraduate medical curricula by the medical experts but represent broader activities integrating and embracing, in a nested manner, several smaller EPAs [7]. As the responsibility of entering residents increases quickly in the first months of their postgraduate training, it is not surprising that depending on context, ability and discipline, a relevant number of graduates are already carrying out more advanced EPAs a few months after the start of residency. However, based on our empirical study, we would not suggest that the frequency of performance of the advanced EPAs qualifies them to be considered Core EPAs for entering into residency. It does not seem realistic to expect that the majority of entering residents can be fully entrusted to carry out, for instance, a complete patient admission. If so, this would mean, for example, that without confirmation from a supervisor, the entering graduate, based on his/her interpretation of the patient's history and physical examination, could autonomously decide on far-reaching diagnostic or therapeutic steps, such as ordering a CT scan with contrast media or sending a patient to the surgery theatre. However, the results of this study may indicate that the definition of Core EPAs for entering into residency, despite all its advantages, may be too narrow. While Core EPAs help students to master the transition from undergraduate to postgraduate medical training, there is a need to specify how the Core EPAs for entry into residency feed into the larger, more advanced EPAs residents have to carry out a few months later. This is in line with the recommendations by Chen and colleagues, who emphasized the continuity of medical education and pleaded for an overarching curriculum covering both under- and postgraduate education [18].

Research focusing on the perceived preparedness of beginning residents to perform Core EPAs, from the perspectives of both residents and supervising physicians, discusses the need to revise undergraduate curricula to better prepare students for medical practice [10-13,

19]. We can support those recommendations. Unsurprisingly, our study found that the frequency of performing an activity is positively associated with the level of entrustment. The integration of the Core EPAs and procedures into undergraduate curricula requires the opportunity to practice the activities in order to ease the critical transition to postgraduate education for graduating physicians [20, 21]. Another notable result of this study is that a regular post-graduation survey provides tangible, sufficiently meaningful information to enhance and reflect on the content validity of the Core EPAs for a given institution and context.

This study has several limitations. First, the study was conducted at a single medical school. The transferability of our findings to other contexts needs to be shown in future studies. Second, the questions covering the EPAs were not pilot tested with graduates, which could have led to a valuable refinement of the questionnaire. Third, the response rate in this voluntary post-graduation survey was 18%. While this is not unusual for medical education research [22], it may have created selection bias. Despite this, we feel that the results obtained provided tangible and sufficiently meaningful information to reflect on and enhance the content validity of our institutional Core EPAs for entry into residency. Finally, we did not apply the full entrustment scale as proposed in the literature [15]. We adjusted the scale to our expected level of supervision for graduates, but the administration of the complete scale might have resulted in different findings.

Conclusion

The presented study provides empirical information on the workplace participation of entering residents by means of a set of institutional Core EPAs and procedures. It adds complementary evidence on the validity of the professional activities our medical graduates should be trained in during undergraduate education. The results of this study and the chosen methodological approach may guide and assist medical faculties and organizations in enhancing the content validity of Core EPAs for entry into residency.

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Additional Files

Questionnaire extract: Questions regarding the Charité EPAs

How many times did you perform the following activities since the start of your residency?

	Not once	1-5 times	6-10 times	11-25 times	26-100 times	>100 times	>500 times	No information
Along the clinical encounter								
Take a medical history, perform a physical examination and summarize the results in a structured manner (typical presentation, common disease pattern)								
Compile a diagnostic plan and initiate implementation (typical presentation, common disease pattern, typical course of disease; tiered diagnostics)								
Interpret test results and initiate further steps (common diagnostic methods)								
Compile a treatment plan and initiate implementation (common disease pattern, typical course of disease)								
General medical procedures								
Venous blood sampling								
Capillary blood sampling								
Inserting a peripheral catheter								
Taking a blood culture								
Taking a smear (oral, nasal, wound, anal, urogenital)								
Giving an intracutaneous injection								
Giving a subcutaneous injection								
Giving an intramuscular injection								
Giving an infusion								

Placing a nasogastric tube								
Taking an ECG								
Putting on or changing a bandage								
Writing a prescription								
Communication with patients								
Seek consent for medical procedures and diagnostics (inform patient about course, benefits, risks and alternatives)								
Inform and advise patients (common consolations, reasons and diseases)								
Communication and collaboration with colleagues								
Present a patient history (structured; according to the target audience and situational requirements)								
Give or receive a patient handover (structured; according to the target audience and situational requirements)								
Write and transmit a patient report (structured; transmit oneself or delegate)								
Additional professional activities								
Recognize an emergency situation and act upon it (estimate the degree of severity, provide on-the-spot aid, call for help)								
Undertake an evidence-based patient case and initiate patient-specific implementation								
Manage an in-patient admission								
Conduct a ward round in the hospital								
Manage an in-patient discharge								
Conduct a weekend ward round in the hospital								
Take a late/night shift (supervising physician available via telephone)								

Please indicate the highest level of supervision under which you performed the respective EPA at least three times since the start of your residency.

Level 1: I observed the activity but did not perform it

Level 2: I performed the activity under direct supervision (supervising physician in the room)

Level 3: I performed the activity autonomously under indirect supervision (supervising physician on the ward, readily available)

Level 4: I performed the activity autonomously under distant supervision (supervising physician not in the hospital, not readily available).

	Level 1	**Level 2**	**Level 3**	**Level 4**	**No information**
Along the clinical encounter					
Take a medical history, perform a physical examination and summarize the results in a structured manner (typical presentation, common disease pattern)					
Compile a diagnostic plan and initiate implementation (typical presentation, common disease pattern, typical course of disease; tiered diagnostics)					
Interpret test results and initiate further steps (common diagnostic methods)					
Compile a treatment plan and initiate implementation (common disease pattern, typical course of disease)					
General medical procedures					
Venous blood sampling					
Capillary blood sampling					
Inserting a peripheral catheter					
Taking a blood culture					
Taking a smear (oral, nasal, wound, anal, urogenital)					

Giving an intracutaneous injection					
Giving a subcutaneous injection					
Giving an intramuscular injection					
Giving an infusion					
Placing a nasogastric tube					
Taking an ECG					
Putting on or changing a bandage					
Writing a prescription					
Communication with patients					
Seek consent for medical procedures and diagnostics (inform patient about course, benefits, risks and alternatives)					
Inform and advise patients (common consolations, reasons and diseases)					
Communication and collaboration with colleagues					
Present a patient history (structured; according to the target audience and situational requirements)					
Give or receive a patient handover (structured; according to the target audience and situational requirements)					
Write and transmit a patient report (structured; transmit oneself or delegate)					
Additional professional activities					
Recognize an emergency situation and act upon it (estimate the degree of severity, provide on-the-spot aid, call for help)					
Undertake an evidence-based patient case and initiate patient-specific implementation					
Manage an in-patient admission					
Conduct a ward round in the hospital					
Manage an in-patient discharge					
Conduct a weekend ward round in the hospital					
Take a late/night shift (supervising physician available via telephone)					

Correlations between the EPA variables for Core EPAs, Core procedures and advanced EPAs

	Frequency & Supervision level
Core EPAs	
History, physical and synthesis	.36**
Diagnostic plan	.52**
Interpret test results	.48**
Treatment plan	.46**
Obtain informed consent	.48**
Inform and advise a patient	.32**
Present patient history	.21*
Patient handover	.28**
Patient report	.25*
Act in emergency situations	.50**
Evidence-based case presentation	.50**
Core Procedures	
Venous blood sampling	.28**
Capillary blood sampling	.49**
Peripheral catheter	.32**
Blood culture	.55**
Taking a smear	.58**
Intracutaneous injection	.69**
Subcutaneous injection	.62**
Intramuscular injection	.52**
Infusion	.33**
Nasogastric tube	.77**
ECG	.42**
Bandage	.47**
Prescription	.31**
Advanced EPAs	
Complete patient admission	.61**
Ward round	.47**
Weekend ward round	.55**
Complete patient discharge	.63**
Late/night shift	.54**

Spearman's Rho Correlation: **p < 0.01. *p < 0.05
1) Frequency of performing EPAs; 2) Supervision level when performing EPAs

Chapter 5

Exploring the introduction of entrustment rating scales in an existing objective structured clinical examination

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[4] The original publication is available via https://bmcmededuc.biomedcentral.com/articles/10.1186/s12909-019-1736-2

Abstract

Background: The concept of EPAs is increasingly applied to assess trainees' workplace performance by means of entrustment ratings. OSCEs assess performance in a simulated setting, and it is unclear whether entrustment ratings can be integrated into these exams. This study explores the introduction of an entrustment rating scale into an existing OSCE.

Methods: A 6-point entrustment scale was added to the standard ratings in an OSCE administered prior to students' final clerkship year in an undergraduate medical programme. Standard OSCE ratings assess clinical and communication skills. Assessors (n = 54) rated students' performance (n = 227) on a diverse set of clinical tasks and evaluated the addition of entrustment scales to OSCEs. Descriptive and inferential statistics were calculated for analyses.

Results: Student performance varied across the stations, as reflected in both the standard OSCE ratings and the added entrustment ratings. Students received generally high standard OSCE ratings, whereas entrustment ratings were more widely distributed. All students passed the OSCE, and only a small proportion of students did not reach the expected pass threshold of 60% on the standard ratings in the single stations. The proportion of students who did not reach the expected entrustment level in the respective stations was noticeably higher. Both the clinical and communication skill ratings were related to the entrustment rating in most OSCE stations. A majority of the assessors positively evaluated the addition of entrustment ratings into the OSCE.

Discussion: The findings provide an empirical basis to broaden our understanding of the potential use of entrustment ratings in existing OSCEs. They provide directions for future, more specific studies. The ratings might be used for formative feedback on students' readiness for workplace practice.

Keywords: Assessment of performance, Objective structured clinical examination, Entrustment scales, Entrustable professional activities

Background

The concept of entrustable professional activities (EPAs) has emerged as a new approach to the assessment of workplace performance [1-4]. Assessment through EPAs is centred on entrustment decisions by clinical supervisors that link trainees' execution of professional activities with the level of supervision in their progress towards independent practice [5]. Objective structured clinical exams (OSCEs) assess the performance of medical trainees in a simulated setting. As OSCEs are widely used in medical education and the EPA concept is increasingly adopted as an overarching framework, it has been proposed to incorporate entrustment ratings, i.e., entrustment scales, into OSCE assessments [3, 6]. On theoretical grounds, there are pro and con arguments for doing so, while few studies actually report the results of entrustment ratings obtained in a simulated setting [7-9]. The present study aims to generate empirical insights into this matter by exploring the introduction of an entrustment scale into an existing undergraduate medical education OSCE.

Assessment of performance in competency-based medical education (CBME) – both in the workplace and in simulated settings – focuses on the assessment of trainees' competencies [10]. A trainee needs to show the relevant and necessary skill, attitude or behaviour in interaction with a patient. The EPA concept was introduced to better operationalise the assessment of competencies in the workplace [5]. Instead of assessing relevant communication or clinical skills separately, a supervising physician evaluates a trainee by means of entrustment scales to determine how much supervision a trainee needs when he or she, for example, takes a medical history or performs a physical examination. Entrustment scales indicate a range of entrustment levels, indicating whether trainees can perform clinical tasks under close supervision, under moderate supervision or independently [11, 12]. Assessment with EPAs thus builds on the assessment of competencies but expands it by including the factors involved when clinical supervisors entrust a trainee to carry out certain tasks [13, 14].

While the EPA concept emphasises the clinical workplace, it also provides an overarching framework that allows a meaningful integration of workplace and non-workplace learning and assessments of medical trainees [12]. For instance, the results of knowledge tests and simulation-based performance assessments can be aligned with the scope or breadth of specific EPAs and thereby serve as a supporting information source that can feed into decisions on the workplace participation of trainees. One well-established and reliable mode to assess the performance of medical trainees in a simulated setting is the OSCE, which is widely used in undergraduate medical education [15]. In OSCEs, trainees perform certain clinical tasks, and their clinical and communication skills are assessed by means of either analytic checklists or holistic global rating scales [16, 17]. As the clinical tasks in OSCEs show

great overlap with EPAs [1-4], it may be unsurprising that the inclusion of entrustment ratings is proposed for OSCEs [3, 6].

On theoretical grounds, one consideration that might favour the introduction of entrustment scales in OSCEs is that a rather minor modification of the existing assessment forms would allow OSCEs' alignment with an overarching EPA framework. Entrustment scales could simply be added to existing marking schemes instead of developing and implementing completely new assessment forms. One may also argue that the addition of entrustment scales could potentially allow a more meaningful translation of OSCE results for workplace participation for both the trainee ("I am ready for indirect supervision") and the clinical supervisor ("this trainee is ready for indirect supervision").

On the contrary, there are considerations that would not support the introduction of entrustment scales in OSCEs. One is that performance on tasks in OSCEs does not involve any risk for a real patient, which is an important factor in entrustment decision-making. Furthermore, numerous other factors are controlled for the sake of standardisation in OSCEs, and these factors are relevant for entrustment decision-making in the workplace [13, 14]. Another potential problem is the brief contact between the trainee and the clinical assessor and the lack of a direct interaction. This limited interaction is sufficient to evaluate trainees' competencies, but it may not be sufficient to evaluate their trustworthiness.

To date, little empirical research is available on the use of entrustment rating scales in the performance assessment of medical trainees in a simulated setting [7-9, 18, 19]. The aim of this study is to explore the introduction of an entrustment rating scale into a regular OSCE that students of an undergraduate medical programme must pass before they can enter the final-year clerkship. The main goal of this explorative study is to broaden our understanding and to prepare the groundwork for further studies. In particular, we aim to address the following three questions: 1) How does the distribution of standard OSCE ratings, i.e., on clinical and communication skills, including no-pass results, compare to ratings on entrustment scales? 2) How do standard OSCE ratings relate to entrustment ratings? 3) What do assessors think about introducing entrustment ratings into OSCEs?

Methods

Medical school setting

The integrated, competency-based undergraduate medical programme encompasses 6 years at the Charité - Universitätsmedizin Berlin (Charité), Germany. Performance-based exams are administered at the end of the 1st, 2nd and 5th years. Our study was incorporated into the obligatory and summative OSCE examination in the 5th year. Passing this OSCE is a requirement to enter the final clerkship year. The study protocol received approval from the

assessment committee of the study programme as well as from the Charité data protection office and ethics board (No. EA4/136/18).

The OSCE consists of six stations in which students must perform a diverse set of clinical tasks. The content of each station is aligned with the learning objectives of the preceding semesters and includes interaction with standardised patients (SP) or with models. Students have ten minutes to complete each station, followed by a one-minute break. One rater per OSCE station assesses the performance of each student.

Study protocol and participants

An entrustment rating scale was added to the standard marking scheme that assesses the performance of students. The OSCE assessors were asked to provide feedback on their perception and experience of incorporating an entrustment rating scale in the OSCE.

The results of all students taking part in the OSCE of July 2017 were collected. The OSCE took place on three consecutive days, with three parallel circuits. The circuits always had the same content and order of stations but different examiners and SPs. To add some unpredictability for the students, the task and content changed in two stations from one day to another. As a result, there were two versions of stations 1 and 5.

Raters' briefing

Before the start of the OSCE, the assessors received calibration training on the assessment of students' performance and the application of the standard OSCE marking scheme. In addition, they were briefed about the purpose of the study and the application of the entrustment rating scale. They were informed that their entrustment rating was explorative and would not be reported to the students or be part of the students' assessment results.

Standard OSCE rating scales

The standard OSCE paper-based marking scheme consists of two components: one rating of clinical skills and one rating of communication skills. Clinical skills are rated by checklist items on a three-point scale (completely fulfilled = 1, partly fulfilled = 0.6, not fulfilled = 0). Communication skills are rated by an established global rating scale [17, 20]. The scale consists of four items: empathy (response to a patient's feelings and needs), structure (internal consistency of a conversation), verbal expression and non-verbal expression. Students' performance is rated for each item on a 5-point scale ranging from 1 = excellent to 5 = poor. Both the clinical and communication skill ratings are transformed into percent quotations and then combined into one composite OSCE rating per station, in which the clinical skill score has a weight of 70% and the communication skills score a weight of 30%. To calculate the overall

OSCE result covering all stations, the results of all composite OSCE ratings per station are averaged. Students must reach at least 60% to pass the examination.

Entrustment rating scale

The entrustment rating scale was provided on a separate paper sheet (see Table 1). Using a six-point scale, the assessors indicated how much supervision a student would need when performing the observed task in a clinical workplace. The entrustment levels were in line with recommendations in the literature [12, 21]. At the time of the OSCE, students are required to have spent a total of four months in short-term clerkships and been trained in bed-side teachings in the clinical activities that are part of OSCE. The minimal expected entrustment level to be reached was thus set to a level of 3 for the stations. The only exception was the OSCE station on necropsies, where a supervision level of 2 was expected.

Table 1 Entrustment rating scale. The letter L represents the word level

	The student is able to carry out the task …
L 1	in co-activity with the supervisor.
L 2	and the supervisor is present and steps in if needed.
L 3	autonomously, with supervision available within minutes and all findings being double-checked.
L 4	autonomously, with supervision available within minutes and key findings being double-checked.
L 5	autonomously, with supervision available but from a distance (e.g., by phone) and key findings being double-checked.
L 6	autonomously, with remote monitoring and key findings being reviewed.

Assessors' evaluation of incorporating entrustment scales into OSCEs

After the completion of all OSCE assessments, assessors completed a questionnaire with 5 items on the experienced usefulness of the added entrustment scale. Each item could be rated on a five-point scale (1 = I fully disagree – 5 = I fully agree).

Statistical analysis

Analyses were carried out using SPSS 25 [22] and R 3.4.3 [23]. To answer research questions one and three, descriptive statistics were calculated for all OSCE scores on student performance and the assessor evaluation questionnaire. Violin plots were created to better compare the data distribution of standard OSCE scale ratings and entrustment ratings [24]. Linear mixed-effect models were used to estimate the differences in both the OSCE scales

and the entrustment ratings between the six stations. The students were defined as the subjects, the stations were defined as both the repeated measure and the fixed factor, and the OSCE scales and the entrustment ratings were defined as the dependent variables.

To answer research question two, correlation and regression analyses were utilised for each OSCE station to estimate the relationship between the standard OSCE scale ratings and the entrustment scale rating. The standard OSCE scales were first correlated with the entrustment rating to determine whether a linear regression analysis was reasonable. The entrustment rating was entered as the dependent variable.

Results

Participants

In total, 227 students were assessed in the OSCE. Students were, on average, 26 years old (SD = 4), and 60% were female. One assessor of the first station did not complete the entrustment scales, which resulted in missing values for 25 students. In combination with seven randomly occurring missing values for the entrustment scale, this resulted in 2% missing values. In total, 54 physicians from various clinical disciplines at the Charité represented the assessors in the OSCE; 50% of them were female.

Distribution of standard OSCE and entrustment ratings

Table 2 depicts a numeric overview of the OSCE stations' titles and the rating results per station of the clinical and communication skills, the composite OSCE result and the entrustment rating.

Table 2 Descriptive statistics of standard OSCE ratings and entrustment ratings

	Station	Clinical skills rating	Communication skills rating	Composite OSCE result	Entrustment rating	n =
1.1	Humerus Fracture	73.1 (14.5)	87.9 (12.6)	77.5 (12.9)	4.0 (1.6)	71
1.2	Herniated Disc	81.8 (16.3)	78.0 (16.6)	80.6 (14.3)	3.8 (1.3)	156
2	Trigeminal Neuralgia	84.4 (11.7)	88.6 (12.6)	85.7 (9.7)	4.1 (1.4)	227
3	Depression	81.2 (11.5)	87.6 (12.4)	83.1 (9.9)	4.2 (1.1)	227
4	Paediatric Check-Up	86.1 (11.0)	86.6 (15.1)	86.3 (10.7)	3.7 (1.3)	227
5.1	Prostatic Hypertrophy	84.7 (9.0)	86.0 (14.0)	85.1 (8.2)	3.7 (1.3)	80
5.2	Falling	83.0 (12.1)	91.2 (9.1)	85.5 (9.5)	4.2 (.8)	147
6	Necropsy	92.0 (6.8)	/	92.0 (6.8)	3.3 (1.5)	227
Sum		84.4 (5.5)	86.7 (7.1)	85.3 (5.0)	3.9 (.6)	

Legend: Note: Mean percent scores (SD) are shown for the standard OSCE ratings (percent) and the mean score (SD) for the entrustment rating (scale 1–6)

The students reached a mean overall OSCE result of M = 83.5% (SD =5.0%). The mean entrustment rating was M = 3.9 (SD = 0.6) for all OSCE stations. Students' performance varied between the OSCE stations, as reflected by differences in the composite OSCE ratings [F (1, 7) = 44.7, p < 0.001] and the entrustment ratings [F (1, 7) = 27.5, p < 0.001].

Figure 1 displays violin plots of the distribution of the standard OSCE ratings on clinical skills, communication skills and the composite result per OSCE station as well as the distribution of the entrustment ratings. The standard OSCE ratings show some variation between the stations and their topics. However, in general, the ratings on the clinical and communication skills and their composite tend to be located at the upper end of the scales. The entrustment ratings vary between the stations but cover the full scale and tend to be more evenly distributed.

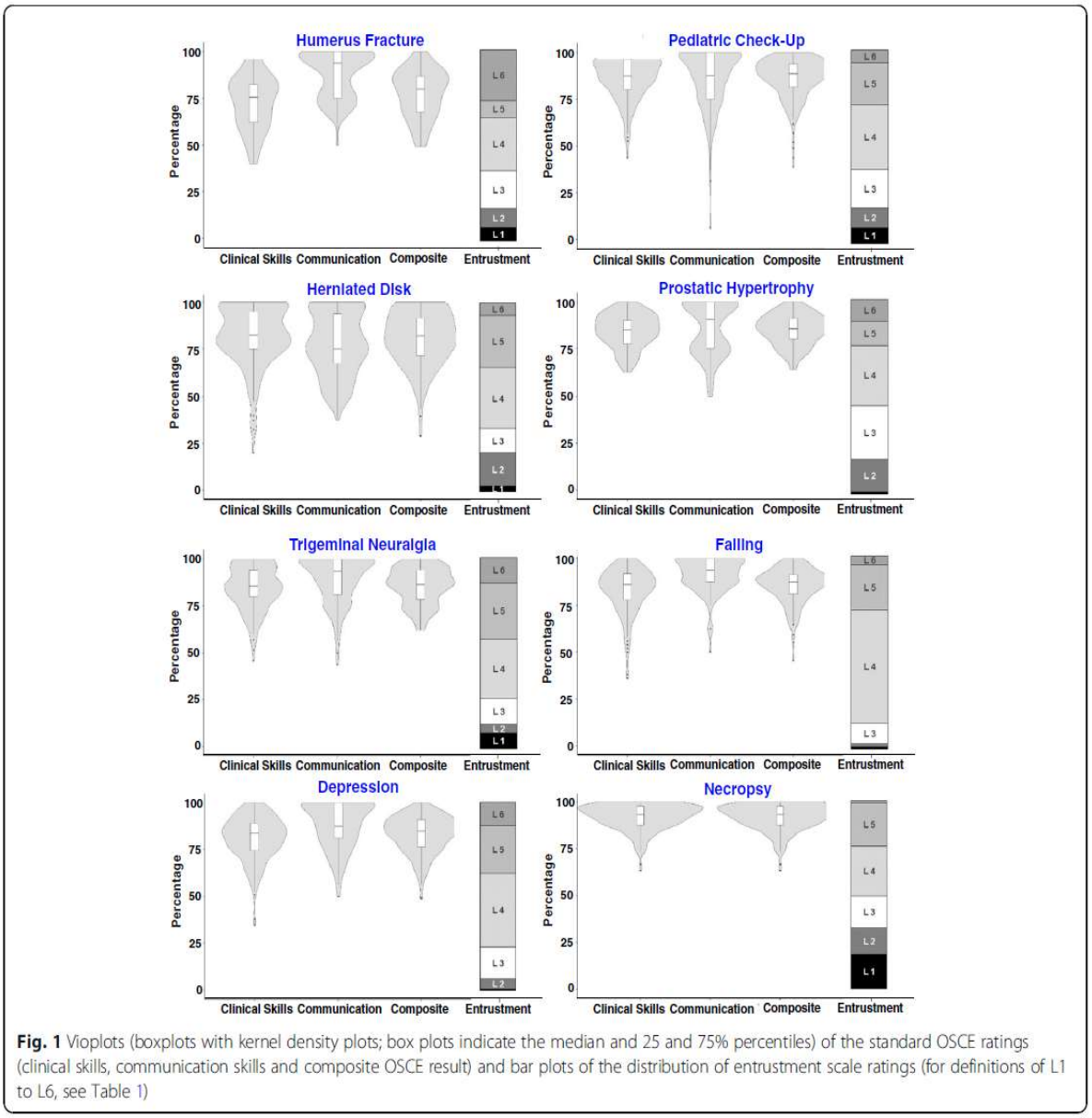

Fig. 1 Vioplots (boxplots with kernel density plots; box plots indicate the median and 25 and 75% percentiles) of the standard OSCE ratings (clinical skills, communication skills and composite OSCE result) and bar plots of the distribution of entrustment scale ratings (for definitions of L1 to L6, see Table 1)

To further explore our data, we looked at the proportion of students under a minimum requirement threshold both for the full OSCE exam and for each OSCE station. The standard pass threshold for the OSCE at Charité is set to 60% for the overall OSCE result. All students managed to reach this threshold and hence pass the exam. Using the same 60% threshold for each station, there is some variability in the percentage of students who failed a station (Fig. 2). Analysis indicates that 12% (n = 27) of the students failed one station and 1% failed two stations (n = 3).

The expectation for the entrustment rating in the majority of the stations would be to carry out the respective task without direct supervision, which would correspond to our rating scale of 3 and higher. Only the necropsy station covered a more complex task, and the expected entrustment level was set to 2 for this station. The percentage of students failing to reach the expected entrustment level differs considerably per station, ranging between 3 and 21% (Fig. 2); 31% of the students did not reach the expected supervision level in at least one station, 15% in two stations and 6% in three stations or more.

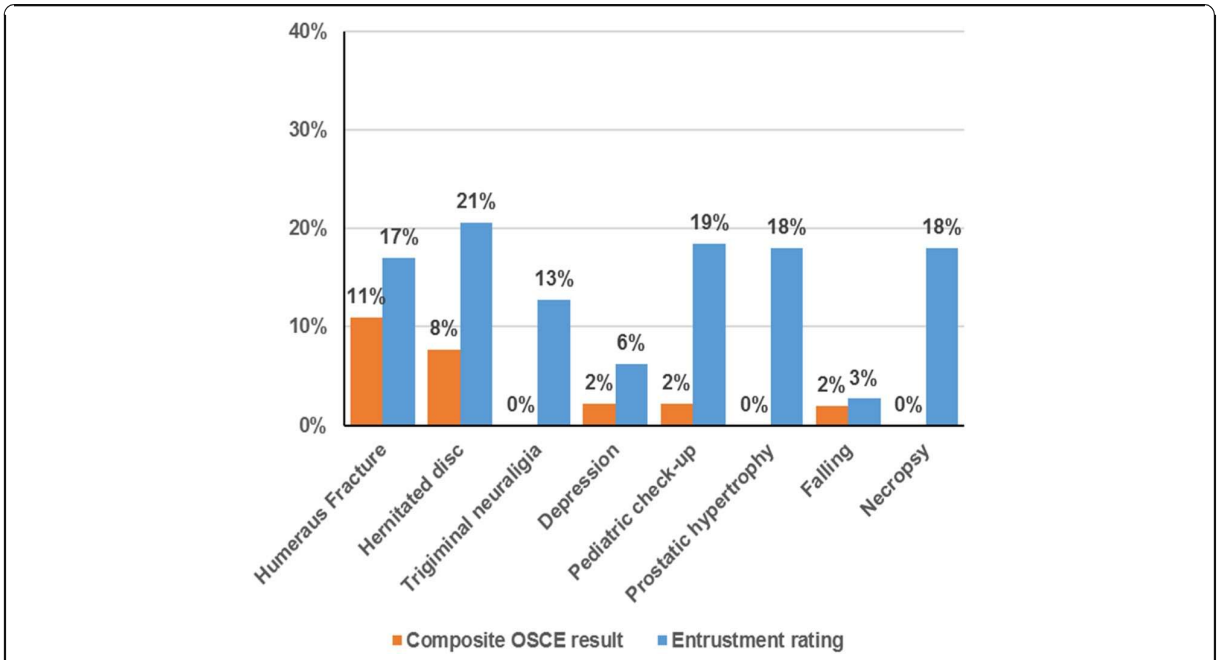

Fig. 2 Percent of students who fail to reach the threshold level per station on the composite OSCE result (at least 60%) and the entrustment rating (at least level 3 in all stations but the necropsy station, where at least level 2 is required)

Relationship between standard OSCE and entrustment ratings

In the humerus fracture station, the clinical skill rating and communication skill rating do not correlate significantly with the entrustment rating. In the prostatic hypertrophy station, the clinical skill rating shows no significant correlation but the communication skill rating shows a significant negative correlation ($r = -0.362$, $p < 0.01$) with the entrustment rating. No linear regression analyses are conducted for these stations.

Table 3 shows that the OSCE standard rating accounts for the variance in the entrustment rating in each station, whereas the degree varies. In the trigeminal neuralgia station, the standard OSCE scales account for 51% of the variance in the entrustment rating [$R2 = 0.52$; $F\ [1222] = 119.25$; $p < 0.001$), whereas the explained variance is 15% in the depression station [$R2 = 0.15$; $F\ [1224] = 21.26$; $p < 0.001$). In the necropsy station, only the clinical skill rating was applied, and the regression analysis shows the lowest amount of explained variance of the entrustment rating [$R2 = 0.03$; $F\ [1221] = 8.41$; $p < 0.01$).

In four out of six OSCE stations, both the clinical skill rating and the communication skill rating positively predict the entrustment rating, with β values ranging between 0.22–0.35 and 0.21–0.52, respectively. The only station where the clinical skill rating has no significant impact on the entrustment rating is in the herniated disc station. Additionally, in four out of six stations, the communication skill rating has a greater effect on the entrustment rating than the clinical skill rating does.

Table 3 Regression analysis of the OSCE scales on the entrustment rating per station

Station		Model			Regression coefficients				
		R2	ΔR2	F		B	SE	β	t
1.1	Humerus Fracture								
1.2	Herniated Disc	.35	.34	34.11***	Checklist Score	.01	.01	.11	1.41
					Global Rating	.04	.01	.53	6.75***
2	Trigeminal neuralgia	.16	.15	21.26***	Checklist Score	.04	.01	.3	4.70***
					Global Rating	.02	.01	.21	3.32**
3	Depression	.52	.51	119.25***	Checklist Score	.03	.01	.35	7.06***
					Global Rating	.05	.00	.52	10.57***
4	Paediatric Check-Up	.44	.44	88.18***	Checklist Score	.03	.01	.26	4.57***
					Global Rating	.04	.01	.49	8.52***
5.1	Prostatic Hypertrophy								
5.2	Falling	.20	.19	18.23***	Checklist Score	.02	.01	.22	2.83**
					Global Rating	.03	.01	.35	4.50***
6	Necropsy	.04	.03	8.41**	Checklist Score	.04	.01	.19	2.90**

Legend: B unstandardised regression coefficient. SE Standard error. β standardised regression coefficient. ***p < 0.001. **p < 0.01

Assessors' evaluation of the entrustment scale rating

A total of 48 assessors participated in the evaluation (response rate 89%). They had an average of 6 years (SD = 5) of experience in supervising medical students or residents.

Table 4 provides an overview of how the OSCE assessors evaluate the addition of the entrustment scale. As an indicator of feasibility, the majority indicate that its application is not time consuming. Regarding its educational value, the majority of the assessors consider the entrustment scale to be useful as a tool for evaluating students' skills and providing individual feedback. Most of them also agree on the statement that the addition of an entrustment rating scale would be a meaningful addition to the standard OSCE assessment. The assessors remained undecided regarding the question of whether the general impression of students' performance can be summarised with an entrustment scale (approximately one third each claimed agreement, neutrality or disagreement).

Table 4 Descriptive statistics of the usability questionnaire

Item	Percentage agree or fully agree	Mean	SD
The application of the entrustment rating scale is not time consuming.	77.1%	4.0	1.1
The entrustment rating scale …			
• is useful for the evaluation of the clinical and cognitive competence of the students.	70.8%	3.8	1.1
• enables feedback on individual performance.	62.5%	3.6	.9
• is in general a useful addition to the OSCE assessment form.	64.6%	3.7	1.3
• can summarize the general impression of students' performance.	35.4%	3.1	1.1

Discussion

This study explores the introduction of an entrustment rating scale into an existing OSCE administered before the final clerkship year in an undergraduate medical programme. Overall, we feel that the findings broaden our understanding of this matter on an empirical basis and provide directions for future, more specific studies on whether and, if so, how entrustment scales should be employed in OSCEs. In the following, we discuss the results for the three main questions raised in light of the current literature and propose topics to be addressed in subsequent studies.

Regarding question one, we found that entrustment ratings show a greater distribution across the whole scale compared to the standard OSCE ratings on clinical or communication

skills, which were located mostly in the upper parts of the scales. This finding is in line with the use of an entrustment rating scale in the assessment of workplace performance [25]. However, it is not clear why raters apply the OSCE and entrustment rating differently. It has also previously been proposed that global ratings capture something different than OSCE checklists do, allowing them to better determine trainees' level of proficiency [17]. Rekman and colleagues [26] suggest that entrustment scales are better construct-aligned scales because they reflect the expertise and priorities of clinical educators. Both the formation and the interpretation of entrustment ratings may thus be more meaningful for clinical assessors. Future qualitative studies may provide more insights into why assessor rate students differently on standard OSCE than on entrustment scales.

In further exploration of the distribution, we applied a pass threshold to the individual OSCE station results. While the non-pass number was low for the standard OSCE ratings, a substantially higher number of trainees would not have passed based on the entrustment ratings. This finding suggests that entrustment scales may identify struggling learners better, and if this is in fact the case, future studies should show this also for their actual workplace performance. Nevertheless, we feel that this is important information on trainees' readiness for workplace participation, as determined by the OSCE assessment. On the one hand, this information can provide trainees with feedback to stimulate their future learning and skills training [27]. On the other hand, it may support clinical supervisors by indicating that certain trainees require a closer level of supervision at the beginning. Whether such evaluations should be best based on non-passing of a single or multiple OSCE stations should be addressed in future studies. With such an approach, we might be able to shift the focus from passing an exam to preparing trainees for the workplace [6].

Regarding question 2, the regression analyses indicated that in most but not all OSCE stations, the ratings of clinical and communication skills accounted for a reasonably high proportion of the variance in entrustment ratings' variance, with the highest R2 score being approximately 50%. This finding is underpinned by previous research showing that the ability of a trainee to perform a clinical skill is one important factor in the entrustment decision-making of clinical supervisors. However, other factors also play a role, such as individual attributes of the trainee or supervising physician, the trainee-supervisor relationship, the task itself and the circumstances [13, 14]. Interestingly, across many stations, the communication skill rating had a greater effect on the entrustment scale rating than the clinical skill rating did. Our scale for communication skill ratings included items on structure, empathy, and non-verbal and verbal communication [20]. These items could have provided clues about trustworthiness dimensions, such as the trainee's integrity or humility. To our knowledge, no study has estimated the effect size of the factors in a simulated setting as we have done. Future studies may undertake similar

regression analyses on trainees' task performance and entrustment ratings in a real life, clinical workplace.

Another interesting finding in this light concerns the two OSCE stations where the entrustment ratings did not relate statistically to ratings of clinical and communication skills. We have no explanation for this phenomenon; it should certainly be the object of future research. It might depend on the structure of these OSCEs, the specific performance expectations or whether the task is classified as a realistic workplace activity. In any case, this finding raises the question of whether entrustment ratings scales can be automatically introduced in any exiting OSCE station. A regression analysis, as performed in this study, may be used to provide evidence for the validity of the entrustment scale rating at a certain OSCE station.

Regarding question three, assessors provided mainly positive evaluations regarding the introduction of an entrustment scale in OSCEs. The majority of assessors agree that the entrustment scale could be a useful addition to the OSCE evaluation form, but they also showed some variability in their evaluations. These doubts should not be ignored, and efforts should be undertaken to understand them in more detail.

Overall, this study provides empirical insights on the addition of entrustment ratings scales into existing OSCEs and offers sufficient support for future research on this matter. In our institution, we plan to further explore the addition of entrustment ratings in OSCEs. In addition to including an assessor training on entrustment ratings, we plan to research the use of non-pass entrustment rating results as formative student feedback that indicates their potential insufficient readiness for the final clerkship year. We acknowledge that entrustment ratings do involve some subjectivity on the part of the assessor. This should not be perceived as problematic but should instead be taken advantage of, as it yields valuable information [28, 29]. It is advised to gather multiple entrustment ratings across various situations in simulated settings and the workplace from various assessors to gain a picture of trainees' professional development and to decide on their readiness for practice [6, 7].

This study has limitations. It represents a single-centre study, which means that the findings might not be generalisable to other contexts. Our assessors did not undergo rater calibration training on utilising the entrustment scale. Assessors who were more familiar with the concept of EPAs and entrustment decisions might have applied the scale differently [28, 30]. We could not calculate any inter-rater variance. The study was situated in a regular OSCE context, in which students in each OSCE station are observed by just one assessor. Furthermore, this study did not explore what medical students think about the introduction of entrustment scales in the OSCE assessment.

Conclusions

The study presented here explored the introduction of an entrustment rating scale into the assessment of an existing pre-final clerkship year OSCE. We found that assessors' ratings on standard OSCE scales were different from their ratings on entrustment scales. The entrustment ratings were influenced by trainees' clinical and communication skill performance, but other factors were also involved. This study generated empirical evidence for further research on this matter. Non-pass entrustment ratings may serve as formative feedback for students on insufficient readiness for practice.

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Chapter 6

Applying occupational and organizational psychology theory to entrustment decision-making about trainees in health care: a conceptual model

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Abstract

In medical contexts around the world, supervising physicians continuously decide what degree of supervision to apply as trainees carry out professional activities. Although the implications for patients can be far-reaching, little is known about how these entrustment decisions are formed. The concept of 'Entrustable Professional Activities' has initiated interest and valuable research on factors that may influence the entrustment decision process.

The aim of the current article is to link models of entrustment developed in the fields of occupational and organizational psychology and military psychology to medical education studies that have explored the factors influencing physicians' entrustment decisions. We provide a conceptual framework of the entrustment decision-making process, which we suggest will contribute to the understanding of how supervising physicians arrive at the decision to entrust a medical trainee with a professional activity.

Keywords: Entrustment, Entrustable Professional Activities, Trust

Introduction

Health care and health care training build on the progressive granting of responsibility and autonomy to learners, a practice with world-wide prevalence [1]. At certain points in their education, medical trainees are expected to have attained sufficient competence to carry out clinical activities unsupervised. An essential part of granting trainees progressive independence is the supervisor's decision to entrust the trainee with specific activities. These daily decisions are also referred to as ad hoc entrustment decisions [2].

Such an ad hoc entrustment decision is often made implicitly, and is often guided by clinical service needs [2]. Take for example a physician supervising a senior medical student taking a history on a 29-year-old female patient with a cough. This supervisor must decide the degree of oversight needed to ensure the trainee gathers sufficient and accurate information to formulate a safe and effective diagnostic and treatment plan. Does the physician need to be present in the exam room to observe the encounter directly or even participate in the interview? Or is a higher level of trust and a lower level of supervision acceptable, such that the supervisor judges from the trainee's post-encounter patient presentation that the student was able to do this well? What if the patient was a 49-year old-male patient also complaining of chest pain? How would the supervisor adjust his entrustment strategy then? These varying entrustment decisions are a matter of daily clinical routine, but are not well understood in detail.

Increasing interest in the concept of 'Entrustable Professional Activities' (EPAs) [3–5] has led to a heightened awareness of the supervisor-trainee entrustment decision process [6]. Ten Cate [7] describes EPAs as essential units of clinical work independently executable by qualified personnel. They require adequate knowledge, skills, and attitude, and they are, in their process and outcome, observable and measurable. EPAs can be entrusted to be performed by trainees under five different levels of decreasing supervision. The higher the level, the more independently the trainee is allowed to perform the EPA [8]. Ten Cate introduced the EPA concept in 2005 in response to concerns about the adverse effects of implementing competency-based assessment frameworks in medical education [9]. The competency-based assessment movement has resulted in the development and global implementation of competency frameworks such as that of the Accreditation Council for Graduate Medical Education [10] and the Canadian Medical Educational Directions for Specialists [11]. However, competency-based assessment of medical trainees has proven challenging [12, 13]. Critics point out that medical competence is more than the sum of separate competencies [14, 15]. EPAs have been introduced as a way to arrange, observe and assess medical competencies in a holistic manner. They integrate multiple competencies and, conversely, competencies map to multiple EPAs. A trainee who has mastered all EPAs of a specialty may generally be assumed to possess all relevant competencies of that specialty. More and more medical departments are now adopting ten Cate's approach and have

characterized sets of EPAs in their specialties, such as family medicine, internal medicine, paediatrics, psychiatry and geriatrics [16–21].

As entrustment decision-making is an essential part of the EPA concept, research has been initiated to investigate the process underlying the supervisor's decision to entrust medical trainees with professional activities. Research conducted in medical education has mainly focused on identifying factors influencing the entrustment decision [6, 22–26]. Hauer et al. [27] conducted a study to investigate how entrustment decisions are shaped by these factors. They proposed a model of trust formation, which depicts the starting point and the outcome of trust, as well as accelerators and barriers to trust formation. Ten Cate et al. [2] provided an overview of different types of trust and entrustment decisions and factors involved in the entrustment decision process.

These valuable studies help to build understanding of entrustment decision-making, which represents a pervasive part of the clinical routine and the training of young physicians. What is not deeply understood is how the various factors influencing entrustment decision-making interact and how context influences their relevance and interplay. One way to build this understanding is to analyse individual supervisors' stepwise thinking when considering the entrustment of a professional activity to a trainee in different contexts. This analysis should clarify how entrustment decisions are actually made and how different clinical contexts affect the size and importance of influential factors. It may also lead to the identification of additional influential factors. Ultimately, this understanding could be used to support more accurate, safer, and fairer entrustment decisions.

While research on trust in health professions education is relatively new, researchers in other domains have devoted substantial energy to studying entrustment processes. In this article, we introduce one leading trust model, developed by organizational psychologist Roger Mayer and his colleagues [28], as well as a modified version applied to understanding interpersonal interaction in a complex, high-stakes, interprofessional context: military command and control [29]. We combine these models with the findings of medical education studies of entrustment. Our aim is to expand understanding of the entrustment decision-making process in health care education to account for how ad hoc entrustment decisions are actually made and how context influences the decision-making process. We provide a research agenda to test and refine our explanations.

Conceptualizing trust

In 1995, Mayer et al. [28] addressed heightened interest in understanding trust in occupational settings, which was triggered by increasing workforce diversity and the emergence of self-directed working teams. They developed a conceptual model of trust (Fig. 1), characterizing how it develops among two parties: a trusting party, called trustor and a party to be trusted,

called trustee. This model was then applied to examining the development of employees' trust in their managers, i. e. upward in hierarchy [30–32]. In comparison, in medical education the primary interest lies in how the supervising physician entrusts a trainee, i. e., downward in hierarchy. However, Mayer et al.'s model appears to be applicable to trust processes independently of hierarchy [32] and provides the opportunity to better understand the supervisor's decision to entrust a trainee.

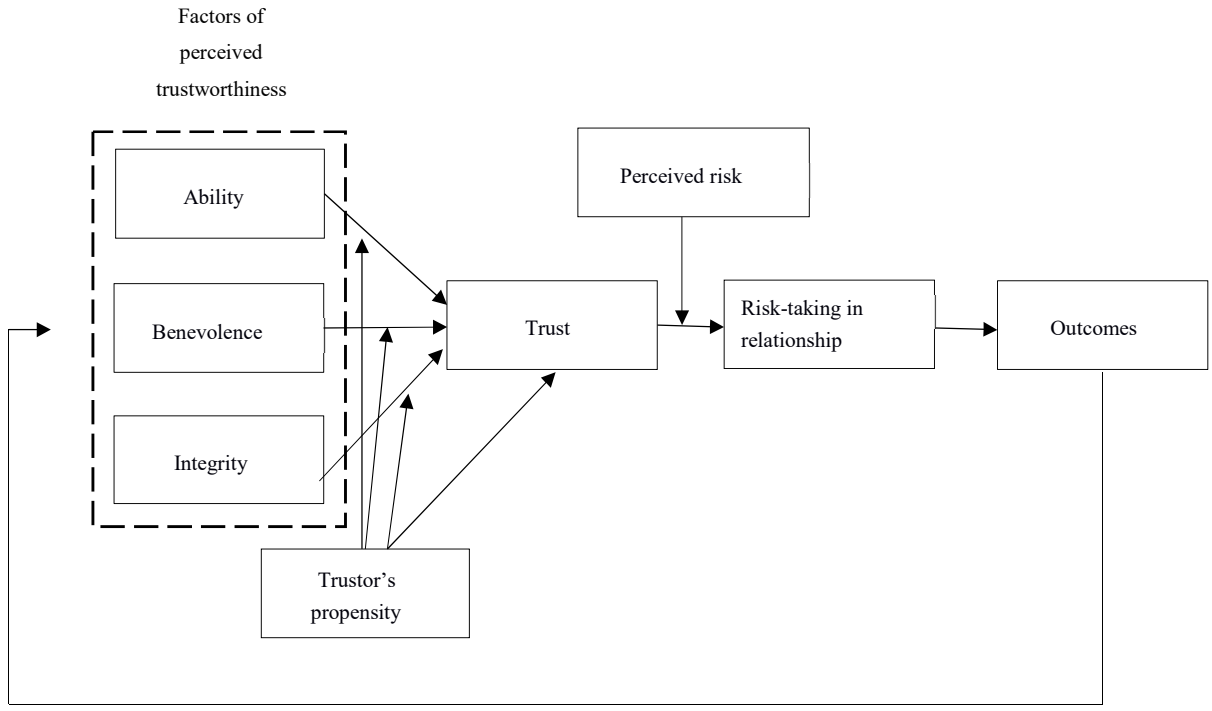

Fig. 1 Model of Trust by Mayer, Davis and Schoorman [28]

Mayer et al. [28] define trust as the 'willingness of a party to be vulnerable to the actions of another party' (p. 712) and hence as the 'willingness to take risk' (p. 712) in a relationship. A key characteristic of Mayer et al.'s model is the discrimination between factors promoting trust, trust itself, and outcomes of trust. The antecedents of trust proposed by Mayer et al. are characteristics of the trustor and the trustee. These include the perceived trustworthiness of the trustee, defined on the basis of his or her perceived ability, benevolence and integrity as well as the trustor's propensity to trust, that is, his or her general willingness to be vulnerable to others. Propensity to trust is thought to be a stable characteristic akin to a personality trait. According to Mayer et al. [28], ability can be described as 'skills, competencies, and characteristics that enable a party to have influence within some specific domain. The domain of the ability is specific because the trustee may be highly competent in some technical area, affording that person trust on tasks related to that area. However, the trustee may have little aptitude, training, or experience in another area (…).' (p. 717). Benevolence and integrity are

defined as more general dimensions of the relationship between trustor and trustee. ‘Benevolence is the extent to which a trustee is believed to want to do good to the trustor, aside from an egocentric profit motive. Benevolence suggests that the trustee has some specific attachment to the trustor.’ ([28], p. 718). Integrity is defined as ‘the trustor’s perception that the trustee adheres to a set of principles that the trustor finds acceptable.’ ([28], p. 719).

The trustor’s propensity to trust and the trustee’s perceived trustworthiness influence the trustor’s intent to be vulnerable to the trustee’s actions. The translation of intent to action, actual risk-taking, is influenced by the perceived risk of the trusting behaviour: ‘If the level of perceived risk is greater than the level of trust, the trustor will not engage in the risk-taking in relationship.’ ([28], p. 726). The outcome of this trusting behaviour in turn is expected to affect future trustworthiness judgments.

Mayer et al. [28] differentiated between the willingness to take risks (trust) and actual risk-taking (trust-related behaviour). They emphasized that willingness to take risks is attitudinal and could therefore be measured using questionnaires. In contrast, actual risk-taking can only be assessed via direct observation. This distinction is important, as a given behaviour might reflect factors other than the judgment of someone’s trustworthiness. For instance, an employee perceiving his manager to be untrustworthy may nevertheless act as trusting because the power differential leaves no other option. In health care, a supervisor may entrust an inexperienced trainee with an urgent task because no one else is around, or she may not trust an experienced trainee because of prior entrustment decisions with bad outcomes. Mayer et al. [32] argued for the general applicability of their model and discussed its extensive application to a wide range of contexts such as agribusiness, finance and political science. Yet, they have critically pointed out that it largely omits the impact of context on behaviour.

Cianciolo et al. [29] argued that previous trust research has failed to find a consistent relation between intent to trust and actual risk-taking behaviour due to disregard of context. When context is not clearly defined, situational characteristics can make trust-related behaviour difficult to recognize and seem unpredictable. In an attempt to develop behavioural measures of trust within military command and control organizations, Cianciolo et al. [29] extended Mayer et al.’s trust model by introducing the concept of ‘unit of analysis’ as a way to meaningfully differentiate contexts and reduce intervening variables between intent to trust and the degree of risk-taking. They adopted Mayer et al.’s definition of trust, but stressed that what entrustment ‘looks like’ behaviourally depends on the conditions under which it is enacted. For example, in tightly knit, homogenous teams executing well-defined tasks, high levels of trust may be inferred from economical communication among teammates because each can anticipate the other’s information needs. In diverse teams with complex, ill-defined tasks, high levels of trust may be inferred from fluent information sharing because participants identify as

a team and share common goals. Health care examples of this phenomenon have been documented in Sutcliffe et al. [33], Pullon [34] and Lancaster et al. [35]. In both cases, prioritizing the group task at hand over managing interpersonal relations is a form of risk-taking, but willingness to be vulnerable appears different due to contextual factors.

In summary, the presented models of trust feature several characteristics that we believe are important for a research agenda that advances understanding of physician supervisors' entrustment decision-making. They distinguish between trusting attitude on the one hand and actual, observable trust-related behaviour on the other hand. In these models, trust-related behaviour is the outcome of a context-bound entrustment decision-making process that is preceded by an accumulation of smaller decisions. These models propose a conceptual structure for the decision-making process which could be helpful for characterizing how and when supervisors' intent to entrust results in the entrustment of a professional activity.

Integrating trust theory with empirical findings on medical entrustment decisions

Four categories of factors have been identified in a range of studies to influence entrustment decision-making: trainee characteristics, supervisor characteristics, characteristics of the task at hand and contextual factors [23–25, 36]. In addition, the relationship between the supervisor and the trainee has been identified as an important category [6, 27]. These studies provide a long list of factors in each category, summarized in an overview table by ten Cate et al. [2]. Fig. 2 illustrates how the findings of ten Cate et al. may be integrated with the trust models developed by Mayer et al. [28] and Cianciolo et al. [29] in a unified conceptual model of the entrustment decision-making process.

In this model, the intention to entrust a professional activity is influenced in part by characteristics of the trainee (trustee), which are summarized under Mayer et al.'s broad categories of ability, benevolence, and integrity. Characteristics of the supervisor (trustor) are also important. In their model, Mayer et al. focused on the trustor's propensity to trust. This trait has also been found to affect medical entrustment decisions, but additional factors, such as the supervisor's experiences with the trainee, have been shown to exert an impact [2]. Mayer et al. described how the relationship between the trustor and the trustee longitudinally influences the development of trust [28]. Ten Cate et al. [2] also assert that the duration and intensity of the supervisor-trainee relationship are important. The supervisor gains an impression of the capabilities and the personality of the trainee, which will influence future entrustment decisions. The longer the contact with the trainee, the better the supervisor can estimate whether the trainee has the capability to perform a professional activity. If the supervisor does not have much contact with the trainee, he or she might rely on credentials or the first impression of the trainee. On the development of trust, ten Cate et al. [2] distinguish between presumptive trust (based solely on credentials), initial trust (based on the first

impression) and grounded trust (intensive contact with the trainee). In addition, supervisor role ambiguity as coach, advocate, and evaluator and the shared expectations between the supervisor and the trainee also seem to have implications for their trusting relationship.

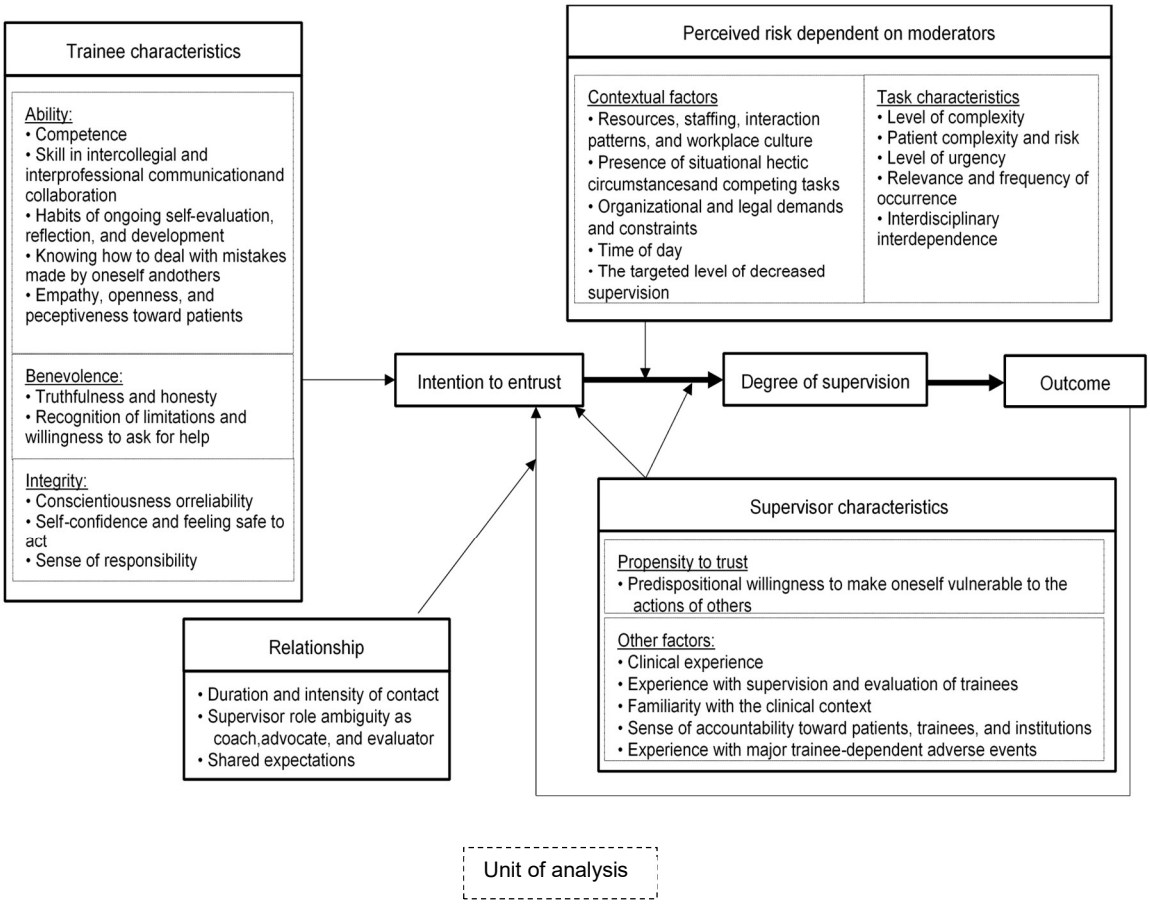

Fig. 2 Conceptual framework of the entrustment decision-making process

The entrustment is posited to depend on the degree of perceived risk, which is influenced by situational circumstances and the nature of the professional activity [28, 29], as well as the supervisor's characteristics [29]. Research on medical entrustment decision-making has identified contextual factors that may influence perceived risk, such as time of day and available assistance, and task characteristics, such as complexity and level of urgency. The degree of entrustment is expressed by a higher or lower level of supervision.

Cianciolo et al. [29] emphasized the importance of specifying how contextual factors influence the entrustment decision-making process. Clearly defining the context in which particular entrustment decisions are made strengthens the link between a supervisor's judgment that a trainee is trustworthy and his or her degree of observed supervision. This enables more confident conclusions that a given level of supervision stems from the attending's judgment vs. a unique and nonreplicable set of conditions. Cianciolo et al. [29] proposed the

concept of ‘unit of analysis’ to refer to distinct ecologies whose contextual features differentially influence the factors affecting entrustment intentions and opportunities to mitigate risk when trustworthiness judgments are not 100%. In their work with military command and control teams, Cianciolo et al. identified three units of analysis that differed in their degree of interdependence among actors, geographical distribution between actors, and task complexity. In medicine, units of analysis, or trust ecologies, might differ along the same dimensions such that exerting supervisory control looks different and is less sensitive to trainee characteristics in intensive care units staffed by categorical residents over the night shift than in primary care clinics staffed by resident-attending teams during business hours. Units of analysis might also differ by specialty. Tiyyagura et al. [36] found, for example, that parental preferences influence supervisors’ decisions to entrust paediatrics trainees. Attempting to define units of analysis makes it possible to explore how exactly ‘context matters’ to the entrustment decision-making process.

Let us apply our framework to the EPA of ‘history taking’. The supervisor will first have to judge the trainee on his or her ability, benevolence and integrity. These judgments might depend on reputation or experience with the trainee. The supervisor has to decide whether the trainee is generally capable and trustworthy of taking a valid and conclusive history of a patient. Is the trainee capable of talking to the patient without the patient getting upset? Is there a chance that the trainee will confuse the patient? Could the trainee miss a significant finding? How reliable will the trainee’s report and differential diagnosis be, and is the supervisor willing to base future actions on it? Additionally, characteristics of the supervisor will influence the intention to entrust the trainee. Is he or she generally a trusting person? What experiences does he or she have with this trainee or with trainees generally?

Once the supervisor has formed the intention to entrust the trainee, it depends on factors related to the EPA and the context whether and to what extent the trainee will actually be entrusted. How difficult/complex is the patient? Has the trainee sufficient experience with this sort of case? How urgent is the situation? How long has the trainee been on the ward? The supervisor will have to weigh the risk of something going wrong against his belief that the trainee can manage this patient on his own. Dependent on all these judgments, the supervisor will estimate the degree of supervision required. The outcome of this decision will in turn influence future interactions with the trainee [2].

Discussion

The aim of this article was to provide a conceptual framework to deepen our understanding of how supervising physicians arrive at ad hoc entrustment decisions in clinical practice. Following the recommendations made by Bordage [37], the use of frameworks is an attempt

to identify potentially important variables and their interrelatedness and to make these assumptions explicit and testable.

In order to provide a conceptual basis for understanding how a clinical supervisor arrives at the decision to actually entrust a clinical trainee with a professional activity, we utilized factors identified through empirical research in medical education and combined these with theoretical models on trust from the fields of organizational and occupational psychology. From the current research we obtained a valuable overview of the factors influencing the supervisor's entrustment decision. What we aimed to provide with our conceptual model is an understanding of how these factors might interact and under which circumstances the intention to entrust results in a particular level of supervision of the trainee. This information could be used to improve the accuracy and fairness of intentions to trust as well as the effectiveness of supervisory control.

One important task for future research is to explore which variables exert an influence on the entrustment decision and at which point. Mayer et al. [28] stress the importance of clearly defining and differentiating between factors contributing to trust and trust itself. Applying this argument to our proposed model, it also seems important to come to an agreement on definitions and labels for the variables involved in the entrustment decision-making process. We need to understand which factors mainly influence the intention to entrust a trainee and which ones influence the degree of supervision provided to the trainee (behaviour). We have provided an example of a possible chronological description of a supervisor's thinking while entrusting a trainee with the EPA 'history taking'. Research studying real-time chronological thinking observations would further add to the understanding of the entrustment decision.

A related area of research is identifying the units of analysis or trust ecologies that simplify the variables involved and allow confident inferences about trust intentions from observed supervisory behaviour. We propose department or specialty as a possible unit of analysis. This might be explored via ethnographic study followed by empirical studies that compare specialists' entrustment decisions in response to different trust scenarios [38].

Additionally, it is not yet clear how strong the effects of various factors are. Teman et al. [26] asked attending surgeons to estimate the impact of various factors on their decision to trust a general surgery resident. This could be extended by manipulating trainee factors within an experimental study and testing the effect on physician's willingness to trust. Field studies or studies conducted with simulated clinical situations within a ward could also be of high value.

Another research area is the identification of unknown influential variables in the entrustment decision-making process. The variables included in the model are those which have been considered as important in the entrustment decision-making process in the medical context [2]. The studies in medical education conducted so far have used either focus groups [25], Delphi studies [39], or questionnaires and interviews in combination with video-taped case

vignettes [22, 23]. However, cognitive psychology research has pointed out that retrospective reports and general statements on cognitive processes have only limited validity as they might not reveal all influential variables [40, 41]. On the one hand, verbal reports might provoke reactive effects [40]. Asking a physician to describe how he judges whether the trainee in a case vignette is able to perform an EPA without supervision might focus his attention on factors which are easy to articulate and easily accessible. On the other hand, subconscious influential factors might not be detected [40]. Subconscious factors within the trustor are partly included in the trust models by Mayer et al. [28] and Cianciolo et al. [29]. Mayer et al. discussed the propensity to trust as an influential variable, and Cianciolo et al. name personality traits such as neuroticism or agreeableness as possibly having an impact. The influence of propensity to trust has been supported in medical entrustment research [2], and it is possible that additional subjective subconscious variables such as the first impression of a trainee or mood and gender of the supervisor have an impact [42]. Supervisors should be aware of potential subconscious variables and be able to differentiate between them. Intersubjectivity in supervisors is being acknowledged as valuable, because full objectivity can never be obtained [43]. The positive effect of gut feeling has been documented by studies [44], but supervisors should be in the position to identify potential biases and to correct for them [42].

Consequently researchers must be careful in choosing the method to study variables influencing the entrustment decision-making process. Research should apply those methods which yield most information about the unconscious and subjective factors.

The combination of trust theory with research on entrustment decision-making contributes to a model-based understanding of the entrustment process. Making entrustment decisions more transparent will eventually result in better grounded entrustment decisions and hence enhanced patient safety.

Cianciolo and Kegg [38] present a model of effective entrustment decision-making which focuses on understanding and improving supervisors' risk-mitigation strategies. They propose that effective entrustment decisions could be reached by relying more on trainee observations and by accounting for subjective factors such as supervisors' characteristics. However, this model remains theoretical, and the size of the effects of these variables on the entrustment decision-making is unknown. Our present model highlights the conceptual structure of the entrustment decision-making process and the influence and interaction of variables, yet further work is required to test the established propositions. Conceptual models are thought to be dynamic, and we have provided some suggestions for a research agenda which could challenge and alter the framework. We propose that this model will be helpful to clarify and deepen our understanding of the medical entrustment decision-making process.

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Chapter 7

General Discussion

General Discussion

In Germany, as well as in many other countries, medical students graduating from undergraduate programs not only finish a medical degree but also receive a licence to practise medicine and to take over responsibilities for patients. As a patient being treated in the hospital, one could ask whether the beginning resident was sufficiently trained to take a history and to perform a physical examination in the undergraduate curriculum. Does he or she show all relevant competencies necessary for the execution of the activity? Was his or her performance assessed, and did he or she receive sufficient feedback? Was he or she entrusted to perform the activity? The precise impact of residents' performance on patient outcomes is unknown (Kennedy et al., 2009). However, it has been repeatedly criticized that medical graduates are insufficiently prepared for medical practice (Gartmeier et al., 2017; Ochsmann et al., 2010; Ochsmann et al., 2011; Monrouxe et al., 2016; Salzman et al., 2018) and need to receive more practice making independent decisions to improve their performance (Sandhu et al., 2015). Worldwide, Core EPAs are implemented as outcomes in undergraduate curricula to heighten the involvement of students in the workplace and to better prepare them for patient care. This thesis accompanied and complemented the process of defining Core EPAs as outcomes for the undergraduate curriculum at the Charité and the first steps of its implementation. As research on this topic is highly up-to-date, this thesis contributes to the national and international discussion on the EPA concept with a wider scope.

The studies covering the definition and content validation of a set of Core EPAs marked the beginning of the project. In a three-round Delphi study, faculty members developed a set of 12 Core EPAs (Chapters 2 & 3). To gather complementary content validity evidence, Charité graduates were surveyed on their workplace involvement based on the defined EPAs (Chapter 4). In an attempt to integrate the EPA concept into the existing assessment system, another project explored the introduction of entrustment ratings to the OSCE of the ninth semester (Chapter 5). In a theoretical contribution, a conceptual model of the entrustment decision-making process was developed to deepen the understanding of how supervising physicians make the decision to entrust a trainee with an EPA (Chapter 6). The discussion will evaluate the research questions and the findings in the context of the ongoing developments of implementing EPAs at the Charité and the current literature. The overarching limitations of the presented studies, as well as practical implications and directions for future research, will be discussed.

Definition and content validation of a set of Core EPAs

At the beginning of this dissertation project, the concept of EPAs was relatively new to the national and international medical education community. The aim was to define and validate a set of Core EPAs that are appropriate for both the undergraduate curriculum at the Charité and

its graduates' workplace reality. The research question of Chapter 2 focused on how to define a set of Core EPAs for the undergraduate curriculum in a local context. The methodology chosen was in line with the recommendations of the literature (Taylor et al., 2020; ten Cate, 2013; ten Cate et al., 2015). Experienced physicians who were also involved in the curricular planning of the undergraduate curriculum were included as experts in the Delphi study. Following the guiding principles in EPA content definition, an iterative process resulted in a set of 12 EPAs. Chapter 3 describes in detail which EPAs beginning residents are expected to perform under distant supervision in the first days of residency. Each EPA description contains seven categories: title; specification/limitations; knowledge, skills and attitudes (KSA); conditions and implications of the entrustment decision; the most relevant domains of competence; assessment sources; and the expected supervision level at the stage of training. The development of an EPA is a challenging process, as the EPA description can quickly become too broad or too deconstructed (Pugh et al., 2017; Tekian et al., 2020). The description of the EPAs is still essential, as supervising physicians and trainees need a shared mental model of what the entrustment of the professional activity implies (Martin et al., 2020; Tekian et al., 2020). The specifications of some EPAs changed remarkably over the course of the three rounds, as panel members perceived them to be too difficult. They also expressed the need to clarify the consequences of the entrustment decision, which resulted in the category "conditions and implications of the entrustment decision", which is a category that was also proposed by Chen and colleagues (2016). The resulting categories of the Core EPAs are in line with the recommendations in the literature (Chen et al., 2016; ten Cate, 2013; ten Cate, 2014; ten Cate et al., 2015; ten Cate & Taylor, 2020). Additional categories proposed are the method of arriving at the entrustment decision (Chen et al., 2016; ten Cate, 2013; ten Cate, 2014), the expiration date of the entrustment decision (ten Cate et al., 2015; ten Cate & Taylor, 2020) and the potential risks in case of failure (ten Cate & Taylor, 2020). The EPAs defined in this thesis contain those categories that were deemed to be most relevant for the local context. A continuous revision process based on future evidence is envisioned.

Internationally, several sets of Core EPAs have been developed since the beginning of this thesis (AAMC, 2014; AFMC, 2016; Michaud et al., 2016; ten Cate et al., 2018). Even though there are differences between the sets with respect to the number of EPAs, the included categories and the description of the EPAs, the EPAs are generally similar with respect to their breadth. For example, all of the named sets include an EPA on taking a history and performing a physical examination. Thus, even though sets of Core EPAs need to be adapted to the expectations and circumstances in the specific context, there seems to be a general consensus on the types of professional activities that beginning residents are expected to perform without direct supervision.

The applied approach of defining Core EPAs by means of group consent techniques is widely accepted. However, even though the consensus of experienced physicians and medical educators is certainly of importance, the views of other stakeholders are of added value (AAMC, 2014; AFMC, 2016). To gather additional evidence for the content validity of the Core EPAs, Chapter 4 examined whether the defined Core EPAs represent realistic workplace expectations for beginning residents by means of a survey of graduates. Previous research studying graduates' perspectives on Core EPAs has mainly focused on their confidence or their preparation for performing the activities (Lindeman et al., 2015; Marty et al., 2021; Ryan et al., 2016; Smith, 2018; Winn et al., 2018). The presented study took the novel approach of asking graduates how often they performed the activities and under which level of supervision. Additional evidence was found for the validity of the majority of Core EPAs, but there were some mixed results with respect to the medical procedures listed under the EPA "Perform general procedures of a physician". Graduates indicated that they did not perform the majority of the defined procedures as often and as autonomously as expected. This finding initiated discussion of shortening the list of procedures. Another interesting finding of the postgraduate survey was the fact that beginning residents often perform broader, more complex EPAs. These findings emphasize the possible advantage of linking the identified Core EPAs to broader EPAs, as this could emphasize the continuity of medical education with a focus on patient care and not on passing exams or completing training phases (Sklar, 2019).

In parallel to the research at the Charité, a sub-working group of the German Medical Faculty Association (Medizinischer Fakultätentag, MFT) developed a set of broader Core EPAs that were implemented in the practical year at some medical faculties in Germany (Berberat et al., 2019). This set includes overarching interdisciplinary and speciality-specific Core EPAs, such as "Consultation with a patient with a chronic illness" or "Conducting a planned house or home visit" (Berberat et al., 2019). These EPAs formulate a different expectation for beginning residents, linking to the professional activities expected to be performed autonomously by second-year residents. Collaborations have emerged to develop EPAs for the German Graduate Profile (Absolventenprofil) and include them in the revised and aligned NKLM and object catalogue for the state examination (IMPP, 2021; MFT, 2021). The Graduate Profile EPAs are a combination of the defined Charité Core EPAs and the broader EPAs developed by the German Medical Faculty Association (MFT). The Charité EPAs were adapted and integrated as "Nested EPAs" with six "Master EPAs" to provide a comprehensive impression of the expectations for a German medical graduate. The Master EPA "Inpatient Admission" includes, for example, 11 nested EPAs that constitute this activity. The preliminary list of the Graduate Profile EPAs has been published (IMPP, 2021; MFT, 2021) and will be the object of research in the next years. The finalized Graduate Profile EPAs will be set as standard

outcomes, and German medical faculties will be expected to integrate them into their curricula. The third and final state examination will also cover certain Graduate Profile EPAs.

Including the entrustment-supervision scale in an OSCE

The integration of German Graduate Profile EPAs into undergraduate curricula will require decisions on the necessary assessment system. While the focus of EPA assessment clearly lies in the workplace, other forms of clinical skill, competence and performance assessment can be integrated into an overarching framework (Peters et al., 2017). Taking into consideration Miller's pyramid of assessment, the OSCE represents a way to evaluate whether students can show how to perform an EPA in a standardized setting (Miller, 1990). Chapter 5 explored whether entrustment ratings could be integrated into the regular OSCE at the end of the fifth year, where students perform a range of professional activities in a controlled setting while being evaluated by assessors. On theoretical grounds, there are arguments in favour of inclusion (e.g., it is easy to implement and may provide meaningful feedback) and against it (e.g., the use of an artificial situation and a controlled setting). The present study was among the first to study entrustment-supervision scales in a simulated setting and the first to study their applicability in a regular undergraduate OSCE (Eliasz et al., 2018; Harendza et al., 2017; Johnston et al., 2019; McMurray et al., 2017; Wijnen-Meijer et al., 2013). In contrast to the standard ratings, the entrustment ratings were more evenly distributed, and a considerable percentage of students did not reach the expected entrustment-supervision level in the stations. The standard ratings were skewed towards the upper end of the scale, all students passed the OSCE, and few students did not reach the expected composite OSCE results in single stations. The findings further indicated that in most stations, both standard ratings accounted for a considerable proportion of the variance in entrustment ratings, with the communication rating having a larger effect across several stations. Overall, the findings indicate that the entrustment rating captures something that goes beyond the assessment of clinical and commination skills and could be of benefit.

Two out of eight stations did not show a relation between the clinical and communication skill ratings and the entrustment rating. This finding could potentially be explained by factors such as "a) the amount of variability in the data, b) differences in the shapes of the 2 distributions, c) lack of linearity, d) presence of 1 or more "outliers", e) characteristics of the sample, and f) measurement error" (Goodwin & Leech, 2006, p. 252). The impact of these factors is more prominent in smaller sample sizes, and the identified stations had a smaller sample size than the other stations. In addition to statistical issues, other factors could be responsible for the lack of association between the ratings. Even though much time and effort was invested in the development of good OSCE stations, there might still be differences in the quality of the stations and the authenticity of the included patient cases (Pell

et al., 2010). Additionally, assessors could be a source of variation in OSCE assessments (Pell et al., 2010). It is also possible that the content and structure of these stations is not suitable for filling out the entrustment-supervision scale. Overall, the assessors rated the addition of the entrustment positively, but there was also a considerable percentage of assessors who were more restrained in their evaluation. This is line with research conducted on the inclusion of an entrustment-supervision scale in an OSCE Progress Test (Halman et al., 2020).

The presented approach to integrating entrustment ratings in OSCEs is supported by further studies, which concluded that entrustment ratings could be included in simulated settings and are of added value (Fincke et al., 2020; Halman et al., 2020). A study by Malau-Aduli and colleagues (2021) pointed out that even in regular OSCE examinations, some assessors indicated that they based their checklist ratings on the question of whether the trainee poses a threat to patient safety and whether he or she could be in charge of taking care of patients. These findings support the notion of Crossley and colleagues that entrustment ratings are aligned to the supervising physician's "constructs of developing clinical sophistication and independence, or 'entrustability'" and are thus a naturally occurring method of evaluation (2011, p. 562). Students and residents who were experienced with the EPA concept also advocated for the inclusion of entrustment-supervision scales or the EPA concept in OSCEs (Geraghty et al., 2020; Khan et al., 2020).

However, concerns were also voiced regarding the inclusion of entrustment-supervision scales in settings other than the workplace, as trainees' performance in a classroom setting might yield little informative value because the circumstances are completely different (Persky et al., 2021). The simulated setting in an OSCE aims to control as many influential factors as possible by standardizing the patient and the patient encounter. Several factors have been identified that influence the entrustment ratings given by supervising physicians in the workplace, including the relationship between the trainee and the supervising physician and the involved risk for the patient (ten Cate et al., 2016). The brief contact that students have with the assessors and the absence of any risk for the patient likely has an effect on the entrustment decision. To date, few studies have explored the comparability of entrustment decisions made in a simulated setting and the workplace, and the results are mixed. A study performed by Weersink and colleagues (2019) found positive associations between the two entrustment ratings, whereas other studies found no association between the ratings (Andler et al., 2020; Prudhomme et al., 2020). The authors of the latter studies hypothesized that the differences in the complexity and variety of cases assessed in the workplace in comparison to the simulated setting are the cause of the divergence.

It is of utmost importance to take the concerns and possible doubts of assessors and students seriously, as their understanding and application of the entrustment-supervision scale is key to its successful implementation. It might be necessary to clearly specify the purpose of

the entrustment-supervision scale in an OSCE setting. At the Charité, the inclusion of the entrustment-supervision scales aims to provide a different view on students' performance and to build a connection to the workplace. The results are formative, are meant to guide students' learning and have no direct effect on the involvement of students in the workplace.

Understanding the entrustment decision-making process

The successful implementation of EPAs as outcomes in the undergraduate curriculum will require informing, advising and guiding all stakeholders involved, especially students and supervising physicians. Among other aspects, the entrustment decision is crucial to the EPA concept. Even if the entrustment decision is implicitly a part of the daily routine, its inclusion as part of the assessment system requires a deepened understanding of it (ten Cate et al., 2020).

At the beginning of this dissertation project, several studies and overviews were published on the factors influencing the entrustment decision (Choo et al., 2014; Hauer et al., 2014; Kennedy et al., 2008; Sterkenburg et al., 2010), which were summarized by ten Cate and colleagues (2016). They identified factors related to the trainee, the supervising physician and their relationship, as well as factors related to the context or circumstances and the activity itself. However, the question remained of how these factors might interact. In Chapter 5, the focus was on the question of how supervising physicians make the decision to entrust a trainee with an EPA. A conceptual model of the entrustment decision-making process was developed, which is based on the trust models developed by Mayer and colleagues (1995) and Cianciolo and colleagues (2011). It distinguishes between the intention to entrust a trainee with an EPA and the actual entrustment behaviour and emphasizes the importance of the "unit of analysis", thus the setting in which the entrustment decision is made. It provides a framework that allows certain assumptions about the entrustment decision process to be made explicit and testable (Bordage et al., 2009). In recent years, the field has developed further, and new findings and ideas concerning the entrustment decision-making process have been published (Bannister et al., 2018; ten Cate & Chen, 2020; ten Cate et al., 2020). Some studies have further elaborated on the factors influencing the entrustment decision by means of focus groups or surveys (Duijn et al., 2018; Yoon et al., 2020). Others have actually studied entrustment behaviour by means of observational studies (Sagasser et al., 2017; Sandhu et al., 2018a). Ten Cate and Chen (2020) provided a mnemonic to better remember the factors related to the trainee that have been found to influence the entrustment decision: "A RICH entrustment decision", which stands for agency, reliability, integrity, capability and humility. The last four factors were previously reported to have an influence (Kennedy et al., 2008). Trainees who can be counted on and who take over responsibility (reliability), who are honest (integrity), who show the relevant competence (capability) and who ask for help when needed (humility) are more likely to be entrusted to perform the activity at hand. Ten Cate and Chen (2020) added agency as an

additional factor, which means that trainees need to show proactive behaviour and need to show interest in their patients and their own professional development.

Research on EPAs and their entrustment is a very active field, and each of its results provides a piece to the whole puzzle of understanding the complex entrustment decision-making process. Klasen and Lingard (2021) pointed out that one should still be cautious in assuming linearity in the process, as entrustment decisions might also be triggered by unknown, unforeseeable things. Thus, even if one identifies and validates a set of factors known to influence the entrustment decision, it will not be possible to feed them into an algorithm to predict the entrustment decision of a physician. However, even if it might not be possible to arrive at a complete and all-embracing understanding of the entrustment decision-making process, the conducted studies are valuable because they help to make the implicit explicit. In the clinical context, these entrustment decisions are part of the daily routine, and supervising physicians and trainees should be aware of and need to be trained about the potential biases that are in place.

Limitations of the current research

Samples

The Delphi study (Chapters 2 & 3) included 34-36 experts in the respective rounds, representing a range of medical disciplines. We purposefully selected physicians at our university who were experienced physicians and who were involved in the curriculum planning process, as they could help to ensure an alignment between the theoretical elaboration in the form of EPAs and the workplace reality (Taylor et al., 2020). This approach is completely in line with recommendations on conducting a Delphi study (Humphrey-Murto et al., 2017). However, the narrow pool of participants presumably had an influence on the defined set of EPAs. The results of any study on the definition of EPAs as outcomes might be influenced by the background of the participants (e.g., medical specialty, medical setting). Additionally, the study of graduates of the Charité (Chapter 4) had a response rate of only 18%. Even though this is not uncommon for research in this field (Bosch et al., 2017, Marty et al., 2021), the results should be interpreted with caution.

Entrustment-supervision scale

The applied entrustment-supervision scales in the presented studies were based on the recommendations in the literature (Peters et al., 2017). However, additional scales have been defined and implemented, which differ in the number of supervision levels and the wording (ten Cate & Chen, 2020). They all aim to reproduce the distinct levels of supervision that can be found in the workplace, but it is not yet certain which scales are suitable for reliably assessing the required level of supervision. The number of published articles on the application of

entrustment-supervision scales as assessment instruments is rising; however, the results currently form a rich and complex picture. Several studies attest that entrustment-supervision scales have good reliability (Mink et al., 2018; Sandhu et al., 2018b; Weller et al., 2014; Weller et al., 2017), the ability to discriminate between novices and more experienced trainees (Halman et al., 2018; Klapheke et al., 2017; Mink et al., 2018; Rekman et al., 2016; Rhodes et al., 2017; Schumacher et al., 2020; Valentine et al., 2019; Warm et al., 2016;) and the ability to detect bad performances (Rekman et al., 2016; Weller et al., 2017). In contrast, the results of other studies do not support the good reliability of entrustment-supervision scales (Kelleher et al., 2020; Ryan et al., 2021) and suggest that they might not reflect the trainees' capabilities but might be biased by the supervisors' intuitions (Kane & Lorant, 2018).

These differing, contradictory findings could partially be explained by the high variability in the EPAs and settings used, as well as the entrustment-supervision scales. Some scales tend to be retrospective in nature, indicating the needed level of supervision in a specific situation, and other scales are prospective, indicating the level of supervision a trainee needs for specific tasks in the future (ten Cate & Chen, 2020). The retrospective scale requires reporting on the actual level of supervision in a specific situation, whereas the prospective scales require estimating how much supervision a trainee needs in future situations with unknown patients and circumstances. A study by Cutrer and colleagues (2020) found that ratings made on a retrospective scale differ from ratings made on a prospective scale, suggesting that they capture different constructs. The studies presented in this dissertation project used both retrospective and prospective scales, and different findings might have been made with a different scale using different supervision levels and/or different wording.

Familiarity with the EPA concept and entrustment decisions

One reason for the popularity of the EPA concept in the medical education community is its "face validity". It builds on daily professional activities and the philosophy of gradually increasing the independence of physicians. In the presented studies, it was consequently assumed that participants would understand the concept of EPAs and entrustment decisions quite quickly, which might have been problematic. The participants in the Delphi study (Chapters 2 & 3) received an introduction to the EPA concept, but misunderstandings regarding the definition of EPAs and confusion regarding the distinction between EPAs and competencies were still detected. This likely had an influence on the defined set of EPAs. Graduates in the survey (Chapter 4) received the list of EPAs and the differing entrustment-supervision levels and were asked to fill out the questionnaire without any background information. The descriptions of the EPAs are quite detailed, but it is still not known whether participants had the same understanding of the activity. It might be that participants had slightly differing ideas of what is included in the performance of an EPA and might have therefore

given different answers. In addition, recent research proposes that supervising physicians might have trouble understanding the entrustment-supervision scales, as they might not represent their own way of increasing or decreasing supervision (Postmes et al., 2020). The ratings of the graduates (Chapter 4) and of the assessors in the OSCE (Chapter 5) might have been different if they had been more familiar with EPAs and the defined entrustment-supervision scales.

Design

In the Delphi study, we used the Core EPAs of the Association of American Medical Colleges (AAMC) as the basis for our own set of EPAs. While this is a legitimate approach, a scoping literature review suggests that the majority of articles published on the development of EPAs referred to the work of the AAMC, possibly leading to its overgeneralization (Meyer et al., 2019). Without providing a predefined list of EPAs, the results of the Delphi study might have been different. Similarly, the graduate survey aimed to find evidence for the developed set of EPAs. However, we did not include the possibility for graduates to add potentially missing activities.

Statistical analyses

The statistics applied in this thesis are primarily descriptive. The Delphi study and the survey of graduates builds on the percentage of participants agreeing to a specific statement. The Delphi study could have benefitted from analysing the effect of medical specialty on the agreement on EPA descriptions. The graduate survey could have benefitted from analysing the effect of medical specialty or gender on the performance of EPAs. However, due to the small sample size in both studies, further inferential analyses were not possible.

Linear mixed-effect models and correlational and regression analyses were applied in the OSCE study, and the entrustment-supervision scale was treated as an interval scale. There has been some discussion on the appropriateness and plausibility of treating entrustment-supervision scales as interval scales, which connects to the general discussion around the application of parametric tests on ordinal scales (Jamieson, 2004; ten Cate et al., 2020). Taking into account the sample size in the study, the literature suggests that parametric tests are sufficiently robust to provide unbiased results (Norman, 2010). Additionally, Spearman–rho correlations and ordinal regression analyses were conducted, and the results did not show deviations from the reported results. The manuscript would have benefitted if the entrustment-supervision scale had been explicitly referred to as ordinally scaled and if the selection of the parametric tests had been discussed.

Implications for practice and for future research

The results and findings of this dissertation have practical implications for both the local and national contexts. With the publication of the German Graduate Profile EPAs in the NKLM and the object catalogue for the state examination (IMPP, 2021, MFT; 2021), all German medical faculties are required to implement these as outcomes for their undergraduate curricula by 2025. It is of utmost importance to evaluate how the faculty react to the implemented changes, as well as to study whether the changes have the intended effect (Hung et al., 2020; Obeso et al., 2018). In what follows, the practical implications and the associated possibilities for further research will be discussed.

As the Graduate Profile EPAs are the consensus of a working group, further research with physicians and students across Germany is required to find evidence for their content validity and to study the feasibility of their implementation. At the Charité, future projects will build on the range of studies that have already been conducted on the implementation of EPAs. For example, an assessment instrument based on EPAs and entrustment levels was developed (Peters et al., 2019) and was applied to provide students with feedback on their readiness for the practical year (Rollinger et al., 2020). Additionally, a focus group study was conducted with students in the practical year on the question of whether EPAs could be a useful addition to the curriculum (Holzhausen et al., 2016), and another focus group study was carried out with experienced physicians on the potential of EPAs to structure the practical year (Czeskleba et al., 2020). All findings will be used to guide the design and application of future local research projects.

The mapping of Graduate Profile EPAs to undergraduate curricula is also a possible research field. This might include both the actual process of mapping the EPAs to the learning objectives and courses and the evaluation of students and physicians. At the Charité, professional activities in the form of learning objectives are already implemented as a longitudinal curricular structure (Maaz et al., 2018), and the link between these learning objectives and the Graduate Profile EPAs will be emphasized in the module course books as well as the web-based platform for learning objectives and courses at the Charité.

As described in the limitation section, the selection of appropriate entrustment-supervision scales is also an active field of research. Various scales have been developed, and further evidence of validity is needed. The entrustment-supervision scale proposed by Carrie Chen (2015) is widely applied and accepted in the community and has also been recommended for use in combination with Graduate Profile EPAs (IMPP, 2021, MFT; 2021). Further studies are needed to evaluate the scale and to adapt it when necessary to the needs of students and staff.

The evaluation of the entrustment-supervision scale is especially important if it will be used as an assessment method across Germany (Smit et al., 2019). At the Charité, the findings

presented in Chapter 4 were used to decide on the inclusion of the entrustment-supervision scale for a prolonged period in the OSCE assessment of the ninth semester. Since 2019, students have also received feedback on assessors' entrustment ratings for each OSCE station. Further studies will be conducted to gather more evidence on the usefulness and validity of the added scale by studying the perception of both assessors and students. The results will guide the decision on the permanence of the inclusion of the entrustment-supervision scale.

In addition, research projects are planned to study the inclusion of EPAs and entrustment-supervision scales in the PTM. The PTM is offered to over 10000 students across 14 faculties in Germany and Austria and provides regular feedback on their current state of knowledge as well as their development of knowledge over the course of study (Charité - Universitätsmedizin Berlin, 2021a). Students at the Charité are, for example, obligated to complete the PTM once every semester. The inclusion of EPAs intends to enable feedback on the students' development of practical competence.

In addition to the linkage of the EPA concept with existing assessment formats, such as the OSCE and the PTM, new forms of workplace-based assessments of EPAs need to be introduced. Therefore, it is important to acknowledge the complexity and intricacy of implementing effective workplace-based assessments in undergraduate education (Tekian et al., 2020). The actual workplace involvement of students is often limited, and workplace-based assessments are scarce (Berberat et al., 2019; Eichhorst et al., 2021; Engel et al., 2008; Lomis et al., 2017). This is in contrast to the idea that entrusting students with a task related to patient care requires the development of trust, which takes time (El-Haddad et al., 2016; Evans et al., 2019). In Germany, structural changes to the curricula aim to address this shortcoming, but it will be a challenge to break old patterns (BMBF, 2017). The ideal is to build an EPA-based assessment system in which supervising physicians and students are sensitized to the relevance of the appropriate supervision and the provision of effective feedback (Karp et al., 2019; Watling & Ginsburg, 2019). At the Charité, efforts are undertaken to create more opportunities for students to receive useful feedback on their workplace-based performance, especially in the practical year. In line with other institutions implementing EPAs in undergraduate medical curricula, all assessments regarding EPAs will be seen as formative in nature (Lomis et al., 2017). This approach has also been suggested by medical students who experienced the implementation of Core EPAs in medical schools in the USA (Geragthy et al., 2020). The results of the assessments are solely intended to provide students with an impression of their performance phrased in terms of their autonomy in the workplace, which they could use to engage in self-directed learning (Carraccio et al., 2017). The formed entrustment decisions will have no further effect on their curricular progress. The introduction

of workplace-based assessments, their acceptance among students and physicians, and the effect of the assessments are rich areas of future research.

For students to keep track of the received ratings and feedback, the implementation of an electronic portfolio seems to be inevitable (ten Cate et al., 2015). The development of an electronic portfolio integrating the Graduate Profile EPAs will be another area of research. At the Charité, an EPA-based e-portfolio was developed and evaluated in the EU funded project "Workplace-based e-assessment technology for competency based higher multi-professional education" (WATCHME) between 2014 and 2017. Based on these experiences, the feedback tool "LevelUp" was released in 2019 at the Charité, integrating students' formative and summative assessment results on one central platform (Roa Romero et al., 2021). The Charité EPAs are also included to enable feedback on workplace performance. Future research projects will focus on the implementation of the Graduate Profile EPAs in LevelUp and the development of a mobile app to ease the provision and collection of EPA assessments and feedback in the workplace.

In addition, a collaboration with the company AMBOSS resulted in the integration of EPAs on their website (AMBOSS, 2021a). AMBOSS is the most popular learning platform for German medical students, offering the possibility of testing medical knowledge based on old and commented questions from the state examinations (AMBOSS, 2021a). Approximately 90% of students use AMBOSS to prepare for state examinations (AMBOSS, 2014). AMBOSS is continuously broadening their range of products to better prepare students and physicians for medical practice, and the Charité EPAs were included to provide students with an idea of which activities they are expected to perform at the end of the undergraduate curriculum and which they should practise in the practical year (AMBOSS, 2021b). Future projects could cover the inclusion of the Graduate Profile EPAs in AMBOSS and the evaluation of how students could use them to guide their learning.

In addition to medical education, there are other degree programs that could benefit from the introduction of the EPA concept. The Charité offers a range of study programmes to students (Charité-Universitätsmedizin Berlin, 2021b), and EPAs are currently being developed for the Bachelor's Degree in Nursing Care, dental medicine and the qualification programme of educators in higher education. The definition and implementation of EPAs as outcomes across a wide range of study programmes is an additional research field.

Irrespective of the setting in which EPAs are introduced in a curriculum, the education and training of the stakeholders involved will be another area of research. While there are already recommendations available on how to educate faculty members about EPAs and the related concepts and implications (Peters et al., 2017; Lupi et al., 2018; Bray et al., 2020; Rivkin et al., 2020), each faculty member might encounter different obstacles and methods of resolution, depending on the respective circumstances. A recent article by van Loon and

Scheele (2020), for example, cautions against the provision of guidelines that are too detailed, as they suspect the faculty members will become demotivated with too many new rules and a lack of creativity.

Conclusion

The definition of a set of Core EPAs and the first steps of its integration into the undergraduate medical curriculum at the Charité represent the scope of this thesis. EPAs have the potential to improve and heighten the prominence of students' practical training and to better prepare them for patient care, which is the ultimate goal of medical education. A set of 12 Core EPAs were developed in a Delphi study with physicians at the Charité and were further content-validated by means of a survey of graduates. The defined set of Core EPAs served as a main foundation for the German Graduate Profile EPAs, which all German medical faculties are called upon to integrate as outcomes in the coming years. The manuscript on how to develop EPAs for undergraduate curricula might serve as a guideline for medical faculties interested in the EPA concept. The explorative study on the integration of an entrustment rating scale in an objective structural examination graduate survey yielded interesting findings concerning the added value of the scale. Similarly, our conceptual model of the entrustment decision-making process aimed to be a thought-provoking contribution to empirical research on this topic. All results contributed to the very active research field around EPAs both nationally (Wijnen-Meijer et al., 2020) and internationally (O'Dowd et al., 2019; Meyer et al., 2019; Shorey et al., 2019), which could collectively inspire and guide medical schools worldwide.

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Curriculum Vitae

For reasons of data protection, the Curriculum Vitae is not included in the online version.

List of Publications

Articles in peer-reviewed journals (articles marked with an * are part of this thesis)

Roa Romero, Y., Tame, H., Holzhausen, Y., Petzold, M., Wyszynski, J.-V., Peters, H., . . . Dittmar, M. (2021). Design and usability testing of an in-house developed performance feedback tool for medical students. BMC Medical Education, 21(1). doi:10.1186/s12909-021-02788-4

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Selection of conference presentations

Holzhausen, Y., Maaz, A., Knoll, N., & Peters, H. (2021, August 27-30). *Implementing Entrustable Professional Activities as Outcomes for the Undergraduate Medical Curriculum at the Charité Berlin* [Oral presentation]. AMEE 2021, The Virtual Conference.

Holzhausen, Y.,Alexander, M., Tame, H., Peters, H., & Petzold, M. (2021, August 27-30). *LevelUp -keeping track through an integrative feedback tool* [Oral presentation]. AMEE 2021, The Virtual Conference.

Fehr, F., Holzhausen, Y., Rotthoff, T., Steinweg, B., Eißner, A., & Peters, H. (2019, September 25- 28). *EPAs in der medizinischen Aus- und Weiterbildung* [Workshop]. Jahrestagung der GMA 2019, Frankfurt am Main, Germany.

Peters, H., Holzhausen, Y., Maaz, A., Breckwold, J., & Czeskleba, A. (2019, August 24-28). *Development of EPAs for Teaching in Undergraduate Medical Education* [Oral Presentation]. AMEE 2019, Vienna, Austria.

Gusic, M. E., Chen, H. C., Holzhausen, Y., Peters, H., & ten Cate, O. (2019, August 24-28). *Making entrustment decisions explicit: Preparing "front-line" teachers for performance assessment based on a learner's need for supervision* [Workshop]. AMEE 2019, Vienna, Austria.

Holzhausen, Y., Rotthoff, T., Maaz, A., & Peters, H. (2018, September 19-22). *EPAs als Assessment: Potentiale, Methoden und Herausforderungen* [Workshop]. Jahrestagung der GMA, Vienna, Austria.

Peters, H., & Holzhausen, Y. (2018, September 11-12). *Ärztliche Tätigkeiten (EPAs) zur Erfassung der Kompetenz von Studierenden*. Schulung an dem Institut für Ausbildung und Studienangelegenheiten (IfAS) an der Westfälischen Wilhelms-Universität Münster, Deutschland.

de Graaf, J., Peters, H., Bolk, M., Dijkstra, A., van der Horst, M., & Holzhausen, Y. (2018, August 24-25). *Experiences with Entrustment Decision Making in EPA-based medical training:*

Practical insights from the Netherlands and Germany [Workshop]. Second World Summit on Competency-Based Education, Basel, Switzerland.

Holzhausen, Y., Maaz, A., März, M., Sehy, V., & Peters, H. (2018, August 25-29) *Introducing Entrustment Scales in Objective Structured Clinical Examinations* [Oral presentation]. AMEE 2018, Basel, Switzerland.

Gusic, M. E., Bradey, E. B., Chen, H. C., Holzhausen, Y., Peters H., & ten Cate, O. (2018, August 25-29) *Preparing Supervisors for Entrustment Decisions about Learner Performance: Effective approaches for training and support of clinical faculty* [Workshop]. AMEE 2018, Basel, Switzerland.

Holzhausen, Y., Renz, A., Loo, K., Maaz, A., & Peters, H. (2017, September 20-23). *PROJEKT: Workplace based e-Assessment Technology for Competency-based higher multi-professional education (WATCHME)* [Oral presentation]. Jahrestagung der GMA, Münster, Germany.

Kadmon, M., Berberat, P., Holzhausen, Y., Maaz, A., Rotthoff, T., & Peters, H. (2017, September 20-23). *Entwicklung von Entrustable Professional Activities (EPAs) für das Praktische Jahr* [Workshop]. Jahrestagung der GMA, Münster, Germany.

Holzhausen, Y., Maaz, A., & Peters, H. (2017, August 26-30). *Confidence of graduating medical students to perform Core end-of-undergraduate-training Entrustable Professional Activities (EPAs)* [Oral presentation]. AMEE 2017, Helsinki, Finland.

Peters, H., ten Cate, O., Holzhausen, Y., Teherani, A., Posthumus, I., & Chen, C. (2017, August 26-30). *Assessment with Entrustable Professional Activities in undergraduate medical education: opportunities, pitfalls, and lessons learned* [Workshop]. AMEE 2017, Helsinki, Finland.

Kadmon, M., Berberat, P., Holzhausen, Y., Maaz, A., & Peters, H. (2016, September 14-17). *Entrustable Professional Activities (EPAs) in der medizinischen Ausbildung* [Workshop]. Jahrestagung der GMA, Bern, Schwitzerland.

Holzhausen, Y., Maaz, A., & Peters, H. (2016, August 27-31). *Medical students' perception of the EPA concept: A focus group study* [Oral presentation]. AMEE 2016, Barcelona, Spain

Peters, H., Maaz, A., Holzhausen, Y., Chen, H. C., Wisman-Zwarter, N., Reyman, M. & Hoff, R. (2015, September 5-9). *Design and implementation of Entrustable Professional Activities for translating competency-based education into practice* [Workshop]. AMEE 2015, Glasgow, UK.

Peters, H., Maaz, A., Holzhausen, Y., & Breckwoldt, J. (2014, September 25-27). *Entrustable Professional Activities im Medizinstudium* [Workshop]. Jahrestagung der GMA, Hamburg, Germany.

Peters, H., Breckwoldt, J., Chen, H. C., Maaz, A., Holzhausen, Y., & ten Cate, O. (2014, 30 August- 3 September). *Entrustable Professional Activities in undergraduate medical education* [Workshop]. AMEE 2014, Milan, Italy.

Selbständigkeitserklärung

Hiermit erkläre ich, die vorliegende Dissertation selbstständig verfasst und ohne unerlaubte Hilfe angefertigt habe.

Alle Hilfsmittel, die verwendet wurden, habe ich angegeben. Die Dissertation ist in keinem früheren Promotionsverfahren angenommen oder abgelehnt worden.

Ort, Datum	Unterschrift (Ylva Holzhausen)