

Defining a Competency-based Simulation Training Curriculum for Obstetrics & Gynecology Residents

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Abstract

INTRODUCTION In the last decade, competency-based medical education (CBME) has become the predominant teaching method used in residency training, preparing young physicians to become competent graduates. Due to new challenges in the 21st century, such as workhour reforms, increased breadth of knowledge required, new technology, and increased awareness of patient safety, CBME has supplemented the historical Apprenticeship and Halstedian models of medical education. It focuses on outcomes (attainment of competencies), and promotes active learning, requiring more frequent observations and assessments of learners. Simulation represents a valuable tool in the era of CBME as it allows for both teaching and assessments to take place and promotes deliberate practice; all in a safe and controlled environment with no consequences for patients. The role of CBME and simulation in the specialty of Obstetrics and Gynecology (OBGYN) will be further explored within three manuscripts, with the goal of helping to define a national competency-based simulation training curriculum for OBGYN residents.

METHODS First, a comprehensive review of literature was undertaken to compare curricula from five countries, on an international level, including Canada. Second, a list of entrustable professional activities (EPAs) for OBGYN was defined via a Delphi consensus method. Each EPA was quantified for its importance in residency training and for simulation in addition to setting benchmarks. Third, the role of simulation in OBGYN, including its current use and effectiveness, was further elaborated via a systematic review on the subject.

RESULTS Five countries recognized CBME as a valuable tool in medical education, but there remains a need to develop more assessment tools, including the use of simulation. The review of curricula allowed for item analysis to take place, which yielded 15 EPAs for OBGYN. Although it was clear for experts surveyed that all outlined EPAs were important/essential and that there is

a stepwise increase in competence, based on stage of residency, the role that simulation plays remained uncertain. However, the systematic review, which yielded 316 eligible studies, highlighted that simulation does in fact play a very important role in OBGYN residency training and that both its use and the number of high-quality studies involving simulation has been increasing over the years.

CONCLUSION The introduction of “Competence by Design” in 2019 within Canadian residency training programs has increased the need for more adequate teaching and assessment tools in order to ensure that all graduating residents are ready for practice. This thesis demonstrated that simulation plays an integral role in filling this gap, with many studies showing that it increases assessed knowledge and skills which then translate to the workplace. Thus, a national competency-based simulation training curriculum for OBGYN residents, has the potential to increase the quality of training and patient care.

Résumé

INTRODUCTION Dans la dernière décennie, la formation en médecine fondée sur les compétences (FMFC) est devenue la méthode prédominante pour l'enseignement dans les programmes de résidence afin de préparer les jeunes médecins à devenir des diplômés compétents. Le 21^e siècle a amené des nouveaux défis en médecine, tels que la diminution des heures de travail, une augmentation de l'ampleur des connaissances requises, des nouvelles technologies, et plus de conscience pour la sécurité des patients. Conséquemment, la FMFC vient suppléer les modèles historiques de formation médicale de l'apprentissage et de Halsted. Cette démarche est axée sur les résultats (l'acquisition de compétences) et promeut l'apprentissage actif, nécessitant des observations et des évaluations plus fréquentes des apprentis. La simulation représente un outil important dans le cadre de la FMFC, car elle permet l'enseignement et l'évaluation, ainsi que la pratique délibérée, dans un environnement contrôlé et sécuritaire, sans conséquences pour les patients. Le rôle de la FMFC et de la simulation dans la spécialité de l'obstétrique-gynécologie (OBGYN) sera exploré davantage dans trois manuscrits, le but étant d'aider à définir un curriculum national en simulation fondée sur les compétences pour les résidents en OBGYN.

METHODES

Premièrement, une revue de littérature compréhensive comparant les curricula de cinq pays, incluant le Canada, a été fait. Deuxièmement, une liste d'activités professionnelles fiables (APC) a été définie à l'aide d'un consensus par la méthode Delphi. L'importance de chaque APC pour la formation des résidents et pour la simulation a été quantifiée et des repères académiques ont été conçus. Troisièmement, le rôle actuel de la simulation dans le domaine d'OBGYN, incluant son utilité et efficacité, ont été élaboré davantage via une revue systématique.

RESULTS Cinq pays reconnaissent la FMFC comme étant un outil de grande valeur en éducation médicale. Cependant, il y a toujours un manque d'outils adéquats pour l'évaluation médicale, incluant la simulation. La revue des curricula a permis au développement de 15 APC spécifique au domaine d'OBGYN. Les experts interrogés étaient en accord que chaque APC était important/essentiel et qu'il y avait une augmentation progressive des compétences, dépendant de l'étape de la formation. Néanmoins, ces experts restent incertains du rôle de la simulation. Toutefois, la revue systématique de 316 études éligibles, souligne que la simulation a en effet un rôle très important dans la formation médicale en OBGYN et que son emploi ainsi que le nombre d'études de haute qualité augmentent avec les années.

CONCLUSION L'introduction de "La Compétence par Conception" en 2019 pour la formation médicale des résidents au Canada a augmentée le nécessité d'avoir plus d'outils d'enseignement et d'évaluation afin d'assurer que les finissants sont prêts pour la pratique indépendante. Cette thèse démontre que la simulation joue un rôle intégral pour combler ce besoin. Plusieurs études démontrent que la simulation augmente les connaissances et les habiletés, et ceci même dans le contexte clinique. Ainsi, un curriculum national en simulation fondée sur les compétences pour les résidents en OBGYN a le potentiel d'augmenter la qualité de formation médicale et les soins aux patients.

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Conflicts of Interest

I have no conflicts of interest or disclosures to declare.

Dr. Rajesh Aggarwal is a consultant for Applied Medical.

Preface and Contribution of Authors

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- Planning of study
- Design, methodology, data analysis
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Section 1: Introduction

Introduction

Background

1. History of Medical Education

Apprenticeship Model of Learning

The earliest form of medical education documented in history is that of the apprenticeship model, similar to what we commonly refer to today as “hands on learning”. It was the most common method of training surgeons until the 19th century[1-3]. This model is even outlined in the Hippocratic Oath which essentially is a contract between master and apprentice whereby the apprentice would “regard him who has taught [me] this [‘art’] as equal to [my] parents, and to share, in partnership, [my] livelihood with him” [4]. In this way, medical knowledge, theory and techniques were passed on from master physician to apprentice for thousands of years. The student directly observes then imitates the actions of a skilled master[3]. In the 19th century, the hospital became instrumental to medical training as students learned from the new “disease model”, still under the instruction of a master physician. The patient (both living and dead) became important to learn the pathological processes of disease, and methods of diagnosis changed massively, from relying on ancient texts to clinical examinations and signs made by disease on the human body[5]. The first major shift from the apprenticeship model to the Halsted “see one, do one, teach one” model took place in the late 19th to early 20th century [1, 2, 6-8].

Halsted Model of Learning

In 1910, an American educational specialist named Abraham Flexner wrote the “Flexner Report”, which set specific standards and policies for medical education and was based on the values and teaching methods at Johns Hopkins University [1, 9]. Dr. William Osler pioneered clinical teaching during this time and introduced the concept of bedside rounds, medical rounds,

and formalized the residency system to include learning from the patient; this was the beginning of the clinical clerkship and postgraduate residency training as we know it[2, 8, 10]. Dr. William S. Halsted was the first to introduce a formal residency training program for young surgeons; previously all were self-trained or learned via the apprenticeship model[11]. He integrated Osler's method of teaching and the concept that medicine is founded on basic scientific knowledge into his principles of residency surgical training [1, 2, 7]:

- 1- "The resident must have intense and repetitive opportunities to take care of surgical patients under the supervision of a skilled surgical teacher.
- 2- The resident must acquire an understanding of the scientific basis of surgical disease.
- 3- The resident must acquire skills in patient management and technical operations of increasing complexity with graded enhanced responsibility and independence."

This traditional teaching method is still valid today, in combinations with other adult learning principles[6]. With some modification, it remains the predominant model of medical education today and can also be linked to some of the principles of the newest paradigm shift in medicine: competency-based medical education (CBME). The third principle above is akin to the concept of scaffolding, used in CBME, which will be outlined in the first manuscript.

New Challenges in 21st Century

There are increasing ethical concerns over the safety of patients and as medicine has changed from a paternalistic approach to a more patient-centered approach, the traditional way of learning and training has also undergone some modifications and evolved to promote patient safety[2, 6, 9]. It is no longer acceptable for students to be considered 'competent' in performing a procedure or skill after only seeing it done once, and patients are not interested in being guinea pigs and being practised on. Medical education is now bound to the interests of patients. This

concern also has led to the reduction in resident duty work hours to avoid overworked and tired residents which could also impact patient safety[6, 12, 13]. Unfortunately, one important consequence of workhour reforms is that there are fewer teaching moments in the work-place for residents to learn from due to less clinical exposure[12]. Moreover, the breadth of knowledge of new diseases and therapies as well as technological advances has also increased tremendously over the last 100 years, thus residents are expected to learn more in a more limited amount of time[2, 3, 9, 14-16]. Limited healthcare resources and efficiency requirements have also led to a conflict between “service delivery” and dedicated teaching time[14-16]. Therefore the “see one, do one, teach one” method, cannot be used alone anymore; novel educational and training paradigms have become necessary to meet the challenges of the 21st century[4, 14-16].

Passive to active learning - The adult learner

In both medical education and the realm of education in general, there has been a paradigm shift from passive learning (teacher-centred) to active learning (learner-centered) in order to accommodate adult learning principles and to develop competencies[17-19]. The learning pyramid illustrates how active participation in the learning process results in higher retention rates of learning. Students retain only 5-30% of material covered in a lecture, reading, audio-visual, and demonstration (passive learning techniques) versus 50-90% by group discussion, practice by doing, and teaching others (active learning techniques)[6, 20]. New forms of higher education such as role-playing, simulation, case studies, and small group learning have become integrated into teaching curriculums around the world[18]. The idea of the Learning Paradigm is “not to transfer knowledge but to create [more powerful learning] environments and experiences that bring students to discover and construct knowledge for themselves.[19]” This learner-centered shift has led to the development and integration of innovative approaches for the teaching and assessment

of clinical knowledge and skills, which have been incorporated into residency training curriculums. This includes, but is not limited to simulation with or without standardized patients (SPs), objective structured clinical examinations (OSCEs), and objective structured assessment of technical skills (OSATS)[16]. With the current medical education focus on competence, these are being widely used since objective assessment of knowledge and skills is critical in CBME.

2. Competency-based Medical Education (CBME)

CBME is defined by the Royal College of Physicians and Surgeons of Canada as “an outcomes-based approach to the design, implementation, assessment, and evaluation of a medical education program ” [21]. This new model focuses on learning or outcomes rather than time. We are moving away from the “tea-steeping model” of medical education; whereby we assume that putting the resident (tea bag), in residency (hot water) for a fixed period of time yields a competent physician (perfect cup of tea)[22, 23]. Instead, there is increased emphasis on direct and indirect observation of knowledge, skills and behaviors. This outcomes-based approach uses an organizing framework of competencies, milestones and entrustable professional activities (EPAs) requiring regular assessment of performance in order to ensure that every graduate is prepared for practice [24]. At each stage of training during residency, specific competencies are targeted and measured by EPAs and milestones, with a stepwise increase in ability seen from novice to expert (Dreyfus model of skills acquisition), and instructional scaffolding (Zone of proximal development theory) from modeling to ability to teach and supervise others [13, 21, 25-27]. These terms will all be defined in the first two manuscripts.

3. Simulation-based Education (SBE)

Simulation is a representation of a real-world task, “a technique that creates a situation or environment to allow persons to experience a representation of a real event for the purpose of

practice, learning, evaluation, testing, or to gain understanding of systems or human actions” [28, 29]. It represents one of the many tools in the educational tool box and is a complimentary approach to the apprenticeship model, especially considering the decreasing clinical exposure seen in residency. Simulation should be considered an adjunct to traditional clinical learning in the workplace. SBE in medicine is defined as “the use of a number of modalities to re-create some component of the clinical encounter for the purposes of training or assessment” [30]. It is gaining increased credibility as a learning tool and is becoming integrated into many teaching curricula in addition to ward-based and traditional didactic lectures [31, 32]. SBE offers the opportunity for learning and practicing in a safe and controlled environment, without putting patient’s safety at risk [13, 16].

Going back to the learning pyramid, we know that there is higher retention rates (75%) when one “practices doing” something in a “hands-on” way [6, 20]. SBE can thus complement clinical teaching and may even accelerate achievement of expert performance or mastery when looking at the learning curve [27, 33, 34]. According to the “Dreyfus Model of Skill Acquisition”, there is a certain amount of scaffolding that takes place from novice to expert learner. Mastery requires many years of *deliberate practice*, a concept originally observed in musicians and described by Ericsson. Expert-level performance is due to expert-level practice, not simply a result of innate talent [13, 33-36]. According to Ericsson, there are four essential components of deliberate practice: the task must be intentional with goal to improve performance, built around pre-existing knowledge and skill level, have immediate feedback and be repeatedly performed [35]. Medical education has begun to apply the concept of deliberate practice for the acquisition of medical knowledge and skills [37]; SBE can allow for deliberate practice to occur in a controlled and safe environment [32].

When looking back at the history of simulation, obstetric simulators seem to be among the earliest examples. They have been around since the 9th century, as small wax or wooden figures and in the 1600s and 1700s, these simulators, known then as “phantoms”, were used to teach midwives normal and abnormal childbirth. [38] We’ve come a long way since these antiquated models. Simulation now includes a range of interventions that can be individual, team-based, and even multidisciplinary/interprofessional. These interventions typically include simulators such as mannequins and/or standardized patients, part task trainer, and computer or virtual reality technology. They can be simple or more complex such as theatre-based and team-based. Moreover, they can take place in a variety of different learning environments, either in dedicated simulation centers or in situ, within the actual clinical workplace. [29, 38]

There are numerous studies illustrating that learners enjoy SBE and that learning does take place in this setting. However, the burning question remains whether learning in the simulation setting transfers to learning and behavioral changes in the workplace and whether these changes actually affect patient outcomes. Kirkpatrick’s pyramid outlines four increasing levels of impact for the evaluation of training programs [29, 39, 40]:

- Level 1: change in reaction in the learner
- Level 2: learning in the simulated setting
- Level 3: transfer of learning to the workplace
- Level 4: impact of learning on patient outcomes

Level 4 represents the highest level of evidence when it comes to research outcomes for SBE, as it represents learning linked directly to patient outcomes. The third manuscript describes and illustrates this principle as it applies to OBGYN.

4. Assessment of Clinical Competence

Frequent assessment of competence is a critical component of CBME as there needs to be a way to ensure that competencies are acquired at all stages of training [21, 32]. Instruction and assessment are intimately linked. Miller's pyramid [41] is an outcome framework, useful for interpreting different levels of assessment and achievement of competencies in medical education. The first two levels "knows" and "knows how", measure basic knowledge and understanding of this knowledge. The third and fourth levels, "shows how" and "does, on the other hand, measure performance, either 'in vitro' such as in simulations, or 'in vivo' in the real clinical setting [29, 41]. These represent the highest levels of assessment. A recent systematic review [42] also showed evidence that simulation-based assessments (SBA) with good validity evidence often correlate positively with workplace assessments and patient outcomes thus simulation can be used as a surrogate for 'in vivo' assessment at the "does" level. Different methods of assessment should be used to assess learning across competencies from "knows" to "does". Not only is simulation a useful teaching method, but it also represents one of the various options in the assessment tool box and is particularly alluring in medical education since it can engage learners in realistic scenarios mimicking clinical situations and can help measure what learners "can do" rather than simply "what they know" [29]. SBA can be used both formatively, allowing for opportunities for feedback, coaching, debriefing, and deliberate practice, and increasingly they are being used summatively [29]. From a patient safety perspective, SBA can help ensure that learners are competent before working with real patients [29]. We are beginning to see the integration of simulation curricula into residency training programs. In Canada, the specialty of anesthesiology was the first to develop and implement the Canadian National Anesthesiology Simulation Curriculum (CanNASC) [32]. As such, trainees must satisfactorily complete a set of standardized

simulation scenarios throughout their training prior to certification. A similar project to incorporate SBA on a national scale is underway for the specialty of OBGYN [43, 44].

Objective of Thesis

I will start by identifying differences in current OBGYN training programs with a narrative review comparing curricula from five countries around the world, including Canada. (Manuscript 1) Note that since the publication of the manuscript, as of July 1st, 2019, the Royal College of Physicians and Surgeons of Canada (RCPSC) has implemented “Competence by Design” for OBGYN residency program. Next, via a Delphi survey (Manuscript 2), OBGYN specific EPAs were defined, including their importance for simulation. This study was done prior to the publication of the RCPSC’s EPAs for OBGYN. Finally, the current role of simulation as it pertains to OBGYN will be elaborated in a systematic review on the subject (Manuscript 3).

Ultimately, the objective of this thesis project is to help define a competency-based simulation training curriculum for obstetrics and gynecology (OBGYN) residents. Modifications to the current OBGYN curricula, including a standardized national simulation curriculum, may potentially increase the quality and efficiency of training, which could have a direct impact on patient safety and quality of care.

Section 2: Manuscripts

Manuscript 1

Competency-Based Medical Education and Assessment of Training: Review of Selected National Obstetrics and Gynecology Curricula

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**Competency-Based Medical Education and Assessment of Training: Review of Selected
National Obstetrics and Gynecology Curricula**

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ABSTRACT

There are global variations in obstetrics and gynaecology (OBGYN) training curricula, both in length and in their structure and content. The ultimate goal for all residency programs is to ensure a skilled, competent physician, capable of independent practice by the end of their training. An online search was employed for nationally recognized OBGYN training curricula. The curricula of Australia, Canada, the Netherlands, the United Kingdom, and the United States of America were individually reviewed and evaluated for their use of competency-based medical education, as well as methods of assessment, including simulation. These were also compared to the World Federation for Medical Education's Global Standards for postgraduate medical education.

Comparing the OBGYN curricula of these five countries led to quite similar results. Even though curricula reviewed have or will be integrating competency-based medical education into their residency program, there is a need to develop adequate assessment tools, including simulation, in order to train competent physicians capable of independent practice. Standardization of curricula leads to a decrease in the variability and an increase in the quality of training, as well as allowing for measurements and comparisons across centres. Ultimately, modifications to the curricula or even consensus for an international standard, including a standardized national simulation curriculum, may potentially increase the quality and efficiency of training, which could have a direct impact on patient safety and quality of care.

Key Words : curriculum, obstetrics, gynecology, simulation, medical education, competency-based education

INTRODUCTION

There are variations in the training of obstetricians and gynecologists worldwide. One of those differences is in the length of training, from four to seven years depending on the country reviewed. Despite these variations, the end goal of residency training remains the same: a physician capable of safe, independent practice in their area of specialization. A study comparing competence of surgeons trained in North America and Europe, where working hours and length of training differ, failed to show a difference in technical skill and cognitive knowledge at the beginning of practice.[1] Thus, despite shorter training in some countries, the end product seems to be equivalent. There is also evidence that patient outcomes, notably major complications, may be associated to the quality of training received. [2] Accordingly, providing high-quality health care by providing high-quality residency training, will lead to improvement of patient safety and quality care. The medical education system has remained relatively unchanged over the past 100 years, despite important changes in healthcare.[3] This is the reason why in recent years, we are seeing a shift from the more traditional Halstedian apprenticeship model of residency training (“see one, do one, teach one”) to the more contemporary model that is competency-based medical education (CBME).

CBME is gaining popularity worldwide as a novel approach to educate and assess junior physicians.[4-6] It is “an outcomes-based approach to the design, implementation, assessment, and evaluation of a medical education program using an organizing framework of competencies”[7]. The aim of CBME is to regularly assess performance outcomes as opposed to the traditional “time-based” model. It is a way of ensuring that physicians possess the knowledge, skills, and attitudes required for every stage in their career. The goal of a CBME program is to determine which competencies and assessment tools a resident needs at different stages of their residency in order

to ultimately meet patient's needs for that specific area of medicine. The idea is that there will be stages of training and at each stage and for each rotation, there will be a focus on specific acquisition of identified competencies, which will be measured by entrustable professional activities (EPAs) [8] and milestones. For each domain of competence, there is a corresponding spectrum of ability from novice to master, as described by Dreyfus and Dreyfus [9].

Competencies are defined as “sets of general qualities that every medical specialist should acquire” or more generally “the ability to do something successfully”. [8, 10] The Dutch further define competencies as “the synthesis of knowledge, skills and attitudes that are reflected in professional activities”. [11] As an example, the CanMEDS Medical Expert Role is a competency that involves “the ability to apply medical knowledge, clinical skills, and professional attitudes in the provision of patient-centred care”. [12] In 2009, the International CBME collaborators defined a ‘competent’ physician as possessing the required abilities in all domains in a certain context at a defined stage of medical education or practice. [13] Thus competence is a dynamic construct that develops or recedes over time depending on the environment. The concept of “entrustable professional activity” (EPA) was introduced by ten Cate & Scheele in 2007 in order to “bridge the gap between competency-driven education and clinical practice” because in clinical practice, “competencies are intertwined in complex ways that make them less explicit and measurable”. [8, 14] An EPA is a specific task or activity that can be ‘entrusted’ to a person once sufficient competence has been achieved. They represent the day to day work of the professional, being executable, observable, and measurable entities and can be the focus of assessment.[10] A milestone is defined as “an observable marker of an individual’s ability”. [7] Milestones are usually specialty-specific and characterize expectations for residents at various stages of their training for a particular competency.[15]

For example, “Performance of assisted -delivery including caesarean section” would be one of many milestones in a larger EPA, “Complicated Childbirth”. (Refer to Table 1 for a detailed example of an EPA, outlining its competencies and milestones.) In sum, competencies have been defined as descriptors of physicians, whereas EPAs are descriptors of work.[10] Typically each EPA integrates multiple competencies and milestones. [7, 8, 10] For residents, this means a more personalized and targeted medical experience, focused on their particular learning abilities and personal development, allowing for individual learning curves. As such, some residents will be able to advance more quickly than others compared to the current traditional model.

Medical and surgical simulation is also gaining popularity in the medical field as a means of complementing the more traditional patient experiences. It allows the opportunity to improve skills and do ‘the real thing’ in a safe learning environment. [16, 17] However, its integration into the medical curriculum is still in its infancy. Simulation training will be an important and valuable tool in the assessment of residents in the CBD program, allowing direct observation of many technical and non-technical skills.

A number of different competency frameworks for physicians have been developed and integrated into the obstetrics and gynecology (OBGYN) curricula worldwide. Notably, the General Medical Council’s (GMC) Good Medical Practice (GMP) Domains used in the United Kingdom, the Accreditation Council for Graduate Medical Education (ACGME) competencies in the United States of America (USA), and the Canadian Medical Education Directives for Specialists (CanMEDS) in Canada. The Netherlands curriculum is based on the CanMEDS, and Australia was influenced by all three frameworks. All of these will be described in further detail in the descriptions of the individual curricula.

The objective of this narrative review is to compare OBGYN curricula from five countries around the world and to identify variation, especially in the context of CBME and assessment of training, including the use of simulation. This can provide valuable information on ways to improve curricula in order to deliver high-quality training for better and safer patient care.

METHODS

An online electronic search was conducted for nationally recognized OBGYN curricula. This search yielded curricula from Australia, Canada, the Netherlands, the United Kingdom, and the United States of America from the websites of their respective national medical colleges. The structure of each of the curricula were initially reviewed qualitatively and then compared to a worldwide standard for postgraduate medical education, the World Federation for Medical Education's (WFME) "Postgraduate Medical Education WFME Global Standards for Quality Improvement." [18] This consists of a total of 9 areas of standards with 36 sub-areas. There are two general types of standards described: basic standards that must be met and standards for quality development which should be met, but are not an absolute requirement. Since this review's main focus is on competency-based medical education and assessment of training in OBGYN, only the first three areas and basic standards were evaluated and compared against the selected national curricula. These areas are:

- 1) Mission and Outcomes
- 2) Educational Programme
- 3) Assessment of trainees

Each curriculum was assessed and compared to each standard and given a rating based on how well the specific standard was met:

- Meets the standards

- Meets the majority of the description of the standards
- Meets some of the description of the standard
- Does not meet the standard or information not available (not stated)

More than 50% of the subdivisions of a specific standard needed to be met in order to qualify for “meets the majority of the description of the standards”.

The results are presented in two sections. The first is a general initial overview of each of the curricula. This is followed by a comparison against the WFME’s standards. Each curriculum was also evaluated for their use of competency-based medical education as well as methods of assessment, including simulation training.

RESULTS

One of the major variations noted in the curricula reviewed was in the length of training. While the program is 4 years in the United States, it is 5 years in Canada, and even longer in the Netherlands (6 years), Australia (6 years), and the United Kingdom (7 years). Some countries also have an additional 1-2 years of foundation training prior to the formal OBGYN training program. (Refer to Table 2)

Australian OBGYN Curriculum

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) are the programme providers in Australia and New Zealand. The RANZCOG training regulations handbook[19] provides a comprehensive overview of the structured six-year training program. The first four years are considered Core Training, while the remaining two years are Advanced Training. The curriculum is greatly influenced by the CanMEDS roles, as well as the six areas of competence defined by the ACGME, and the International Guidelines developed by the WFME.

The curriculum[20] is based on CBME and is framed around three key competencies considered essential characteristics for the specialist. These key competencies are:

1. Clinical Expertise
2. Academic Abilities, and
3. Professional Qualities.

They use a table format to state the main learning outcomes in general terms and link them all to the above general competencies. However, there are no described benchmarks for the different objectives, except for certain procedural skills, some of which are required to be performed by year two or four either with minimal or significant input. A list of procedural and surgical skills is provided to the trainee, along with the recommended minimum amount. In-hospital training is supplemented by the College's eLearning program, which contains self-directed modules that cover all areas of the curriculum. Attributes are progressively acquired during the training program as the trainee becomes more competent and confident and progresses from “novice” to “proficient” across and within the three domains considered essential for effective practice. Remediation through a learning development plan (LDP) is clearly outlined for the ‘below expectation’ trainee.

The handbook also provides the trainee with a structured assessment program. Assessments include a high-stakes mandatory specialist written and oral exam to become certified as a member of the RANZCOG (MRANZCOG exams) which are to be completed by the end of the 4th year of training. There are workplace-based assessments for diagnostic ultrasound and colposcopy. Maintaining a logbook is also mandatory and must be submitted to the College. It allows keeping a personal record of all required procedural and other training experiences and aids to see if competency levels are achieved. Completion of a research project is necessary and there are also

a number of courses that a trainee must complete. Self-assessment, multisource feedback, and logbook are reviewed and signed by the Training Supervisor during the formative three-monthly and summative six monthly assessments. The use of simulation for both training and assessment is not mentioned in the handbook. In fact, a recent survey concluded that the addition of simulation to the RANZCOG curriculum would benefit trainees. [21]

Canadian OBGYN Curriculum

The Royal College of Physicians and Surgeons of Canada (RCPSC) oversees medical education in Canada. They put forth the “Specialty Training Requirements in Obstetrics and Gynecology”[22], which outlines the five-year training program. The program is further divided into Junior Resident and Senior Resident roles. Specifically, this document mandates the minimum and maximum number of rotations required in different disciplines within and outside the department.

The curriculum is framed around seven key competencies, named CanMEDS roles, considered essential characteristics for the specialist that lead to optimal health and health care outcomes. These key competencies are:

1. Medical Expert, which holds a central role
2. Communicator
3. Collaborator
4. Leader
5. Health Advocate
6. Scholar, and
7. Professional

The “Objectives of Training in the Specialty of Obstetrics and Gynecology”[12] lists different milestones to be achieved, framed within the 7 CanMEDS competencies above. A description of each of these roles can be found in the “CanMEDS 2015 Physician Competency Framework” document. [23]

No detailed methods of assessments for these competencies and milestones are named within the curriculum, except for the general requirement to demonstrate all of these attitudes and skills as well as to pass the final high-stakes specialty written and oral examinations prior to graduating from the training program. This will change in the near future, as a new CBME project is underway, called “Competence by Design” or CBD [7]. Some of the individual OBGYN programs throughout Canada have already started to integrate CBME into their specific objectives of training. [14] Moreover, simulation is mentioned for the training and assessment of residents in two Canadian programs as well. [24, 25]

Dutch OBGYN Curriculum

The NVOG (Dutch Society of Obstetrics and Gynecology) are the national programme providers in the Netherlands. CBME was initiated in the Netherlands in 2004. The Dutch National Competency Based Curriculum for Obstetrics and Gynaecology, called BOEG (Better Education for Obstetrics and Gynecology) is outlined in detail.[11] It is a five to six year training program with three phases of about two years each. The total duration varies depending on competencies already acquired before beginning their training and on personal learning curves. The three phases of training are:

1. Basic (Novice)
2. Intensification (Intermediate)
3. Consolidations and sub-specialization (Junior specialist)

Their curriculum is based on the fact that one practitioner cannot deliver high quality care in all aspects of OBGYN. Thus, the focus is to be able to train competent general OBGYNs who share common basic skills but have specific areas of differentiation, depending on their area of interest. BOEG enhances patient safety by ensuring that residents demonstrate that they possess appropriate skills for level of training by a system of structured certification of competencies. The Competency Profiles outlined in BOEG are based on the same 7 CanMEDS competencies used in Canada. These competencies were translated into themes that constitute a limited number of broad EPAs. The activities or interventions that are contained within each theme are ‘nested EPAs’ or milestones. The program consists of 28 themes or EPAs (15 basic and 13 subspecialty). For each EPA there is a gradient of competency or competency level:

- Level 1: Has knowledge of (observation of modelled behavior)
- Level 2: Performs with full supervision
- Level 3: Performs with limited supervision
- Level 4: Performs without supervision
- Level 5: Able to supervise others and teach them

For each of these EPAs, they also list the minimum number of target experiences required, including a list of 16 surgical procedures with an overall number and how many should be done at level 4. For example, for the EPA “Complicated Childbirth”, it is expected that by the end of their 4th year, residents will have done at least 50 cesarean sections (of which 10 at level 4), 30 vacuum extractions (of which 20 at level 4), 15 manual placental removals (of which 5 at level 4), and 15 repairs of 3rd/4th degree tears.

Residents are awarded a *statement of awarded responsibility* (STAR) when they pass a given EPA. Overall assessment is based on an electronic portfolio centered on in-training

assessment of EPAs with STARs. A STAR is requested by the resident through the portfolio, when he/she feels sufficiently competent and provides justification for the request. The program director must then approve it. There are certain competencies that residents at a given stage of training should have attained, demonstrated by adequately performing specific activities/EPAs. (See Table 3). The vast majority of learning activities are still workplace-based with a small part of training that most often consists of theoretical courses. Assessments include a number of in-training assessments, research, mandatory courses, and an annual knowledge exam (progress test). Simulation is also mentioned as a means for evaluation, without providing more details. Of note, it is the low-stakes formative assessments and learner self-reflection that are pivotal to progression within the training program and not the summative annual national examination. [14] There is a system in place to help identify the poorly-performing resident, involving remediation through intensive coaching and guidance by the program director that makes an “adjusted plan”.

British OBGYN Curriculum

The Royal College of Obstetricians and Gynaecologists (RCOG) is the programme provider in the UK along with the GMC. Both their ‘Training Matrix’ and ‘Trainees' Guide to the O&G Curriculum and Specialty Training’ outline the seven year core residency training.[26, 27] There are three phases of specialty training (ST): Basic Training (ST1-2), Intermediate Training (ST3-5), and Advanced Training (ST6-7).

The curriculum is competency-based, and centered around the four GMC GMP domains, a generic competency framework:

1. Knowledge, Skills and Performance
2. Safety and Quality
3. Communication, Partnership and Teamwork

4. Maintaining Trust

The core curriculum comprises 19 modules (or EPAs) and two basic ultrasound modules. Each module lists knowledge criteria, clinical competencies (milestones), professional skills and attitudes, training support, and assessment or evidence as well as the associated GMP domains (generic competencies). Competencies need to be attained at a defined level to progress through the curriculum, ranging from level 1 to 3.[28]

- **Level 1 ('Observation')**: demonstrates detailed knowledge and understanding and is aware of common complications/issues relating to the competence/clinical skill/situation
- Level 2 ('direct supervision')**: capable of performing the task or managing the clinical problem but with senior support
- Level 3 ('independent practice')**: can manage the majority of cases with no direct supervision or assistance, while having the insight to recognize that senior support will be needed in certain complex cases/complications.

These competencies are signed off in an electronic logbook based on different means of assessment. The handbook provides the trainee with a detailed review of the structured assessment program. Assessments consist of a number of work-based assessments, including Mini Clinical Examination Exercise (Mini-CEX), Objective Structured Assessment of Technical Skills (OSATS), Case-based discussions (CbD), Advanced Training Skills Modules (ATSMs), and Other methodologies (Oms) such as simulation and drills. There is also an annual research project, mandatory courses, and eLearning modules to be completed. A high-stakes mandatory specialist written and oral exam to become certified as a member of the RCOG (MRCOG exams) are to be completed by the end of the 2nd and 6th year of training.

American OBGYN Curriculum

The American College of Obstetricians and Gynecologists [29], along with ACGME, and the American Board of Obstetrics and Gynecology (ABOG), are the programme providers in the United States. The four-year OBGYN training program is outlined in detail in the educational objectives and core curriculum.[30] There are a total of six learning objectives, each of which are composed of many sub-categories and linked to the six ACGME general competencies:

1. Patient Care (PC)
2. Medical Knowledge (MMK)
3. Interpersonal and Communication Skills (ICS)
4. Professionalism (P)
5. Practice-Based Learning and Improvement (PBLI)
6. System-Based Practice (SBP)

A number of procedures and skills are listed for each of the learning objectives that a resident must either understand or understand and perform. With the arrival of the ‘Next Accreditation System’ (NAS), and the Milestone Project, which began in 2013, we saw the introduction of sub-competencies and milestones, arranged in five levels of observed behaviour from novice to expert based on Dreyfus and Dreyfus’ model [9], where level 4 is the target for graduation. There are presently 29 OBGYN sub-competencies. [31]

- **Level 1 (Novice)**: The resident demonstrated milestones expected of an incoming resident
- **Level 2 (Advanced Beginner)**: The resident is advancing and demonstrates additional milestones, but is not yet performing at a mid-residency level
- **Level 3 (Competent)**: The resident continues to advance and demonstrates additional milestones, consistently including the majority of milestones targeted for residency

- **Level 4 (Proficient)**: The resident has advanced so that he or she now substantially demonstrates the milestones targeted for residency.
- **Level 5 (Expert)**: The resident has advanced beyond performance targets set for residency and is demonstrating “aspirational” goals which might describe the performance of someone who has been in practice for several years. It is expected that only a few exceptional residents will reach this level.

At the moment, the assessment of residents is parallel to Canada, with the general requirement to demonstrate all of the listed attitudes and skills as well as to pass the final high-stakes ABOG specialty written and oral examinations prior to graduating from the training program. However, with this new milestone project, all programs have begun to report milestones data as part of the NAS; thus, this will most likely become part of the assessment process in the near future. Certain specialties have already introduced various new ways of assessment similar to the UK, Netherlands, and Australia, including workplace-based assessments. It is not clear, in the US OBGYN curriculum, which of these assessment tools are being used because they only provide a general guide. Although the role of simulation in their curriculum is unclear, the ACOG has a Simulations Working Group that has published a toolkit for those who want to use and integrate simulation into their curriculum. [29] However, there is currently no national standard.

Comparison with WFME Global Standards for Postgraduate Medical Education

The World Federation for Medical Education (WFME) is the international body that represents all medical teaching institutions, medical teachers, students, and medical doctors in all aspects of their education. The main goal of medical education is the improved health of all people through provision of high quality health care. Thus, the WFME stands to promote the highest

scientific and ethical standards in medical education as well as encouraging the development of learning methods, new instructional tools, and innovation.

They published the first *Global Standards for Quality Improvement of Medical Education* in 2003, which have recently been revised and republished in 2015. [18] These global standards have been implemented and used extensively all over the world, as they outline a framework for defining institutional, national, and regional standards for basic medical education (BME), postgraduate medical education (PME), and continuing professional development (CBD) in order to help ensure that the competencies of medical doctors are globally applicable and transferable.

PME is the phase of medical education in which doctors develop competencies under supervision after completion of their basic medical training. It has stemmed from an apprenticeship model that ends with the attainment of specialist qualifications entitling the young doctor to undertake unsupervised practice. The organisation of PME programmes varies considerably from country to country, sometimes even varying within a same country, from highly sophisticated learning programmes to more traditional based almost entirely on practical clinical training under supervision. The WFME guidelines for medical education may help provide an international convergence for PME.

There are a total of 9 areas of standards with 36 sub-areas outlined in the WFME global standards (see Supplementary Material S1). There are two general types of standards described: basic standards that must be met and standards for quality development which should be met, but are not an absolute requirement. Since this review focuses on competency-based medical education and assessment of training in Obstetrics and Gynecology, only the first three areas and basic standards will be evaluated and compared against the selected national curricula. These areas are:

- 1) Mission and Outcomes

2) Educational Programme, and

3) Assessment of trainees

Each curriculum was assessed and compared to each standard above and given a rating based on how well the specific standard was met or described. Refer to the Table 4 for an illustration of this comparison.

Mission and Outcomes

All curricula met the description of standards in this area.

Educational Programme

As part of the framework of postgraduate medical education programs, instructional and learning methods used to integrate practical and theoretical components must be outlined and there must be supervision and regular appraisal and feedback. Canada and USA curricula fail to mention whether or not they do so. Also, none of the curricula mention whether they ensure that training is complementary to and integrated with service demands.

Assessment of trainees

This is the weakest area for all curricula. Australia, the Netherlands, and the UK have detailed descriptions of a variety of different assessment methods (as outlined in respective sections), however none specify the exact passing criteria, including number of retakes allowed. They do outline in depth the feedback timing and methods. Canada and the USA are lagging behind with respect to the incorporation of new assessment methods and use of a training log-book to record training. This may change in the coming years as Canada implements the CBD model and the USA continues to develop the milestones project. There is also no mention in their curricula description of the feedback of residents.

DISCUSSION

This review of OBGYN curricula highlights the global variation between residency training programs, most notably in their length of training as well as their means of assessment within a competency-based approach. When taking into account foundation years after medical school, postgraduate OBGYN training is completed in 5 years in Canada and the United States, whereas it takes a minimum of 9 years in the United Kingdom. Despite this variability in duration of training, the ultimate goal remains the same: to yield competent physicians capable of working independently at the end of their training. The purpose of using the WFME standards was to objectively compare OBGYN curricula in order to identify potential areas of improvement and not to create an overall ranking. The comparison yielded very similar results. All five curricula reviewed see a great need for CBME in the training of OBGYN residents. With the exception of Canada, all countries have already started to implement in depth a CBME-based OBGYN curriculum. This is expected to occur in Canada for OBGYN by 2019, as part of a multi-year plan to roll-out Competence by Design (CBD) [7].

Within medicine, CBME has been proposed for over 50 years, but it is only in the last 15 years that it has really begun to be the center of an ongoing debate to reform medical education. It is an educational approach that has the potential to transform how we prepare physicians of today, in order to better align with each specialty of medicine and the needs of society.[14] The rationale for CBME, summarized by Frank et al. in 2010, includes a curriculum that focuses on the learners, that underlines outcomes, ensuring that all graduates are competent, consequently emphasizing on their acquired abilities, skills, and attitudes, rather than solely focusing on time and knowledge [13]. Thus, with outcomes in minds, abilities and competencies that each graduate needs are defined and developed into milestones and EPAs. Ideally EPAs are developed for each stage of

residency, which will allow for the assessment of specific competencies for OBGYN residents, depending on their level of training. This will enable us to go from an opportunistic learning method, to a more structured type of learning.

Some important challenges of CBME include the threat of reductionism or becoming too granular with endless nested lists of abilities if competencies are broken down into the smallest observable units of behaviour [13]. A CBME approach also requires a certain degree of flexibility for the learner. This will also be challenging as the current system is quite inflexible with respect to service needs [14]. There needs to be a balance between training and service. The clinical environment must therefore be aligned with the intended curriculum of the CBME program, prioritizing the training of learners. Importantly, residents will also need to become more active participants in their own learning. Training programs need to cultivate a safe, well-supervised educational environment including multiple opportunities for assessment and timely feedback, essential to both CBME and patient safety.[14]

Another important factor is faculty buy-in and the need for faculty development especially in the area of assessment. [15] There is a great need for faculty development when it comes to CBME, as assessment tools will change drastically from the current system: new instructional methods and assessment tools are needed to facilitate acquisition of these competencies by learners and their subsequent entrustment. The faculty will need to make competency-based decisions on the level of supervision required by trainees, as they are ultimately making entrustment decisions for unsupervised practice.[10, 32] More frequent assessments and specific feedback from supervisors will be required to ensure that each learner meets specific EPAs in order to advance to the next stage in their residency. The idea is that continuous assessment drives and promotes learning. [7] This will require a huge investment of time to provide capable faculty assessors. Tools need to be

clear and easily understood and educational time will have to be built into clinical encounters. The curricula reviewed vary in their description of assessment of residents. The Australian, Dutch, and UK curricula all have detailed descriptions of their various assessment tools, both formative and summative, with the UK curriculum and modules being the most comprehensive reviewed because they include a means to document EPAs. The Netherlands is the only curriculum that does not have a high-stakes final certification examination. This may change in the upcoming years if a pan-European consensus for OBGYN training is achieved, as described in Project for Achieving Consensus in Training (PACT). [33]

Alternative training settings such as workshops, short courses and eLearning modules are being introduced because the breadth of knowledge that a physician must acquire can no longer be managed totally by hospital experiences.[20] Assessment of clinical competence can be done in a variety of ways based on four levels, as shown in Miller's pyramid.[34] The lower cognitive levels "knows" and "knows how", can be assessed by the classical high-stakes written and oral exams. However, knowledge does not necessarily transfer into competence and is just one of the many facets that need to be assessed. The higher behavioural levels of Miller's pyramid, "Shows how" and "Does", is where we need to concentrate our efforts. Means of assessment at this level include the Objective Structure Clinical Examination (OSCE), the Objective Structured Assessment of Technical Skills (OSATS), standardized patients, and simulation. The highest level includes workplace-based assessments (ex: Mini-clinical evaluation exercise (Mini-CEX), Direct Observation of Procedural Skills (DOPS), Cased based discussions (CbDs)), portfolios, logbooks, peer evaluation, and 360° feedback. Although simulation may test at a lower level of Miller's pyramid, it may give us an outlet to do work- based assessment, since this is challenging and difficult to implement in the clinical environment of day-to-day practice.

Medical and surgical simulation will become an important and valuable tool in the training and assessment of residents in the CBD program, allowing direct observation of many technical and non-technical skills. Simulation has been defined as “a technique that creates a situation or environment to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain understanding of systems or human actions.” [35] There is growing evidence that the skills learnt in simulated scenarios translate into improvements in real-life performance. [36-41] Although few studies have shown a direct impact on patient outcome, simulation-based training leads to improved clinical performance, as well as improving knowledge and comfort in procedures. It has also been shown to improve teamwork and communication.[42]. A recent survey in the Journal of Obstetrics and Gynaecology of Canada showed that although simulation training has increased in the Canadian residency training programs, there is a great need for a standardized and valid national simulation curriculum which would facilitate the integration of CBME. [41] This should be the focus of future studies.

CONCLUSION

This review highlights general variations in OBGYN training programs across the globe. There are variations in the training curricula, both in length and in structure/content, particularly when it comes to assessment. Even though all curricula reviewed have or will be integrating competency-based medical education into their training program, there is still a great need to develop a variety of adequate assessment tools, including simulation, in order to ultimately train competent physicians, capable of unsupervised practice. Ultimately, modifications to the curricula or even consensus for an international standard, including a standardized national simulation curriculum, may potentially increase the quality and efficiency of training, which could have a direct impact on patient safety and quality of care.

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- 1) **Dr. Milena Garofalo:** primary role in the review, data analysis, and manuscript writing.
- 2) **Dr. Rajesh Aggarwal:** research supervisor whose role was to guide, and help with the editing of the manuscript

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TABLES

Table 1: Example of EPA, Milestones, and Competencies in Obstetrics and Gynecology- Adapted from the Dutch curriculum [11]

EPA/Theme: Complicated Childbirth	
COMPETENCIES	MILESTONES
Medical Expert	<ul style="list-style-type: none"> • Diagnose obstetrical complications and summarize complex cases. • Discuss consequences for next pregnancy. • Provide pharmacological therapy for haemorrhage. • Performance of assisted -delivery including caesarean section. • Treat bleeding, shoulder dystocia and uterine inversion. • Repair 3rd and 4th degree lacerations and cervical lacerations.
Communicator	<ul style="list-style-type: none"> • Provide patient –specific information to patient (and partner) about diagnosis, management and patient organizations that may be of use. • Inform stakeholders (obstetrical team, obstetrician, general practitioner). • Delivery of bad news and grief counseling.
Scholar	<ul style="list-style-type: none"> • Applies evidence-based medicine in the practice. • Educates team members
Collaborator	<ul style="list-style-type: none"> • Practices teamwork and takes appropriate control in acute situations. • Ensures a suitable role distribution between residents, gynecologist and differentiated gynecologist and other participants in the care network
Manager	<ul style="list-style-type: none"> • Triage and deal with primary, secondary and tertiary care institutions. • Management of multiple delivery rooms. • Organize the aftercare process.
Health Advocate	<ul style="list-style-type: none"> • Counsel patient on preventative measure for next pregnancy if applicable.
Professional	<ul style="list-style-type: none"> • Support the patient and family during this life event. • Reflect on own management and experiences of events.

Table 2: Postgraduate OBGYN training pathway

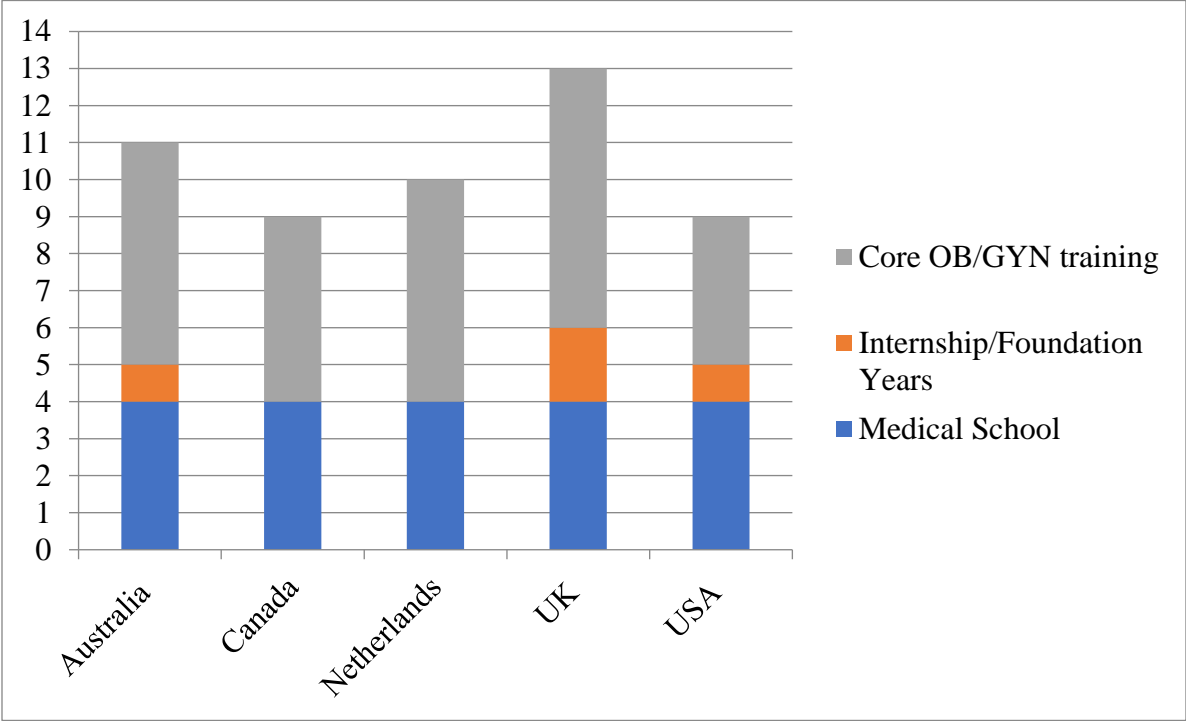


Table 3: Competency levels expected at different stages of training in the Dutch curriculum for the 15 basic EPAs[11]

Benchmarks for attaining levels of competency (levels 1-5) throughout training	Benchmark I Year 2	Benchmark II Year 4
Uncomplicated Antenatal care	5	
Complicated Antenatal Care	3	4
Intrapartum care	5	
Complicated Childbirth	3	4
Basic High Risk Childbirth	3	3
Uncomplicated Postpartum & Newborn Care	5	
Complicated Postpartum & Newborn Care	3	4
Basic Reproductive Medicine	2	4
Benign Outpatient Gynecology	3	4
Basic Surgery	3	4
Basic Urogynecology & Pelvic floor	2	4
Sexual Health	3	4
Basic Oncology	2	4
Peri – operative care	3	4
Vulnerable elderly	3	4

Table 4: Comparison of OBGYN Curricula against WFME standards

WFME Standards		Australia	Canada	Netherlands	UK	USA
Mission and Outcomes	Overall mission of the programme					
	Professionalism and professional autonomy					
	Educational outcomes					
	Participation in formulation of mission and outcomes					
Educational Programme	Framework of the PME Programme					
	Scientific Method					
	Programme Content					
	Programme Structure, Composition and Duration					
	Organisation of Education					
	The Relation Between PME and Service					
Assessment of trainees	Assessment Methods					
	Relation Between Assessment and Learning					

Key

	Meets description of standards
	Meets majority of description of standards (>50%)
	Meets some of the description of standards (<50%)



Either not stated or does not meet the description of standards

PME: postgraduate medical education

SUPPLEMENTARY MATERIAL

Supplementary Material S1: Summary of WFME Global Standards for Postgraduate Medical Education [18]

1. Mission and Outcomes	Mission
	Professionalism and Professional Autonomy
	Educational Outcomes
	Participation in Formulation of Mission and Outcomes
2. Educational Programme	Framework of the PME Programme
	Scientific Method
	Programme Content
	Programme Structure, Composition and Duration
	Organisation of Education
	The Relation Between PME and Service
3. Assessment of Trainees	Assessment Methods
	Relation Between Assessment and Learning
4. Trainees	Admission Policy and Selection
	Number of Trainees
	Trainee Counselling and Support
	Trainee Representation
	Working Conditions

5. Trainers	Recruitment and Selection Process
	Trainer Obligations and Trainer Development
6. Educational Resources	Physical Facilities
	Learning Settings
	Information Technology
	Clinical Teams
	Medical Research and Scholarship
	Educational Expertise
	Learning in Alternative Settings
7. Programme Evaluation	Mechanisms for Programme Monitoring and Evaluation
	Trainer and Trainee Feedback
	Performance of Qualified Doctors
	Involvement of Stakeholders
	Approval of Educational Programmes
8. Governance and Administration	Governance
	Academic Leadership
	Educational Budget and Resource Allocation
	Administration and Management
	Requirements and Regulations
9. Continuous Renewal	

Manuscript 2

OBGYN Modified Delphi Survey for Entrustable Professional Activities: Quantification of Importance, Benchmark Levels, and Roles in Simulation- Based Training and Assessment

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OBGYN Modified Delphi Survey for Entrustable Professional Activities: Quantification of Importance, Benchmark Levels, and Roles in Simulation-Based Training and Assessment

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ABSTRACT

OBJECTIVE Competency-based medical education (CBME) is playing a central role in physicians' training. It focuses on competencies, measured by entrustable professional activities (EPAs). The aim of this survey is threefold: for each EPA (1) quantify the importance for Obstetrics & Gynecology (OBGYN) residency training; (2) set benchmarks; (3) identify the importance of simulation.

METHODS The EPAs were defined based on review of five OBGYN curricula. Two rounds of a modified Delphi via online questionnaire were performed from January to March, 2017. Experts were North American OBGYN program directors. Using a Likert scale, they rated the importance of each EPA for residency training, identified benchmark levels of competence, and roles of simulation. Consensus was defined as $\geq 80\%$ agreement.

RESULTS Item analysis yielded fifteen EPAs. Survey response rate was 17.47% (40 out of 229) for part 1 and 6.55% for part 2 (15 out of 229). All experts rated the importance of each EPA for residency training as “moderately important” or “absolutely essential”. For benchmarking, experts agreed with a stepwise increase in level of competence, dependent residency stage. Two EPAs, “Gynecological Technical Skills & Procedures” and “High Risk Childbirth”, reached consensus (rating 4 or 5) for simulation

CONCLUSION CBME requires EPAs and benchmarks for each residency stage. Simulation will become a valuable tool in this model. However, experts remain neutral about its role, except for technical skills. An OBGYN curriculum based on predefined EPAs, benchmarks, and adequate assessment tools, including simulation, needs to be further explored for CBME to be successful.

Key words: simulation, competency-based education, obstetrics, gynecology, EPA

INTRODUCTION

Competency-based medical education (CBME) is playing a central role in today's training of physicians.[1-4] The concept of CBME is to ensure stages of training, with focus on specific acquisition of competencies, measured by entrustable professional activities (EPAs) and milestones.[5, 6] Competencies are defined as “the synthesis of knowledge, skills and attitudes that are reflected in professional activities”. [7] The concept of EPA was introduced by ten Cate & Scheele in 2007 in order to “bridge the gap between competency-driven education and clinical practice” because “competencies are intertwined in complex ways that make them less explicit and measurable”. [3, 5] An EPA is a specific task or activity that can be ‘entrusted’ to a person once sufficient competence has been achieved. EPAs represent day to day work: they are executable, observable, and measurable entities and can be the focus of assessment.[8] A milestone is defined as “an observable marker of an individual’s ability”. [6, 9] Typically each EPA integrates multiple competencies and milestones.[5, 6, 8, 9]

Based on a review of national Obstetrics & Gynecology (OBGYN) residency curricula from five countries (Australia, Canada, Netherlands, UK, and USA), it was concluded that all curricula have or will be integrating CBME into their training programs.[10] Nonetheless, there is a need to develop adequate training and assessment tools, including simulation, to ultimately deliver competent physicians, capable of unsupervised practice. Although some programs within Canada have already started piloting CBME and EPAs, [11] the national Canadian “Competence By Design” (CBD) program is expected to roll-out officially for OBGYN in 2019.[9]

Assessment of clinical competence can be done in a variety of ways based on four levels, as shown in Miller’s pyramid.[12] The lower cognitive levels “knows” and “knows how”, typically assessed by written and oral exams, do not ensure that knowledge is transferred into competence.

This contrasts with the higher behavioural levels of Miller's pyramid, "Shows how" and "Does", where competence can be demonstrated. Examples include simulation, Objective Structured Clinical Examination and Assessment of Technical Skills (OSCE/OSATS) and workplace-based assessments (WBAs). Simulation may serve as an additional or alternative outlet to WBAs since these remain a challenge in everyday clinical practice. Simulation will thus be a valuable tool in the training and assessment of residents in the CBD program, allowing direct observation of many technical and non-technical skills. It allows the opportunity to improve performance by mimicking reality in a safe learning environment. [13-15]

The aims of this Delphi survey are threefold: first, quantify the importance of each pre-defined EPA with respect to OBGYN residency training, second, set benchmark levels for each EPA, and third, identify the importance of simulation-based training and assessment for each EPA. The ultimate goal is to provide a framework for building a national curriculum based on predefined EPAs and benchmarks levels at each stage of residency training and develop training and assessment tools using simulation. This was based on expert consensus using a modified Delphi consensus method.

METHODS

We defined the individual items (EPAs) used in the survey based on a review of five international OBGYN curricula.[10] This process was undertaken with engagement of a medical educator and an OBGYN clinician. We established that the EPAs defined in the Dutch curriculum would be the framework, since it most closely resembles the Canadian model. [7] We excluded potential EPAs that constituted general characteristics that could be part of the description and milestones for other more specific OBGYN EPAs. (ex: ethical and legal issues, patient safety, communication) We performed two rounds of a modified Delphi survey via online questionnaire

through “Survey Monkey” to (1) rate the importance of each EPA for residency training, (2) rate the importance of simulation-based training and assessment for each EPA and (3) identify benchmark levels of competence, for each specified stage of residency training. Experts in the study were OBGYN residency program directors across Canada and United States, who received an email request to participate in an online questionnaire. Experts were asked to rate the importance of each EPA for residency training based on a Likert scale from 1 to 5:

1. Not at all important
2. Minimal importance
3. Neutral
4. Moderately essential
5. Absolutely essential

They were then asked to rate the importance of simulation-based training and assessment for each EPA, using the same Likert scale. Finally, the last part of the survey set out to identify benchmark levels of competence, for each specified stage of residency training. We defined the stages of residency training using Eraut’s summary of Dreyfus and Dreyfus’ model of skill acquisition [16, 17] and the USA “Milestone Project” levels of observed behavior [18]:

Stage 1: Novice

Stage 2: Advanced Beginner

Stage 3: Competent

Stage 4: Proficient

We can parallel these to the 4 stages of residency in the Canadian CBD continuum: Transition to discipline, Foundations of discipline, Core of discipline, and Transition to practice. [19] We didn’t include the fifth stage of expert/master as it is expected to reach this stage later in one’s career,

during continuing professional development. We defined the levels of competence using the competency levels in the Dutch OBGYN curriculum[7], mapped to the Canadian Model and originally based on the instructional scaffolding theory of the zone of proximal development (ZPD) in educational psychology.[3, 6, 20-22] This theory describes three zones: what a learner can do; what a learner can do with guidance (ZPD); and what a learner can do unaided.

Level 1: Modeling - has knowledge of

Level 2: Scaffolding – performs with full supervision

Level 3: Fading - performs with limited supervision

Level 4: Entrustment - performs without supervision

Level 5: Able to supervise/teach others

We collected and analyzed responses from this panel of experts. We defined consensus as $\geq 80\%$ agreement for a rating of 4 (moderately essential) and 5 (absolutely essential). Two rounds of the Delphi survey took place. In the second round, experts were told the mean responses from the first round. Ethics approval was granted by the Institutional Review Board of the McGill University Faculty of Medicine.

RESULTS

The item analysis based on the review of five international OBGYN curricula yielded a list of 15 EPAs:

1. Uncomplicated Antenatal & Prenatal Care
2. Complicated Antenatal & Prenatal Care
3. Intrapartum Care
4. Childbirth
5. High Risk Childbirth

6. Postpartum & newborn care
7. Benign Gynecology
8. Gynecological Technical Skills & Procedures
9. Pre-operative care
10. Postoperative Care
11. Mature Women's Health
12. Gynecological oncology
13. Urogynecology & Pelvic Floor Problems
14. Pediatric & Adolescent Gynecology
15. Sexual & Reproductive Health

The overall response rates for the survey were 17.47% (40 out of 229) for part 1 and 6.55% for part 2 (15 out of 229). Of those that participated in part 1, 17.5% were Canadian program directors and 82.5% were American, giving a Canadian response rate of 38.89% and an American response rate of 15.64%. In part 2, 20% were Canadian program directors giving response rates of 16.67% and 80.00% were American with response rates of 5.69%. Most experts were from academic or university-affiliated community hospitals. (Figure 1) The majority of experts (84.38% to 100.00%) experts rated the importance of each EPA for residency training as “moderately important” (4) or “absolutely essential” (5) (Table 1A). There was much more variability in the responses when it came to rating the importance for each EPA for simulation-based training and assessment. Only two EPAs had a consensus of $\geq 80\%$ for rating of 4 or 5 for both simulation-based training and assessment: “Gynecological Technical Skills & Procedures” and “High Risk Childbirth”. The following highest rated EPA was “Childbirth” at 71.43-72.41%. (Tables 1B and 1C) Experts remained “neutral” (mean of 3 [Standard Error of the Mean (SEM) 0.17 and 0.15] for

all other EPAs, with regards to their importance in simulation. The last part of our survey set out to determine benchmark levels for each EPA at each stage of residency. At Stage 1, the novice learner is expected to be modelling (level 1) or scaffolding (level 2) (mean 1.47-1.56, SEM 0.07-0.08), with 90.48% to 100.00% consensus. At Stage 2, the advanced beginner is expected to be scaffolding (level 2) or fading (level 3) (mean 2.49-2.50, SEM 0.09), with 91.67% to 100.00% consensus. At Stage 3, the competent learner is expected to be fading (level 3) and be entrusted (level 4) for most EPAs (mean 3.51-3.69, SEM 0.10-0.11), with 83.33% to 100.00% consensus. There were two exceptions in Round 1 where consensus was not met: “Postpartum and newborn care” (77.78%) and “Post-operative care” (77.78%), suggesting that for these EPAs, the learner may reach level 5 at an earlier stage in training. At Stage 4, the proficient learner is expected to be entrusted (level 4) and can supervise and teach others (level 5) for most EPAs (mean 4.39-4.54, SEM 0.09-0.11), with 80.00% to 100.00% consensus. (Table 2, Figure 2)

DISCUSSION

This Delphi consensus determined the importance of OBGYN EPAs with respect to residency training, set benchmarks for each stage of residency, and identified the role of simulation in both training and assessment. First, a task analysis yielded a list of 15 EPAs for OBGYN based on a review of international curricula. Second, this list was virtually presented as a questionnaire to a North American panel of OBGYN residency program directors and validated through consensus. For the benchmarks, the majority of experts agreed that for each EPA there is a stepwise increase in the level of competence depending on the stage of residency. Most of the panel in this study were neutral about the role of simulation in OBGYN, except for the learning of surgical and procedural skills. However, the value of simulation for residency training extends beyond that of purely technical skills. There is a growing body of literature showing its use in team-based training,

communication, and crisis-resource management. [23-26] The EPAs listed in this study may have been too broad for the experts to see the potential. Another survey, outlining more specific milestones may elicit a better response.

In the field of medical education, a Delphi consensus is a common way to determine components of a curriculum, develop assessment tools, and define competencies.[27, 28] One of the main benefits of the online consensus group is that it has the potential to include a large number of participants from different and dispersed locations, improving feasibility. It is also inexpensive, anonymous, and limits the dominance of certain individuals that can disproportionately influence the group, avoiding direct confrontation of the experts.[27] However, this may limit the potential for discussion and debate. [29]

Limitations of the study include low response rates, especially in the second round of the survey (6.55%), which may affect the generalizability of our results. This may in part be due to the online platform via email, which are often ignored. In the future, a similar survey may yield better response rates if sent by a group with authority, such as the Royal College of Physicians and Surgeons of Canada. In addition, the survey would likely be better addressed to simulation or medical education experts, rather than program directors, which may yield a better response rate. Subgroup analysis based on demographics was not possible, given the small numbers, which may have introduced a geographical bias. We had 40 responses in part 1 and 15 responses in part 2. Group size in this setting does not depend on statistical power, but rather on group dynamics. Studies have shown that 10-18 participants in a Delphi study is recommended to reach conclusions and that expertise of the panel may be more important than size. [29, 30] Another limitation is missing data: some experts didn't complete all sections. This was taken into account when calculating the means based on the number of responses for each item and not the total responses.

CONCLUSION

In the last 15 years, there has been a reform in medical education with the integration of CBME for training. This model focuses on the learner and aims to ensure that all trainees graduate as competent physicians in all aspects of their specialty. It emphasizes the acquisition of abilities, skills, and attitudes, rather than focusing solely on time and knowledge[31]. Thus, with outcomes in mind, abilities and competencies that each graduate needs are defined and developed into milestones and EPAs. Simulation will become an important and valuable tool in the training and assessment of residents in the CBD program, allowing for direct observation of skills. With CBD just around the corner, all medical specialties, including OBGYN, will need to devise EPAs for each stage of residency and set benchmark levels for the trainees. These benchmarks will identify learners reaching milestones at varying speeds, allowing to tailor each learner's needs individually as well as to identify those that would need additional help earlier on. An OBGYN national curriculum based on predefined EPAs and benchmark levels, as well as adequate assessment tools, including simulation, needs to be further explored for CBME to be successful. The results of this study can help inform future curricula.

Author's contributions:

- 3) **Dr. Milena Garofalo:** primary role in the review, data analysis, and manuscript writing.
- 4) **Dr. Rajesh Aggarwal:** research supervisor whose role was to guide, and help with the editing of the manuscript

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Conflict of interest

Dr. Rajesh Aggarwal is a consultant for Applied Medical.

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TABLES

Table 1A: Importance of each EPA for Residency Training

EPA	Round 1		Round 2	
	<u>Mean</u>	<u>% 4 or 5</u>	<u>Mean</u>	<u>% 4 or 5</u>
Uncomplicated Antenatal & Prenatal Care	4.94	100.00	5.00	100.00
Complicated Antenatal & Prenatal Care	4.84	100.00	4.93	100.00
Intrapartum Care	4.94	100.00	5.00	100.00
Childbirth	4.91	100.00	5.00	100.00
High Risk Childbirth	4.72	93.75	5.00	100.00
Postpartum & newborn care	4.5	93.75	4.86	100.00
Benign Gynecology	4.91	100.00	5.00	100.00
Gynecological Technical Skills & Procedures	4.97	100.00	4.93	100.00
Pre-operative care	4.78	93.75	5.00	100.00
Postoperative Care	4.88	100.00	5.00	100.00
Mature Women's Health	4.72	96.88	4.86	100.00
Gynecological oncology	4.41	93.75	4.57	100.00
Urogynecology & Pelvic Floor Problems	4.44	93.75	4.57	100.00
Pediatric & Adolescent Gynecology	4.13	84.38	4.29	100.00
Sexual & Reproductive Health	4.55	90.32	4.64	100.00

Table 1B: Importance of each EPA for Simulation-Based Training

EPA	Round 1		Round 2	
	<u>Mean</u>	<u>% 4 or 5</u>	<u>Mean</u>	<u>% 4 or 5</u>
Uncomplicated Antenatal & Prenatal Care	2.14	13.79	2.43	14.29
Complicated Antenatal & Prenatal Care	2.79	31.03	2.57	14.29
Intrapartum Care	3.55	58.62	3.31	61.54
Childbirth	3.72	72.41	3.57	71.43
High Risk Childbirth	4.00	75.86	4.14	92.86
Postpartum & newborn care	2.59	31.03	3.00	35.71
Benign Gynecology	2.83	34.48	2.92	46.15
Gynecological Technical Skills & Procedures	4.41	89.66	4.57	100.00
Pre-operative care	2.34	10.34	2.36	14.29
Postoperative Care	2.72	34.42	2.50	14.29
Mature Women's Health	2.24	6.90	2.29	14.29
Gynecological oncology	2.83	24.14	2.57	21.43
Urogynecology & Pelvic Floor Problems	3.17	37.93	3.29	42.86
Pediatric & Adolescent Gynecology	2.72	24.14	2.79	28.57
Sexual & Reproductive Health	2.79	31.04	2.79	28.57

Table 1C: Importance of each EPA for Simulation-Based Assessment

EPA	Round 1		Round 2	
	<u>Mean</u>	<u>% 4 or 5</u>	<u>Mean</u>	<u>% 4 or 5</u>
Uncomplicated Antenatal & Prenatal Care	2.41	17.24	2.50	14.29
Complicated Antenatal & Prenatal Care	2.93	34.48	2.64	14.29
Intrapartum Care	3.48	62.07	3.15	61.54
Childbirth	3.72	72.41	3.64	71.43
High Risk Childbirth	3.90	75.86	4.07	85.71
Postpartum & newborn care	2.66	34.48	3.00	38.46
Benign Gynecology	2.90	37.93	2.79	35.71
Gynecological Technical Skills & Procedures	4.21	89.66	4.07	85.71
Pre-operative care	2.34	10.34	2.50	14.29
Postoperative Care	2.76	34.48	2.50	14.29
Mature Women's Health	2.38	13.79	2.21	7.14
Gynecological oncology	2.83	24.14	2.50	14.29
Urogynecology & Pelvic Floor Problems	3.17	41.38	3.21	35.71
Pediatric & Adolescent Gynecology	2.62	17.24	2.79	28.57
Sexual & Reproductive Health	2.69	27.59	2.79	28.57

FIGURES

Figure 1: Delphi Survey Demographics

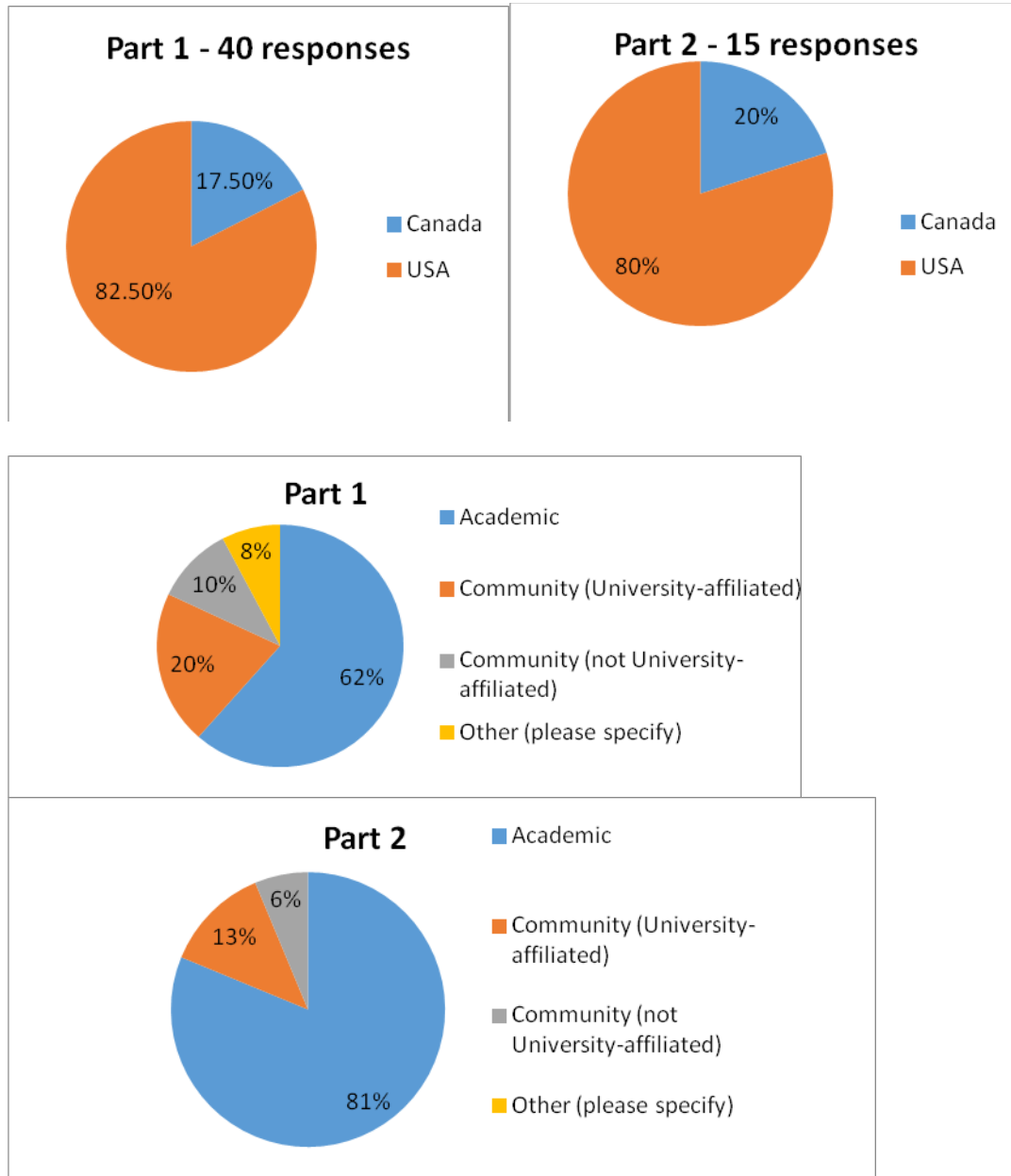
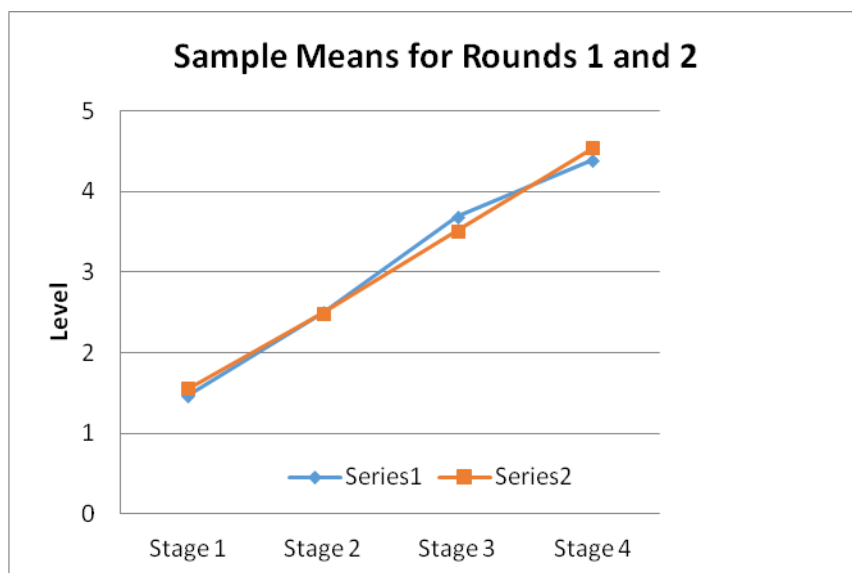
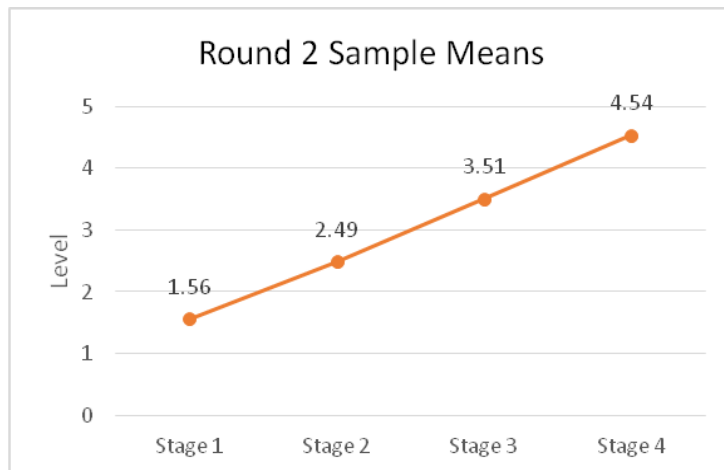
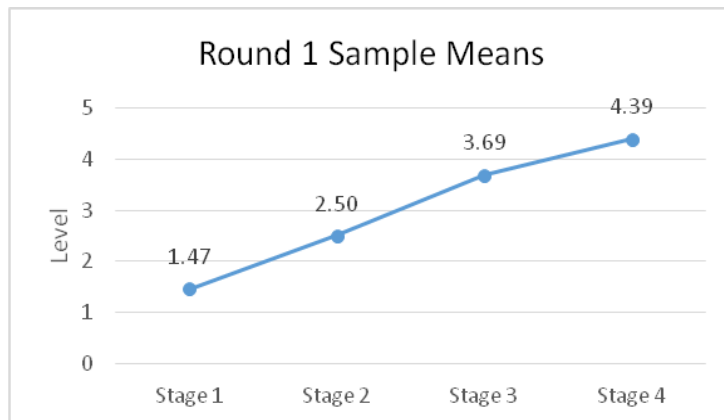


Figure 2: Benchmarks for each Entrustable Professional Activity (EPA) – “For each stage of residency training, what is the expected overall mean level of competence?”



Manuscript 3

Simulation in Obstetrics and Gynecology for the Training of Health Care Professionals: A Systematic Review

Simulation in Obstetrics and Gynecology for the Training of Health Care Professionals: A Systematic Review

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ABSTRACT

Background

Simulation-based training is gaining popularity in medicine. It represents an additional means of achieving or maintaining competence, which could have a direct impact on patient safety and quality of care. Its current role in the field of obstetrics and gynecology (OBGYN), including its use and effectiveness, needs to be better understood.

The objectives of this systematic review are to review and synthesize the existing medical education evidence that addresses the question: “What are the current educational outcomes for health professions learners using simulation in OBGYN?”. This was compared with no intervention or with other educational activities.

Methods

Eligibility criteria: All articles were independently reviewed by two reviewers. Inclusion criteria included original research only, with available full text, English or French, evaluating simulation in the context of OBGYN for training any health care professionals with an outcome based on modified Kirkpatrick’s levels for appraising interventions in medical education.

Information sources: Five databases (Medline [Ovid], Embase [Ovid], Cochrane Library [Wiley], CINAHL [Ebsco] Web of Science [Thomson Reuters]) were searched from inception until December 13, 2016. The search identified articles in any language, which included variations of terms for Obstetrics & Gynecology and terms for Simulation Training.

Risk of bias: Data was extracted systematically from the 316 eligible studies by one reviewer using a pre-determined coding protocol. Data was synthesized qualitatively and by tabular presentation based on the modified Kirkpatrick model. The quality and strengths of the

included studies were appraised using the Medical Education Research Study Quality Instrument (MERSQI).

Results

A total of 7153 titles and abstracts of studies retrieved were screened independently in duplicate by two review authors. This was followed by a full text evaluation of the included studies (n=486), resulting in 316 articles for final inclusion. Most studies took place in the USA (46%), and almost 80% of the included studies published after 2007. There was an equal distribution of studies pertaining to obstetrics and gynecology, the types of learners varied from students to attending staff, and there was a wide variety of simulation modalities described. More than half of the studies (59.4%) had some form of feedback. Most studies involved a single institution, and less than ¼ were randomized controlled trials. The quality of the included studies, as measured by the MERSQI, increased with the years, with a mean MERSQI score of 11.44 (SD 2.55), and median value of 12.0 (range 5-18). Domains with the lowest scores were validity evidence. 75.0% of the studies relayed outcomes pertaining to change in knowledge or skills (level 2). The highest level 4 (changes in patient/health care outcomes) was only represented by 7.3% of studies.

Discussion

Simulation has an important role to play in the field of OBGYN and there are increasing numbers of high-quality studies demonstrating that simulation can improve clinical skills and knowledge in the workplace and positively influence healthcare systems and patient safety.

Systematic Review Registration number: PROSPERO CRD42017055405

http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017055405

Key words: Obstetrics, Gynecology, Simulation training, Internship and Residency, Medical Education

INTRODUCTION

Simulation is defined as the “re-creation or imitation of something real” whereas simulation-based education (SBE) is an instructional method in medical education that uses different simulation modalities (ex: part task trainers, mannequins, virtual reality, standardized patients...etc.) to “re-create some component of the clinical encounter for the purposes of training or assessment.”[1] Simulators have been widely used in the field of obstetrics and gynecology (OBGYN) as early as the 1600s with the use of “phantoms” to teach midwives about difficult childbirth. [2] SBE is gaining popularity in medicine, notably in residency education. It not only allows for the opportunity to enhance learners’ knowledge and skills by mimicking clinical encounters, but it also does so in a safe learning environment, where there are no direct threats to patients. [3] [1]It represents an additional means of achieving or maintaining competence, which could have a direct impact on patient safety, healthcare outcomes, and quality of care.[4, 5] Although the use of SBE for training and assessment in medical education is increasing, its current role in the field of OBGYN, including its use and effectiveness, needs to be better understood.

The objectives of this systematic review are to review and synthesize the existing medical education evidence that addresses the question: “What are the current educational outcomes for health professions learners using simulation in OBGYN?”. This was compared with no intervention or with other educational activities. Thus, OBGYN research addressing the efficacy of simulation as a training methodology as opposed to research using simulation as an investigative methodology was reviewed.

Kirkpatrick’s four-level framework for evaluating training

The effectiveness of any training program can be evaluated using Kirkpatrick’s model for evaluating training programs has been around since 1967 and over the years, it has evolved and

been adapted to the field of medical education. [6, 7] It is a four-level framework that classifies the effectiveness of an educational intervention depending on the outcome. According to the criteria, the effectiveness of learning can be described as an ordinal construct of four levels: Reaction (level 1), Learning (level 2), Behavior (level 3), and Results (level 3). The majority of studies in medical education research report outcomes at levels 1 and 2. [8-10] However, as you move up from one level to the next, the information provided becomes more difficult to gather, but more valuable. For the purposes of this review, an adapted Kirkpatrick model, often cited in medical education research, was used. [11-14] (See Table 1)

Medical Education Research Study Quality Instrument (MERSQI)

To our knowledge, there are three measures that have been used to evaluate the methodological quality of systematic reviews pertaining to medical education: the MERSQI [8-10, 15], the Newcastle-Ottawa Scale (NOS) [9, 15-17], and the Best evidence in Medical Education (BEME) global rating [14]. The MERSQI was first described in 2007, “designed to measure the quality of experimental, quasi-experimental, and observational studies.”[10] It includes 10 items, grouped into 6 domains: study design, sampling, type of data (subjective or objective), validity (internal structure, content, and relationships to other variables), data analysis, and outcomes (based on Kirkpatrick’s levels). Each domain has a maximum score of 3 for a total maximum score of 18 (range 5-18). (see Table 2). Cook et al. 2011 found positive associations between all three of these scoring systems and reporting quality, using the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [8]. The highest inter-rater agreement ($ICC \geq 0.76$) and strongest correlation between reporting and methodological quality was found with the MERSQI score ($\rho = 0.64$, $p < 0.0001$).[8] They also found that studies with higher methodology scores also had higher reporting indices.[8] Furthermore, many other

reviews have published evidence supporting its score validity. [8-10, 15] For studies of simulation-based training coding with both the MERSQI and NOS, a statistically significant strong correlation has been reported ($\rho = 0.60$, $p < 0.0001$).[9] Although, it remains unclear when appraising individual studies whether to use one scoring system over another or a combination of both, the MERSQI was chosen for this systematic review.

METHODS

We conducted and reported on this review in accordance with PRISMA guidelines.[18]

Protocol and Registration

A PROSPERO protocol of the systematic review exists with registration number CRD42017055405. It can be accessed via web at:

http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42017055405

Eligibility criteria

The search identified articles in any language, which included variations of terms for Obstetrics & Gynecology and terms for Simulation Training. We sought to include studies that evaluated original research only, with accessible and retrievable full text, in any language, with no restriction on publication date. Participants included any health professions learner. Only studies evaluating simulation in the context of OBGYN in which there was an educational outcome based on the Kirkpatrick's levels of hierarchy were included. This was modified from our original eligibility criteria, which also included those studies in which the outcome was the validation of a simulator or assessment tool and those that identified system or performance gaps. These were only included if they also had a Kirkpatrick outcome. We defined a health professions learner as any learner involved in clinical care, including, medical students, residents, nurses, physicians, and midwives. Simulation was taken in its broadest definition: "A technique that creates a situation or

environment to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain understanding of systems or human actions.”[3] This would include, but is not limited to, high-fidelity (or theatre-based) simulation, task trainers or simulators, virtual reality, and standardized patients.

Information sources and search strategy

The following databases were searched for relevant studies: MEDLINE (via Ovid 1946 to 13/Dec/2016) Embase Classic + Embase (via Ovid 1947 to 13/Dec/2016); the Cochrane Library (to 13/Dec/2016); Web of Science (via Thomson Reuters, to 13/Dec/2016) and CINAHL (via Ebsco, to 13/Dec/2016). The search strategy used text words and relevant indexing to retrieve reports documenting the role of simulation training in Obstetrics and/or Gynecology. No language or date limits were applied. The full MEDLINE strategy (Appendix 1) was applied to all databases, with modifications to search terms as necessary.

References from the search were imported into an EndNote library. A de-duplication was performed after all databases results were imported

Study Selection

Studies were selected based on the eligibility criteria outlined above. Only those texts written in either English or French (as these were read and understood by the reviewers), were included in final selection. After the removal of duplicates, records were initially screened by title and abstract, after which full texts were assessed for final eligibility. Refer the PRISMA flow diagram for more details (Figure 1). Studies in which the final outcome measured something other than defined by the Kirkpatrick model, such as system or performance gaps or the validation of a simulation model or assessment tool were also included initially (in the title and abstract screening). These studies were ultimately excluded in the final full-text screening if they did not also report an outcome

based on the Kirkpatrick four-level framework. These studies can be the subject of a separate systematic review. When we found duplicate reports of the same study, we included only one report. Two reviewers independently assessed the eligibility of bibliographic records in the first screening (abstract/title). For feasibility reasons, for the final inclusion/exclusion decision (full-text review), a computer-generated random sample of 20% of these originally screened articles was independently reviewed by two reviewers. Any disagreements were resolved by consensus and when necessary, by appeal to a third party. If agreement was $\geq 90\%$, it was assumed that agreement would be $\geq 90\%$ for the remaining articles.

Data collection process, data items, and risk of bias

All relevant data from included studies was extracted by one reviewer. A data abstraction tool using Excel was developed, but not piloted. Duplicate publications from multiple reports on the same study were identified by comparing author names, intervention, sample sizes, and outcomes, and double counting was avoided in this way. To extract data on the methodological quality of the studies, we used the MERSQI. We also extracted data on (1) characteristics of participants (including type of health care learner and setting); (2) type of simulation ; (3) sampling (total number of participants); (4) name of evaluation instrument used if applicable; (5) all outcomes reported, including the Kirkpatrick levels; (6) summary of study results; and (7) study conclusions and interpretations. Studies were summarized according to the Kirkpatrick Model for evaluating educational outcomes. The methodological quality and strengths of the included studies were assessed using the MERSQI. The total MERSQI score was calculated as the percentage of total achievable points (accounting for “not applicable” responses) and then adjusted to a standard denominator of 18 to allow for comparison of scores across studies.

Summary Measures

The primary outcome measure was the Kirkpatrick level of the outcome of each included study (level 1 to 4) as well as the MERSQI score.

Synthesis of results, risk of bias across studies, and additional analysis

Results were not combined in any way. No specific method was used to investigate bias across studies, but rather the quality of the studies was evaluated using the MERSQI score. No additional analyses were done.

RESULTS

A PRISMA flow diagram illustrates the number of records at each phase of the review (Fig. 1). 7153 studies entered the initial screening and 6667 were excluded. The remaining 486 records were evaluated based on the full text. 170 were excluded for one or more of the following reasons: Not original research (2), no full text available (13), no health professional learners (1), no simulation or simulation itself not being evaluated (13), text not available in English or French (18), study unrelated to the field of OBGYN (7), and no Kirkpatrick level of outcome identified (116). No additional records were selected from citing articles, clinical trials registries, or by contacting researchers. During the final inclusion/exclusion decision, a randomized selection of 20% of these originally screened articles (n= 98) resulted in 94% agreement between the two independent reviewers, thus it was assumed that agreement would be >90% for the remaining articles. A total of 316 articles were retained for final qualitative synthesis [19-268][269-334]

The Medline strategy was rerun in May 2018 and yielded 794 additional articles. However, this new search was not included in the review prior to submission due to time constraints and lack of a team to decrease the workload.

The included studies represented 38 countries in total. Almost half (46%) of the included studies took place in the USA. Only 4% were Canadian. The subjects covered were equally

distributed between obstetrics and gynecology (almost 50/50). Examples of obstetrical simulations represented by the sample include (but are not limited to) obstetrical emergencies (ex: postpartum hemorrhage), shoulder dystocia, cord prolapse, eclampsia) including multidisciplinary team and CRM skills, technical skills stations (ex: perineal laceration repair, cervical exam, fetal scalp sampling, FHR, ultrasound, operative vaginal delivery, breech delivery, vaginal delivery), and perimortem C/S. Examples of gynecological simulations included surgical skills via specific task trainers or virtual reality trainers (Laparoscopic, hysteroscopic and robotic skills) ultrasound skills, pelvic exam, pediatric adolescent gynecology simulators, intrauterine device insertion, and counselling (such as contraception, tobacco cessation). Type of health profession learners included multidisciplinary teams, OBGYN and other residents (ex: radiology, surgery), fellows, students (nursing, midwifery, medicine), midwives, consultants/attending OBGYN staff, and nurses. There was a wide variety of simulation modalities used including theatre-based, virtual reality, task trainer, mannequins, standardized patients, animal/cadaver models, computer, hybrid models, in situ simulation, team-based, and serious games. More than half of the studies (59.4%) had some form of feedback, but it was not always clear what kind. This included individual and group feedback, formal debriefing, computer feedback, facilitation, and deliberate practice.

The year of publication of the earliest included study was 1971. However, there was a notable increase in the amount of studies after 2005, with the majority (57%) of the included studies published between 2012 and 2016 and almost 80% of the included studies published after 2007 (between 2008 and 2016). A similar trend was observed with the median MERSQI scores, whereby the quality of the included studies, as measured by the MERSQI score, increased with the years. (See Figure 2) The mean MERSQI score was 11.44 (SD 2.55), with a mode of 12.5 and median value of 12.0, thus almost creating a normal distribution, with most scores concentrated

between 10 and 14 (representing 73%). 22% of studies fell into the lower end of the curve (score of 5 to 9) and only 5% of studies totaled a score of 15 or greater, with only 2 studies having a perfect score of 18. (See Figure 3) The first article, “Simulation-based team training for multiprofessional obstetric care teams to improve patient outcome: a multicentre, cluster randomised controlled trial”, published in 2016 by Fransen et al. was a randomized controlled trial conducted in multiple obstetric units in the Netherlands [129]. Multiple types of simulators were used including high fidelity mannequins like Noelle ((Gaumard, Miami, FL, USA) as well as hybrid models using PROMPT birthing simulator (Limbs & Things, Bristol, UK). A total of 471 medical professionals underwent training and outcomes were analysed for 28657 women via chart review of obstetric complications during the first-year post intervention. Team training reduced trauma due to shoulder dystocia by two-fold and doubled invasive treatment for severe postpartum haemorrhage compared with no intervention. The second article with the highest MERSQI score, “Didactic and simulation nontechnical skills team training to improve perinatal patient outcomes in a community hospital” was published in 2011 by Riley et al [266]. It was also a randomized controlled trial of 3 small community hospitals in Minnesota, USA, mainly looking at obstetrical team-based simulation. Perinatal morbidity and mortality data were prospectively collected for both control and intervention groups. A statistically significant and persistent improvement of 37% in perinatal morbidity was observed between pre and postintervention for the hospital exposed to the simulation program.

Domains with the lowest scores were validity evidence concerning internal structure as well as relationship to other variables, reported in only 22.0% of applicable studies, compared to content validity reported in 63.6%. The vast majority (more than 80%) of studies involved a single institution; only 18.4% of studies were multisite. For the type of study design, most (39.6%)

involved a single group with pretest and post test, with only 21.8% being randomized controlled trials. The remainder of the studies were single group post test only or cross-sectional (19.0%) and two group, non randomized (19.6%). Data was objective and was presented as 'beyond descriptive' in the majority of studies (72.8% and 78.5%, respectively).

With respect to the Kirkpatrick's four-level framework for evaluating training, for the most part, studies reporting higher levels of outcomes also reported the lower levels thus level 4 outcomes for example, also encompassed levels 1 through 3. We found that 5.7% of studies reported only at level 1 (reactions). The vast majority, 75.0%, of the studies relayed outcomes pertaining to change in knowledge or skills (level 2). Change in behaviour (level 3) was reported in 12.0% of studies. The highest level (level 4), which pertains to changes in patient/health care outcomes was only represented by 7.3% of studies. Future research needs to aim at these higher levels of evidence. (See Figure 4 and Table 3)

DISCUSSION

We strived to learn what role simulation plays in the realm of OBGYN as it pertains to educational outcomes, based on Kirkpatrick's levels, which are also represented in the MERSQI tool. Unfortunately, there is little evidence supporting translation of skills and knowledge learned in simulated environments to the real-life clinical world. There is even less evidence to support a positive effect of OBGYN simulation on systems and patient outcomes. The vast majority of the studies stopped at level 2 (change in knowledge and skills in simulated environment). This highlights the need for research aimed at these higher levels of evidence since the field of simulation, in general and not exclusive to OBGYN, is saturated by studies looking at the lower levels 1 and 2. Furthermore, the quality of the studies, as a whole, was evaluated using the MERSQI. It seems that authors are publishing studies with higher outcome levels and with more

and more validity evidence, as we become increasingly familiar with SBE. However, even with increasing numbers of studies involving simulation in OBGYN, there continue to be very few high-quality studies, as reflected by the paucity of studies with high MERSQI scores of 15 or greater. Only 2 out the 316 included studies had a perfect score of 18 on the MERSQI [129, 266]. It is important to note that in both these studies all scoring items pertaining to validity were given a “non applicable” rating since no knowledge/skills assessment tool determined outcomes: chart review pre and post-intervention was used. Medical education simulation research focused on outcomes and effectiveness of different modalities is inconsistent, especially when it comes to methodological rigor. This is highlighted in the new reporting guidelines for simulation-based research published by Cheng et al. in 2016.[335] This will most certainly lead to a more standardized approach, allowing authors to publish replicable studies that can have a positive influence on patient outcomes.

Chang et al. published a literature review in 2013 on the role of simulation training in obstetrics that can very easily be translated to gynecology and other medical domains [336]. They discuss a ‘healthcare quality pyramid’ with four levels of increasing importance: Individual training, team training, health care system, and patient safety and quality. Simulation is linked to this pyramid as highlighted by the article’s four key points:

- 1- Simulation is a valuable healthcare management strategy for individual and team training.
- 2- In-situ simulation is effective at identifying latent threats to patient safety in healthcare systems.
- 3- Simulation may be valuable as a competency and systems assessment tool.
- 4- Leaders in healthcare should embrace simulation as a tool to improve safety and quality.

Our systematic review may have been too broad to look at the many different uses and types of simulations that exist. It would be interesting to repeat the same search strategy but to look independently at these four points. We did identify many studies in which individual and team training outcomes existed; however, studies that solely had identification of a latent safety threat or gap, as well as those that exclusively validated an assessment tool without any Kirkpatrick level evidence, were excluded.

The use of simulation for assessment, both formative and summative, is also growing, as medical educators move towards a more objective assessment of competence of learners, as seen with competency-based medical education. The question remains whether skills learned in the simulated setting can translate to skills in clinical practice. A meta-analysis of 33 studies looking at simulation-based assessments and patient-related outcomes found that they often correlate positively [4]. Thus, it is possible that these tools may one day replace workplace-based assessments if there is enough validity evidence for them, again highlighting the importance of publishing high quality replicable studies using a standardized approach.

Another limitation of our study is that we did not report inter-rater agreement for the MERSQI codes as only the main author was responsible for data extraction. There was also a large heterogeneity of studies in terms of study designs, both quantitative and qualitative, thus preventing any specific conclusions from being drawn. For example, we did not analyse the individual results of these studies and whether outcomes were positive or negative. We realize that the data presented ends with studies published prior to December 2016. A repeat search strategy was conducted in May 2018 and yielded 794 additional articles to screen. However, due to time and personal constraints, the results were not included. This could be the focus of future research, should the need arise.

In conclusion, simulation has an important role to play in the field of obstetrics and gynecology and there are increasing numbers of high-quality studies demonstrating that simulation can improve clinical skills and knowledge in the workplace and positively influence healthcare systems and patient safety. Future studies should use the reporting guidelines for simulation-based research in order to continue to improve the quality of simulation-based studies conducted in the future.

Author's contributions:

- 5) **Dr. Milena Garofalo:** primary role in the review, data analysis, and manuscript writing.
- 6) **Dr. Rajesh Aggarwal:** research supervisor whose role was to guide, and help with the editing of the manuscript
- 7) **Taline Ekmekjian** (Librarian): initial search strategy, methodology, Endnote reference library
- 8) **Dr. Céline Giordano:** initial abstract screening for inclusion/exclusion (second reviewer)

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Conflict of interest

Dr. Rajesh Aggarwal is a consultant for Applied Medical.

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TABLES

Table 1: Adapted Kirkpatrick's four-level framework for evaluating learning [11-14]

Level	Domain	Description and examples
1	REACTION	Learner's views on the learning experience (ex: satisfaction scores)
2A	LEARNING: change in attitudes/perceptions	Subjective (ex: confidence scores)
2B	LEARNING: modification of knowledge or skills	Knowledge: acquisition of concepts, procedures, or principles Skills: acquisition of thinking and problem solving, psychomotor, or social skills. Can be subjective (ex: self-reported changes in knowledge or skills) or objective (ex: if an assessment tool is used for rating – MCQ ^a , OSATS ^b , OSCE ^c)
3	BEHAVIOR: change in behaviors	Transfer of learning to the clinical setting/workplace
4A	RESULTS: change in system or organization	Any change in the organization /system or in the delivery of care
4B	RESULTS: change in patient outcomes	Any improvement in health or wellbeing of patients

^aMultiple choice questionnaire

^b Objective structured assessment of technical skill

^c Objective structured clinical examination

Table 2: Characteristics of the Medical Education Research Study Quality Instrument (MERSQI) score – Adapted from Reed et al 2007.[10]

Domain	MERSQI item (Score)	Maximum Score
Study design	Study design <ul style="list-style-type: none"> - Single group cross-sectional (1) - Single group posttest only (1) - Single group pretest and posttest (1.5) - Nonrandomized, 2 group (2) - Randomized controlled trial (3) 	3
Sampling	No. of institutions studied <ul style="list-style-type: none"> - 1 (0.5) - 2 (1) - 3 or more (1.5) 	3
	Response rate, % <ul style="list-style-type: none"> - Not applicable - <50 or not reported (0.5) - 50-74 (1) - 75 or more (1.5) 	
Type of data	Type of data <ul style="list-style-type: none"> - Subjective assessment by study participant (1) - Objective assessment (3) 	3
Validity of evaluation instrument	Internal structure <ul style="list-style-type: none"> - Not applicable - Not reported (0) - Reported (1) 	3
	Content	

	<ul style="list-style-type: none"> - Not applicable - Not reported (0) - Reported (1) 	
	Relationship to other variables <ul style="list-style-type: none"> - Not applicable - Not reported (0) - Reported (1) 	
Data analysis	Appropriateness of analysis <ul style="list-style-type: none"> - Data analysis inappropriate for study design or type of data (0) - Data analysis appropriate for study design or type of data (1) 	3
	Complexity of analysis <ul style="list-style-type: none"> - Descriptive analysis only (1) - Beyond descriptive analysis (2) 	
Outcomes	Outcomes <ul style="list-style-type: none"> - Satisfaction, attitudes, perceptions, opinions, general facts (1) - Knowledge, skills (1.5) - Behaviors (2) - Patient/health care outcome (3) 	3
Total possible score^a		18

^aScores range from 5 to 18.

Table 3: Number of studies (n (%)) for each scale item of MERSQI

Scale Item	MERSQI item (Score awarded if present)	Present, n (%) (n = 316)	Scale score, mean +/- SD, median (range)
MERSQI	Total score (max 18)		11.44 +/- SD 2.55, 12.0 (5-18)
Study design (max 3)	Single group cross-sectional/ posttest only (1)	60 (19)	
	Single group pretest and posttest (1.5)	125 (40)	
	Nonrandomized, 2 group (2)	62 (20)	
	Randomized controlled trial (3)	69 (22)	
Sampling Number. of institutions (max 1.5)	1 (0.5)	258 (82)	
	2 (1)	15 (5)	
	3 or more (1.5)	43 (14)	
Sampling Response rate, % (max 1.5)	Not applicable	17 (5)	
	<50 or not reported (0.5)	148 (47)	
	50-74 (1)	40 (13)	
	75 or more (1.5)	111 (35)	
Type of data (max 3)	Subjective assessment (1)	86 (27)	
	Objective assessment (3)	230 (73)	
Validity evidence (max 3)	Internal structure (1)	66 (21)	
	Content (1)	202 (64)	
	Relationship to other variables (1)	66 (21)	
	Not applicable	16 (5)	

Data analysis: appropriateness (max 1)	inappropriate (0)	12 (4)	
	appropriate (1)	304 (96)	
Data analysis: complexity (max 2)	Descriptive analysis only (1)	68 (22)	
	Beyond descriptive analysis (2)	248 (78)	
Highest outcome type (max 3)	Satisfaction, attitudes, perceptions, opinions, general facts (1)	18 (6)	
	Knowledge, skills (1.5)	237 (75)	
	Behaviors (2)	38 (12)	
	Patient/health care outcome (3)	23 (7)	

FIGURES

Figure 1: PRISMA flow diagram for each stage of the review

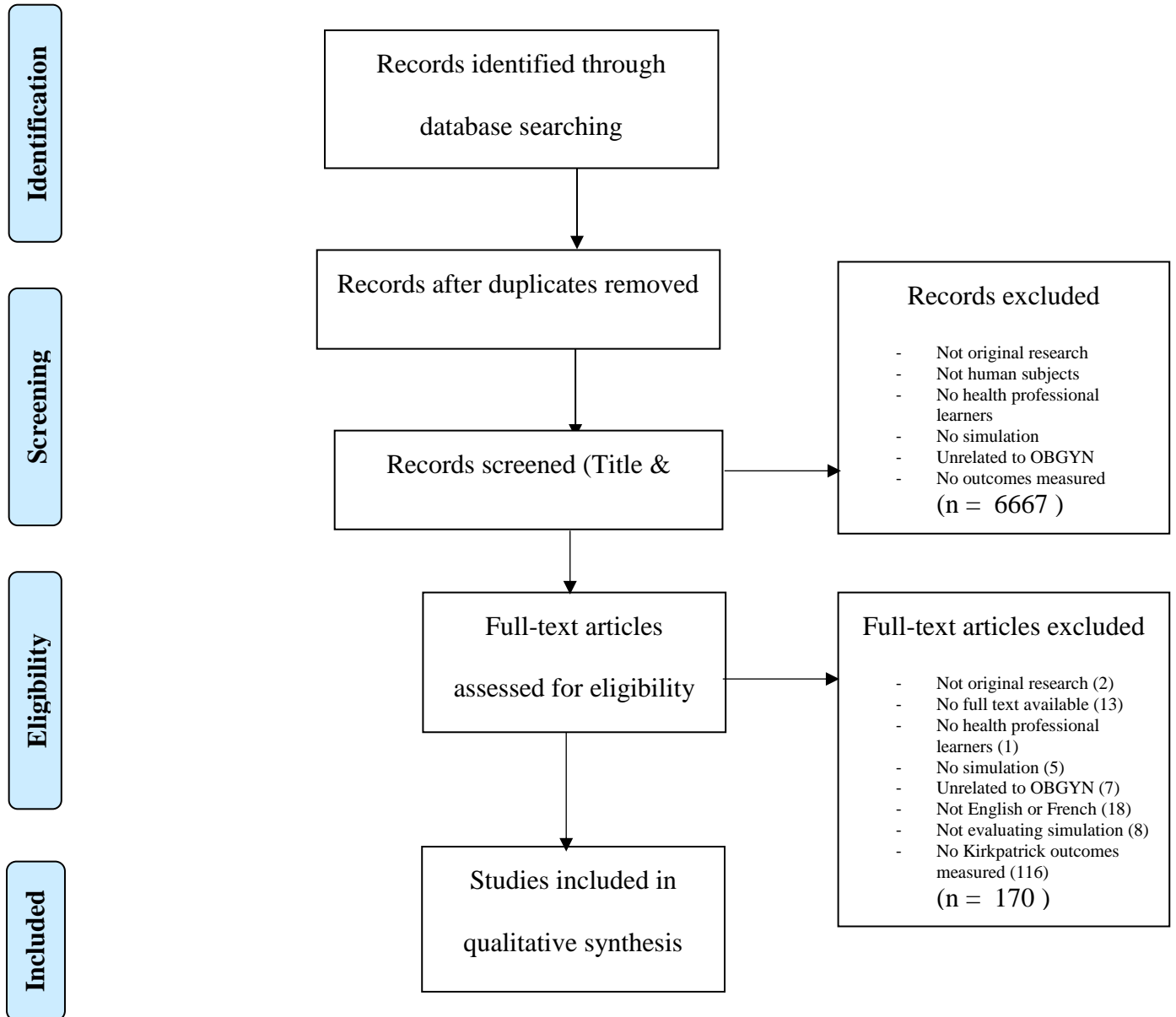


Figure 2: Mean MERSQI scores by years

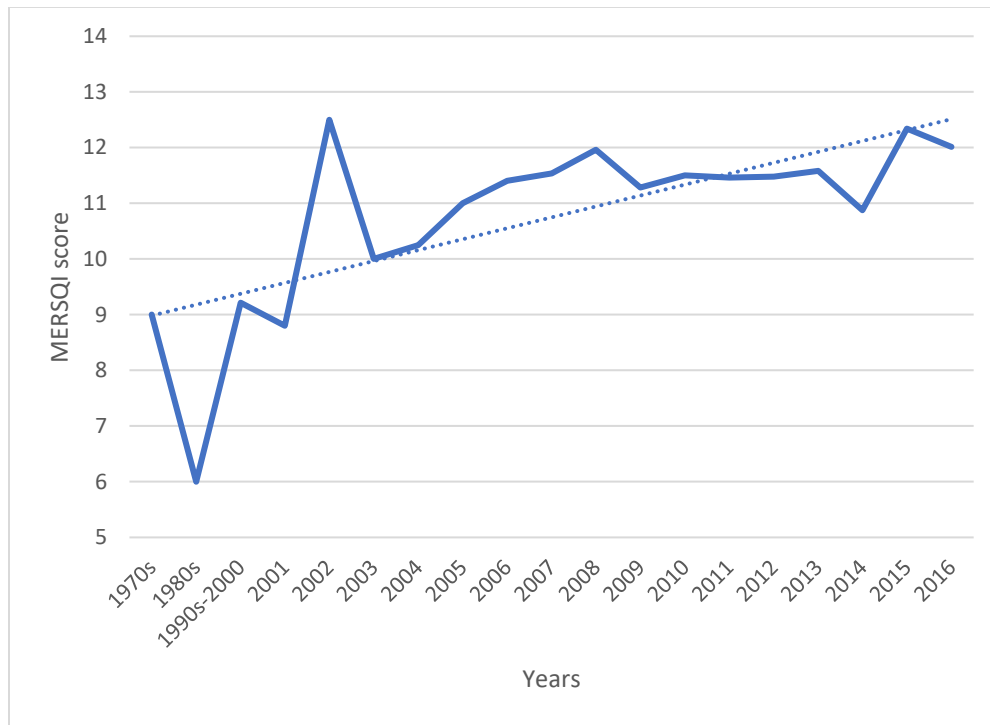


Figure 3: MERSQI score by number of studies

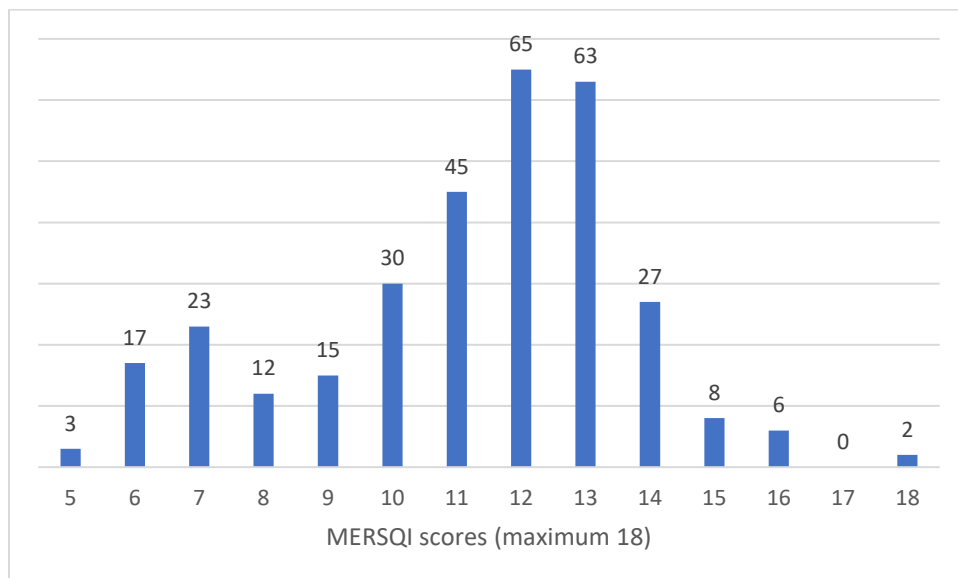
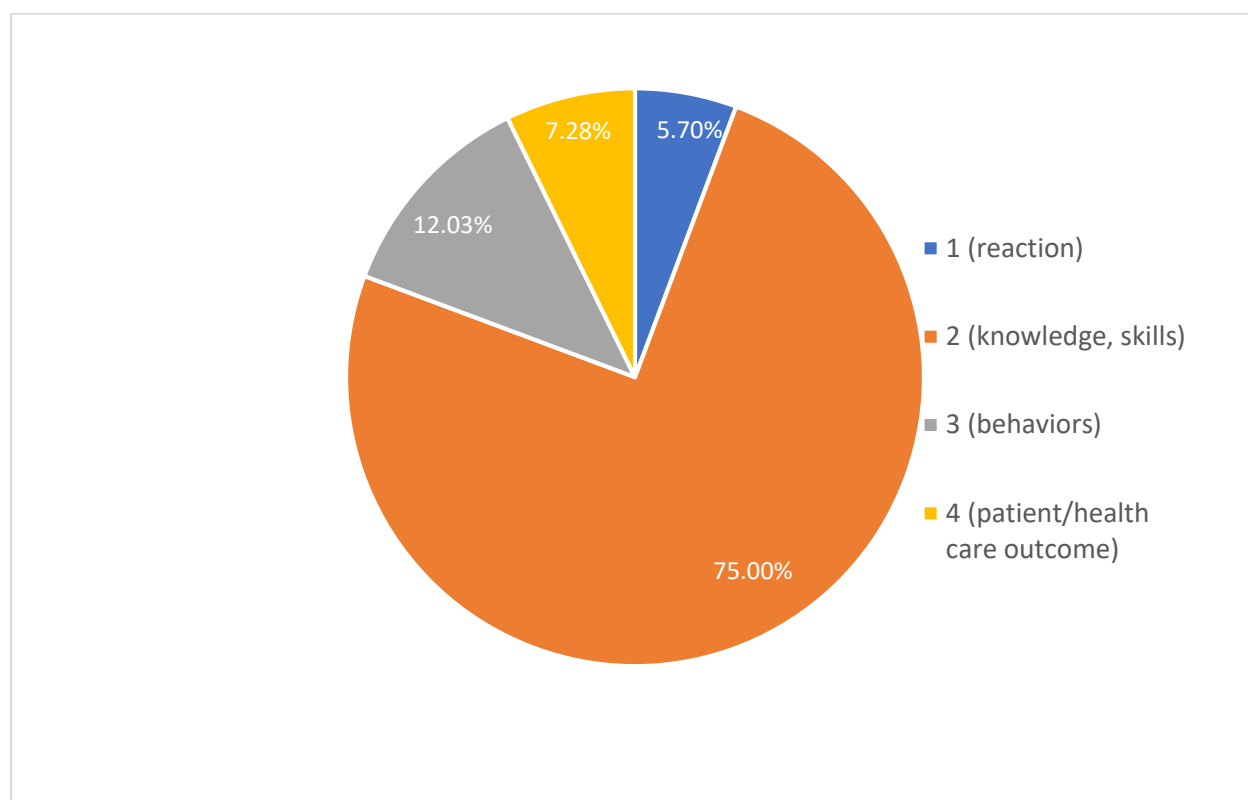


Figure 4: Percentage of studies with Kirkpatrick outcomes (level 1 to 4)



APPENDIX

Appendix 1: Medline Search Strategy

- 1 exp Obstetric Surgical Procedures/ or Obstetrics/ or "Obstetrics and Gynecology Department, Hospital"/ or Gynecology/ or exp Gynecologic Surgical Procedures/ or exp "Diagnostic Techniques, Obstetrical and Gynecological"/
- 2 (obstetric* or gynecolo* or OB?GYN*).tw,kf,jw.
- 3 1 or 2
- 4 exp Simulation Training/ or exp Computer Simulation/
- 5 (simulat* or virtual realit*).tw,kf.
- 6 Manikins/
- 7 (manikin* or mannequin*).tw,kf.
- 8 (standard* adj2 patient*).tw,kf.
- 9 4 or 5 or 6 or 7 or 8
- 10 3 and 9
- 11 remove duplicates from 10

Section 3: Conclusion & Future Work

Conclusion

In conclusion, the ultimate objective of this thesis project was to help define a competency-based simulation training curriculum for OBGYN residents. First, a comprehensive review of literature was undertaken to compare curricula from five countries, Canada, Australia, the United Kingdom, the Netherlands, and the United States of America. All five countries recognized CBME as a valuable tool in medical education. There was however a gap and thus a need to develop adequate assessment tools for use in CBME, including the use of simulation for this purpose. The review of curricula allowed for item analysis to take place, which yielded 15 EPAs for OBGYN. Note that this study took place prior to the publication by the RCPSC of the official EPAs for the specialty. Each EPA in the Delphi consensus study was quantified for its importance in residency training and for simulation in addition to setting benchmarks. Surveyed experts agreed that all outlined EPAs were important/essential and that there is a stepwise increase in competence, based on stage of residency. However, the role that simulation plays remained uncertain, and its role was only recognized as important for technical and procedural skills. There are numerous studies showing its utility in more than just the development of technical skills. The variety in the use of simulation in team-based training, communication, and crisis-resource management, amongst other things, was highlighted in the systematic review on the subject. This systematic review, which yielded 316 eligible studies, highlighted that simulation does in fact play a very important role in OBGYN residency training and that both its use and the number of high-quality studies involving simulation has been increasing over the years.

In July 2019, the RCPSC introduced “Competence by Design” (CBD) within Canadian residency training program. In order to ensure that all graduating residents are competent and ready for practice, we will see the need for more frequent assessments and observations in this CBD

model, both in the workplace and via simulation, which nicely complements clinical learning. The days of relying solely on the apprenticeship model for learning has passed. The value of simulation for training, teaching, assessment (both formative and summative), and even in the improvement of patient outcomes, is rapidly growing as research is emerging, showing the effectiveness of its use for these purposes, all within a safe learning environment.

We are already beginning to see the integration of simulation curricula into residency training programs. “The importance of integrating simulation-based experiences into an overall curriculum plan is one of the key lessons learned from a 35 year systematic literature review on the features and uses of high-fidelity medical simulations that lead to effective learning”[45]. In Canada, the specialty of anesthesiology was the first to develop and implement the Canadian National Anesthesiology Simulation Curriculum (CanNASC) [32]. A similar project, COGS (Canadian Obstetrics and Gynecology Simulation Curriculum), to incorporate SBE and SBA on a national scale is underway for the specialty of OBGYN [43, 44]. A Delphi study published in 2017 yielded consensus on six simulation scenarios that will make up the COGS curriculum [43].

The main idea is that modifications to the current OBGYN curricula, including a standardized national competency-based simulation curriculum, may potentially increase the quality and efficiency of training, which could have a direct impact on patient safety and quality of care. Future work should concentrate on further defining a competency-based simulation training curriculum for obstetrics and gynecology residents and in the implementation of the preliminary COGS curriculum outlined above. This will require key collaboration between simulation and medical educators, program directors, as well as the RCPSC in order to be successful.

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