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What can regulatory bodies do to help implement competency-based medical education?

Markku Nousiainen[a], Fedde Scheele[b], Stanley J. Hamstra[c,d,e] and Kelly Caverzagie[f]

[a]Department of Surgery, Division of Orthopaedic Surgery, University of Toronto, Toronto, Ontario, Canada; [b]Amsterdam University Medical Centre and Athena Institute, VU University Amsterdam, Amsterdam, The Netherlands; [c]Accreditation Council for Graduate Medical Education, Chicago, IL, USA; [d]Faculty of Education, University of Ottawa, Ottawa, Ontario, Canada; [e]Department of Medical Education, Feinberg School of Medicine, Northwestern University, Chicago, IL, USA; [f]Department of Internal Medicine, University of Nebraska Medical Centre, Omaha, NE, USA

ABSTRACT

In response to the numerous challenges resident trainees currently face in their ability to competently acquire the requisite skills, knowledge and attitudes upon graduation, medical educators have looked to a competency-based medical education (CBME) approach as a possible solution. As CBME has already been implemented in many jurisdictions around the world, certain challenges in implementation have been experienced. One important challenge identified relates to how regulatory bodies can either assist or unintentionally hinder implementation. By examining the varied experiences from Canada, the USA and the Netherlands in implementing CBME, this paper identifies how regulatory bodies can support and advance worldwide efforts of furthering its implementation. If regulatory bodies restructure accreditation and regulatory criteria to align with CBME principles, work together in a coordinated fashion to ensure alignment of vital regulatory meaures throughout the training and practice continuum of a physician, and allow for (if not incentivize) individuals and programs to be innovative in adapting CBME to meet their local environments, it is likely that the worldwide implementation of CBME will occur successfully.

KEYWORDS

Planning; outcome-based; institutional accreditation

Introduction

Traditional time-based graduate medical education is increasingly being challenged in a health care delivery environment where priorities have shifted. Greater efficiency and standardization have created conditions for improvements in safe and cost-effective care, but it is becoming increasingly clear that these changes may have adverse consequences for our learners in the long run. Training to competence necessarily takes place within a busy and complex health care environment, and a supervised apprenticeship model is still the most efficient approach. But in doing so, learners have to compete with demands on faculty time and standardized guidelines for care that can sometimes limit access to patients, thus limiting opportunities for acquiring the skills and knowledge needed to practice independently. In response to this, medical educators have implemented competency-based medical education (CBME) as an adjunct, and in some cases, a replacement for time-based training (Holmboe et al. 2017). The premise of CBME is that it should help produce better physicians within the current time and financial constraints of the health care delivery system and, by doing so, improve health outcomes (Holmboe et al. 2017).

Despite the potential benefits that CBME curricula can provide learners, teachers, and patients, it must be recognized that its implementation can be challenging. In particular, the structural changes necessary to deliver its curricula and methods of assessment must be properly organized, the processes of evaluation must be modified, and the culture of education must be changed in order to foster acceptance of the new paradigm (Caverzagie et al. 2017). Specific changes that must occur in the current medical education system include the integration

Practice points

- Experience from Canada, the USA and the Netherlands suggests that regulatory bodies can play a large role in promoting the implementation of CBME.
- Regulatory bodies can play a positive role in implementing CBME in three ways:
  - They can assist in the restructuring of accreditation and regulatory criteria along CBME principles.
  - They can work together (in jurisdictions where multiple regulatory bodies play a role in physician regulation) in a coordinated fashion to ensure the alignment of regulatory measures through the training and practice phases of a physician's career using a CBME lens.
  - They can allow physicians and training programs to adapt the principles of CBME to their individual context.

CONTACT Markku Nousiainen markku.nousiainen@sunnybrook.ca Department of Surgery, Division of Orthopaedic Surgery, University of Toronto, 621-43 Wellesley St. East, Toronto, Ontario M4Y 1H1, Canada

Table 1. Pre-requisites for the successful implementation of CBME: how Canada, the USA and The Netherlands compare.

Pre-requisites for successful CBME implementation	Canada	USA	The Netherlands
Training sites mandated to implement CBME	+++	+++	+++
Funding to support transition to CBME	++	0	+++
Coordinated guidance by regulatory bodies to support the implementation of CBME	+++	+	+++
Incentives for faculty to promote CBME	++	0	0
Ability for faculty/specialties to apply CBME to meet local conditions	+++	++	+++
Ongoing review and refinement of regulatory mandate: a 'CQI' response to perceived barriers	+++	+++	++

The symbols are intended to show a relative comparison between the case examples regarding the ability of each case to support the listed pre-requisite. The symbols were assigned within each column by the authors from each country relative to each pre-requisite. After the table was completed, all authors discussed the relative ratings and made adjustments accordingly.
+++ = active plan, strong supportive environment from regulatory body.
++ = guidance available, but minimal support from regulatory body.
+ = minimal plan, tacit support from regulatory body.
0 = no intended plan or support from regulatory body.

of education re-design efforts, an agreement on defining the relevant educational outcomes, mutual accountability amongst educators, trainees, and health care administrators and the assurance that all stakeholders responsible for regulation in medical education be aligned and supportive in ensuring that this change occurs smoothly and effectively. This paper examines how regulatory bodies, in their important roles, can either help or unintentionally hinder the implementation and successful functioning of CBME in graduate medical education.

In this paper, we define regulators broadly, including those authoritative bodies responsible for ensuring program quality (e.g. accreditors), granting legal access to practice (e.g. licensing/physician registration bodies), and granting operational access to practice (e.g. institutional credentialing bodies, medical specialty boards).

Professional self-regulation

Although self-regulation is a critical component to the medical profession, multiple regulatory bodies exist at several levels (regional and national) to ensure that their members practice at an accepted standard of proficiency. In general, the goals of these regulatory bodies are to ensure that common standards of training occur in graduate medical education programs, that practicing physicians demonstrate adherence to standards of patient care, and that physicians who are not practicing with the accepted standard of care are identified, rehabilitated and possibly removed from practice. Despite these goals, regulatory bodies often exist in complex systems, operating in independent silos due to the fact that they focus on regulating certain aspects of a medical professional's practice and not others. In addition, the policies and procedures used by these bodies to govern were both developed and applied in curricular models of medical education that largely preceded CBME. As such, even though some regulatory bodies may support the implementation of CBME in their jurisdictions, they may not be able to facilitate the ease of its implementation.

Previous work looking at implementation (Rogers 2004; Kotter 2012; Weggeman 2014) and the introduction of novel curricula in medical education (Lesky et al. 2001; Afrin et al. 2006; Bank et al. 2017) has shown that many specific elements must be satisfied for effective change to occur. Regulatory bodies must demonstrate strong and stable leadership that approves and supports the change. This must also be present at the local (training program) level as well, where stakeholders (i.e. faculty, trainees and administrators) must be ready to accept the proposed change and appreciate its relative advantages. Regulatory leaders must incentivize academic medical centers, learning health systems and other learning environments to support CBME with specific goals and timetables established. Clear and specific methods for achieving the goals must be outlined and understood by all of those involved in the change. Effective communication must occur at all levels to ensure that concerns are addressed and successes shared. Structures and processes for stakeholders to learn, develop, co-create, and promote innovation must be developed and encouraged. Failsafe, easy-to-use modes of communication must exist and resources relevant to the new system, such as electronic servers that house learning curricula and assessment tools, must be ready for use.

With these elements in mind, and finding no relevant literature on the topic, we introduce three case examples (countries) to explore potential mechanisms for how regulatory body structure and function can either help or hinder the successful implementation of CBME. The discussion we have about each case example is summarized in Table 1, where the relative ability of each country to implement CBME in light of standard pre-requisites for successful implementation is compared and contrasted. Finally, we also suggest potential solutions that can be taken by educators and authorities in relevant regulatory bodies to support and advance the worldwide implementation of CBME.

Case example #1: Canada

The first case example, involving Canada, shows how regulatory bodies have affected the implementation of CBME. In Canada, two main levels of regulation exist. The Royal College of Physicians and Surgeons of Canada (RCPSC) is responsible for the accreditation of residency/postgraduate medical education (PGME) programs as well as the certification of specialist physicians, while provincial colleges are responsible for the licensure of trainees and practicing physicians. It is up to the program directors of residency training programs as well as PGME deans to ensure that residents receive the appropriate training in their specialty by maintaining accreditation status of their training programs.

Internationally known for its leading role in supporting and researching CBME, it has been the RCPSC that is playing the pivotal role in implementing CBME in the country. Although successful CBME-based pilot training programs were already in place in two universities prior to the RCPSC playing this role, the RCPSC introduced a 'Competence By

Design (CBD)' movement across all PGME programs in Canada, where all specialties would implement CBME between 2016 and 2022 (The Royal College of Physicians and Surgeons of Canada 2019). The RCPSC has played the lead role in initiating the movement, provided the logistical and structural support at the specialty committee level to implement it (the specialty committee, which includes program directors and community representatives, organizes and maintains the function of PGME across the country), and provided on-line learning modules and courses to educate the implementers. It has also worked with the PGME offices at each university to support their efforts in making the implementation fit their local environment. It is important to note that although the RCPSC has assisted in supporting the specialty committees in designing the CBD curricula, the specialty committees have had the final say in how the CBD curriculum and assessment plans will be structured nationally. Once the national CBD template has been constructed, each training program has been given the flexibility to adapt it to its local context (with the assistance of their PGME office). Currently, the national implementation of CBD amongst all specialties is carrying on as planned and CBME will be implemented nationally within a few years' time.

Despite its remarkable success in implementing CBME nationally over the course of six years, it must be noted that the RCPSC has encountered frustration from some of its members at the PGME office and individual physician/surgeon levels. Particular concerns with the CBD movement have included whether CBME is the correct model, how the change in PGME will be funded, how programs will implement the new paradigm locally, how faculty development will be provided, how and who will be responsible for setting up an electronic server that would house the curriculum and assessment tools essential to the CBME movement, and who will have control of the assessment data. Dialogue between the RCPSC and training program stakeholders has occurred and continues to occur to work out these issues. The RCPSC plays a central role in organizing and supporting specialty programs and PGME offices as they develop their own CBD curricula and assessment tools. Specialty committee work is funded by the RCPSC; local implementation is funded by PGME offices. Both the RCPSC and PGME offices provide faculty development programs. A few electronic servers that house curricula and assessment tools have been developed; one by the RCPSC, the others by certain universities. Assessment data is managed by the PGME offices so as to provide their trainees and faculty the information needed to assess competence.

Case example #2: United States

The second case example, involving the United States (US), shows how the structure of regulatory bodies can lead to difficulties in implementing CBME. In the US, the structure and organization of graduate medical education (GME) regulation is more complex than Canada. The Accreditation Council for Graduate Medical Education (ACGME) is responsible for the accreditation of GME programs (the equivalent of PGME in Canada) whereas specialty boards (e.g. American Board of Surgery) are responsible for the certification of individual physicians and surgeons. In addition, state medical boards oversee the licensure of trainees and practicing physicians. Notwithstanding their oversight and support for GME, some aspects of this oversight present barriers to the implementation of CBME.

The ACGME, in partnership with the specialty boards, has revised accreditation standards that allow for and encourage CBME through an initiative known as the Next Accreditation System (NAS) (Nasca et al. 2012). These new standards effectively translate the vision of CBME to implementation strategies at the local level (i.e. the residency programs), leaving space for innovation, including a process to allow for exceptions to time-based training. In CBME, a key principle is promotion or advancement of residents based on demonstrated educational outcomes (e.g. attainment of relevant milestones for that specialty) as opposed to the amount of time in service or the number of experiences encountered. For some specialties in the US, program accreditation and/or individual certification is based upon accumulated experience rather than competence (e.g. number of logged surgical encounters) or length of time (e.g. number of hours spent in ambulatory clinic, number of years in training). These numbers also are used by many hospitals to provide credentials and privileges to physicians after training and while in unsupervised practice. While rooted in good intent, these rules run counter-intuitive to CBME.

Another unintentional barrier to the full implementation of CBME in the US may be related to the complex system for how GME is funded. Government-funded programs (especially Medicare) are responsible for funding the majority of GME with an estimated outlay of over $15 billion annually (Institute of Medicine (IOM) 2014). Medicare, the federal government-funded health insurance program for elderly and the severely disabled, was established in 1965. This legislation included a provision to reimburse academic teaching hospitals for the costs of employing and training resident physicians. With time, this system of payment has become increasingly complex with many teaching hospitals relying upon this critical funding to maintain financial viability with some no longer being able to train residents without this funding (Sullivan 2018). The federal funding of GME itself, however, does not preclude advancement of CBME. Rather, the fact that GME payments are directly tied to a time-based model (namely, the number of months a resident is physically present at that teaching hospital) effectively disincentivizes hospitals and their residency programs from allowing residents to graduate from their program early, a potential, but critical outcome of CBME. Furthermore, this funding model may also inhibit a resident's ongoing development of competence by limiting learning experiences outside of the primary teaching hospital, such as in rural hospitals and clinics which may otherwise be useful for helping residents progress to unsupervised practice (this situation also occurs in the Canadian and Dutch environments).

Another barrier is a well-intentioned Medicare requirement stipulating that a supervising physician must formally examine and evaluate every patient in order to receive reimbursement for the services provided by a resident physician in the inpatient setting. This requirement is present regardless of the complexity of the patient or the particular resident's demonstrated competence. For some

residents, this constant supervision may stand in the way of the development of autonomy and progressive independence as a physician, which is contrary to the goals of CBME.

Having said that, even though supervision is required, hospitals receive reimbursement for patients seen by residents and in many cases this helps the supervising physician see more patients and thus increase the revenue stream for the hospital. This may also work against CBME, in that there is an incentive to keep highly efficient residents in the hospital, perhaps longer than necessary (this issue also exists in the Canadian and Dutch environments).

While there is no formal stakeholder opposition to the principles of CBME, the existing regulations and funding mechaisms potentially inhibit programs and institutions from actively pursuing implementation of CBME. Unlike Canada, the United States has no overarching formal strategy designed to facilitate the implementation of CBME in GME and many potential barriers exist to achieving this goal.

Having said this, the ACGME has initiated a number of programs to examine and possibly overcome some of these barriers (Accreditation Council for Graduate Medical Education (ACGME) 2019a). For example, the Pursuing Excellence Initiative recognizes and promotes best practices for integrating teaching into the busy clinical environment. Other responses to implementing CBME include an examination of GME funding sources and their impact on learning as well as a new peer-reviewed program, Advancing Innovation in Residency Education (AIRE), which allows for exceptions to certain accreditation requirements, such as the time-based curriculum requirement (Accreditation Council for Graduate Medical Education (ACGME) 2019b).

Case example #3: The Netherlands

CBME in the Netherlands has been implemented since 2004 and has become a mandatory approach for PGME (Scheele et al. 2008, 2014). The Dutch accreditation system regulates quality of teaching sites and hospitals, program directors and individual physicians. Biannual quality reports are required and a 5-year evaluation visit is routine. Individual physicians require licensing and subsequently, relicensing every 5 years.

Governance of quality is organized using the philosophy of 'division of authority'. The regulator (a college consisting of health care representatives and funded by the government) is responsible for preparing up-to-date and socially-responsible proposals for legislation concerning accreditation and licensing (The Netherlands College of Medical Specialties 2020). This proposed legislation is then ratified by the government. The justice system (credentialing committee, or in Dutch 'registratie commissie geneeskundig specialismen' (The Netherlands Registration Committee for Medical Specialists 2020), RGS, which is funded by hospitals and physicians) manages the control of compliance to the rules and is responsible for the bureaucracy of accreditation and licensing. The professional societies of the different medical specialties, program directors, training sites and hospitals are responsible for execution of training according to the rules. Individual physicians are responsible for appropriate practice and continuing medical education, including formal reflective activities to make (re)licensing possible.

Regulation and control are based on the philosophy of guidance and trust in professional performance. For example, for the accreditation of a training site in Obstetrics and Gynecology (ObGyn), the Royal Dutch Association of Medicine implements CBME using the CanMEDS framework for general competency training. The regulator (government) develops general strategic rules that apply to all post-graduate training sites and faculty with specific rules applied to ObGyn as a separate specialty. The general and specific strategic rules are translated by professional societies into tactical rules, which are the building blocks for the national curriculum which provides guidance, but allows flexibility for professionals to operationalize and implement in their local practice. Professionals at the training site are obliged to make a local training plan in which operationalization is made transparent. They are also invited to use local culture, creativity and professional vision to make the local plan their own invention and this ownership is intended to increase intrinsic motivation of local teams to implement optimally. Variations while striving for excellence are welcome. Resources for training are well-covered in the Netherlands, so it is up to the professional to do a good job and find a local way to meet with the requirements of the national curriculum.

The continuous discussion between the leaders of this system is about the delicate balance between enforcing regulation and trusting the professional in his/her translation of the guiding regulation. Nevertheless, overly-detailed prescription of operational rules can lead to 'decoupling', a phenomenon in which practitioners appear to comply with regulations while in reality, old habits and cultures are maintained (i.e. 'us against them'). On the other hand, providing no guidance at all leads to loss of shared commitment and limited societally-driven progress in the vulnerable field of medical training. The right balance brings development in the right direction, intrinsically-motivated professionals with amazingly creative ways of translating CBME, significant variation in how training is done, but based on guidance and internalized shared commitments, leading to more or less the same outcomes. The correct balance will be decided through continuously ongoing multi-stakeholder discussions involving the public, medical societies, teaching sites and the *trias politica* described above in which the RGS has the final say.

Conclusion

There is no doubt that regulatory bodies must be aligned with each other and supportive of stakeholders to ensure that CBME implementation is efficient and effective. As the case examples show, the way regulatory bodies are structured and operate affect the implementation of CBME (Table 1). In some jurisdictions, such as in Canada and the Netherlands, where one regulatory body plays the only role in accrediting PGME, implementation has occurred albeit with significant interaction with those that are responsible for organizing and supervising the change. In the US, the complex relationship of multiple regulatory bodies and stakeholders has led to challenges in nationwide

implementation. Other lessons can also be learned through this comparative analysis such as the role that centralized funding (Netherlands) plays to help facilitate a transition to CBME.

If CBME is to be the new paradigm for medical education, we must collectively identify how the barriers to successful implementation can be overcome. A good first step would be to restructure accreditation and regulatory criteria to align with CBME principles as is happening in the US where initiatives such as the Milestones and CLER are helping to move towards an outcomes-based system of accreditation (Institute of Medicine (IOM) 2014). Furthermore, regulatory bodies must begin to work together in a coordinated fashion to ensure alignment of vital regulatory meaures throughout the training and practice continuum of a physician. At the same time, these regulatory bodies must allow for, if not incentivize, individuals and programs to adapt CBME to meet their local environments and innovate in order to meet the needs of the communities that they serve.

Worldwide, there has been steady progress towards achieving the goals of CBME (Fromme et al. 2018; Karthikeyan and Pulimoottil 2019; Veale et al. 2019; Warm et al. 2019; Holmboe et al. 2020); however, the pace by which further change occurs must be quickened if we are to realize the intended benefits of CBME. Systems of professional regulation are increasingly critical actors in this transition and must support and reinforce the progress that has been made and avoid becoming an unintentional barrier to CBME implementation.

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Notes on contributors

Markku Nousiainen, MS, MEd, MD, FRCSC, is Program Director, Division of Orthopaedic Surgery, University of Toronto.

Fedde Scheele, MD, PhD, is Professor of Health Systems Innovation and Education at VU University Amsterdam.

Stanley J. Hamstra, PhD, is Vice-President, Milestones Research and Evaluation at the ACGME, Chicago, Il.

Kelly Caverzagie, MD, is Associate Dean for Educational Strategy, University of Nebraska.

ORCID

Markku Nousiainen http://orcid.org/0000-0002-6750-7768
Stanley J. Hamstra http://orcid.org/0000-0002-0680-366X

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