Instruction and Assessment of the Practice-Based Learning and Improvement Competency

BY

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THESIS

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This thesis is dedicated to my wife, Catherine, without whom it would not have been accomplished and our sons, Ethan and Michael, for providing me with perspectives.

"In science (as in 'everyday life') things must be believed to be seen, as well as seen to be believed; and questions must be answered a little, if they are to be asked at all."

Walter L. Wallace, The logic of science and sociology. New Brunswick: Aldine Transaction, 1971

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LIST OF ABBREVIATIONS

ABMS	American Board of Medical Specialties
ABMS MOC®	ABMS Maintenance of Certification®
ACGME	Accreditation Council for Graduate Medical Education
CFIR	Consolidated Framework for Implementation Research
CLER	Clinical Learning Environment Review
EPA	Entrustable Professional Activity
GME	Graduate Medical Education
HIT	Health Information Technology
HSE	Human-centered Systems Engineering
NAS	Next Accreditation System
PBLI	Practice-Based Learning Improvement
PDSA	Plan-Do-Study-Act
QA	Quality Assurance
QI	Quality Improvement
RRVP	Recognize Resources via Implementation
SBP	Systems Based Practice

SUMMARY

The Accreditation Council for Graduate Medical Education (ACGME) implemented its Next Accreditation System (NAS) which adds a timeline and benchmarks for achieving competencies that "describe the progression of resident competence during training and to culminate in achievement of independent practice." (1, p. 1). The NAS is accompanied by the Clinical Learning Environment Review (CLER) program. The intent of the CLER is to "generate national data on program and institutional attributes that have a salutary effect on quality and safety settings where residents learn and on the quality of care rendered after graduation." (2, p. 1054). The CLER program focuses on using site-teams to gather evidence within GME training sites specifically focused on patient safety, healthcare quality, supervision, transitions in care, duty hours/fatigue management and mitigation, and professionalism (3). Both NAS and CLER are intended to foster a fundamental goal of residency education, to help the resident develop life-long learning skills that support their maintenance of clinical competence.

Life-long learning skills are fundamental to the ACGME *Practice-Based Learning and Improvement (PBLI)* competency that requires residents to demonstrate "the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning" (4, p. 9). One type of resident education program believed to develop PBLI competence uses Quality Improvement (QI) activities that often incorporate a method referred to as Plan-Do-Study-Act (PDSA). These programs culminate in immediate outcomes from the residents' PDSA/QI clinical activities, but whether residents maintain those skills over time or successfully implement PDSA/QI in different clinical contexts is not clear. Successful application of PDSA/QI to different clinical contexts is an outcome that indicates not only learning of this method, but can also serve as a surrogate measure for changes in behavior that exemplify life-long learning that is indicative of PBLI competence.

The primary research question for this study is whether PDSA/QI, when appropriately performed in a clinical setting that allows it to become cyclical or iterative (each cycle provides for serial assessments), can contribute to development of PBLI competence. When a systematic review of that literature (programs that used PDSA/QI to develop PBLI competence) was performed, evidence that residents were instructed and learned PDSA/QI methodology was found, but that skill was not demonstrated in a continuous, serial or iterative manner. This consistent and fundamental deficiency was identified in all of those studies and precluded identification of PBLI competence. While this systematic literature review provided no explicit explanation as to why the PDSA/QI activity was not implemented longitudinally activity, despite its implementation within a resident's longitudinal continuity

clinic, it did suggest that the reason may be related to the residents' "learning environment" or context where the PDSA/QI activity occurred.

The second stage of this literature review explored those learning environments, but the complexity and multifaceted nature of healthcare required a conceptual focus that viewed PDSA/QI as implementation of an innovation. Using implementation theory as a framework facilitated exploration of additional factors or constructs that if unaddressed, impacted the desired outcome of a PDSA/QI program, demonstration of PBLI competence. A realist methodology was used to explore those factors to help explain why some environments could be more supportive of development of PBLI competence.

Implementation theory, and the use of a realist review methodology, identified additional factors or barriers, that if left unaddressed, help explain why PDSA/QI methodology could be learned, but PBLI was still unlikely to develop, even if the one deficiency common to all studies, making the PDSA/QI activity iterative, was addressed. In addition, when used prospectively, implementation frameworks could guide development of more effective programs by identifying and providing an opportunity to address barriers, but the current studies reviewed provided no evidence that their PDSA/QI outcomes resulted in PBLI competence.

I. INTRODUCTION

A. Background

Plan-Do-Study-Act (*PDSA*) is a methodology that was introduced in the business world in the 1950s as a managerial method to maintain product quality and customer satisfaction. Through the use of PDSA, employee(s) measure and interpret unwanted product variance, modify the processes of production and implementation, and then reevaluate the outcomes of their intervention (5). PDSA has undergone further modifications as shown in ***Figure 1***, and incorporation into non-business fields, that include healthcare, especially within process or quality improvement endeavors.

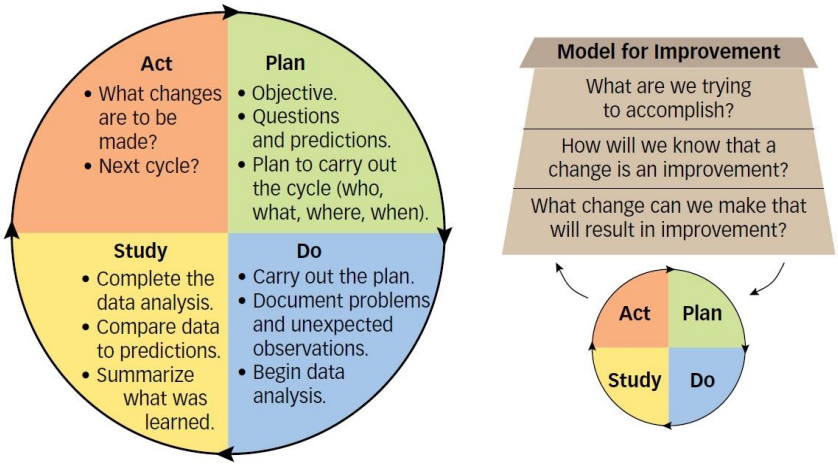


Figure 1. Plan-Do-Study-Act

PDSA has also been adopted by medical residency education and assessment programs as an activity, usually within a Quality Improvement (QI) effort, which can support the development of the *Accreditation Council for Graduate Medical Education* (*ACGME*) competencies of *Practice-Based Learning and Improvement* (*PBLI)* and *Systems-based Practice (SBP)*. So for example, when residents encounter an unexpected outcome in their clinical practice, and on reflection discover a deficiency in their practice, they could use PDSA (usually in a QI activity) to correct that deficiency and "demonstrate" their PBLI competence. If the outcome they identified and successfully addressed with a PDSA activity was the result of a problem within the health care system, then SBP competence is "demonstrated".

Identification of an observable improvement in clinical practice outcomes, by the use of a PDSA/QI activity, signifying a residents' PBLI competence, makes significant assumptions. The first is explicit, namely a PDSA/QI activity, when performed appropriately, represents PBLI competence, and as a competence, will be sustainable and generalize to a resident's future PDSA/QI activities, the same or different, and in other clinical practice situations and environments. The other is an implicit assumption, that differences in health care environments are inconsequential, so success in performing a PDSA/QI activity in one health care environment will result in a similar outcome in a

different setting. However, we know that health care contexts or environments will definitely differ and interactions between residents and context (infrastructure, resources, people, etc.) will impact that activity and often are not under the control of that resident. To not assess, take into account or attempt to address these environmental or contextual differences impacts the interpretation of any PDSA/QI outcome with respect to PBLI competence. In this review, we will explore and clarify these two assumptions: 1) Is "success" in a PDSA/QI activity the same as demonstrating PBLI competence? and 2) What other environment or context factors can be identified that influence an educational PDSA/QI activity and the demonstration of PBLI competence.

The approach chosen to investigate these assumptions included two-steps. We first determined whether the appropriate method of PDSA was used in the QI activity and then what evidence for PBLI competence was demonstrated. Second we identified the context or environment of that PDSA/QI activity to determine how it affected that outcome and what was done to identify and address any unfavorable environmental or context factors to facilitate and support the activity.

An activity that incorporates PDSA/QI and results in clinical practice improvement, constitutes a complex intervention within a complex system because of the multiple interactions between that intervention (PDSA/QI) and the environment or context in which it was used (6). Success is dependent on knowledge and skills, but also on an environment that consists of a multitude of interactions and circumstances, some explicit, but many not explicit. Failure may not reflect a gap in knowledge or skills in the use of PDSA/QI, but an unfavorable pre-existing context in which it was implemented. ***Figure 2*** shows the relationship between context and an outcome and relationship to a resident's PBLI competence.

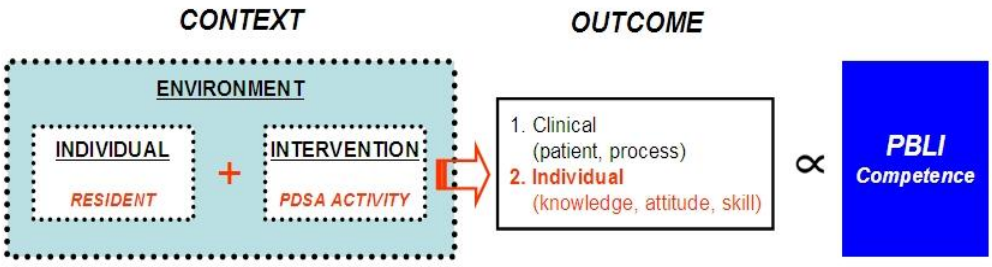


Figure 2. Context, Outcome and PBLI competence

B. **Statement of the Problem**

Predicting an outcome of a PDSA/QI activity is difficult. As healthcare is complex, multifaceted and dynamic, rarely would the same intervention (PDSA/QI) be expected to work the same way in different contexts. However, there is a premise that within certain contexts individuals will make similar choices, and particular contexts influence those choices, so recurring patterns can emerge (7). Since it is unclear as to what works, for whom, in what circumstances as

regards to the development and demonstration of PBLI competency, how can these contexts be identified and then appraised?

To explore this relationship between PDSA/QI context and outcome (PBLI competence), a qualitative synthesis methodology was chosen as an approach to uncover underlying contexts to explain the interactions between intervention (PDSA/QI) and PBLI outcomes (8). The qualitative methodology that appeared to be the most relevant was *Realist Review or Synthesis* since it allows the synthesis of evidence through its focus on explaining why (or why not) an intervention (PDSA/QI) worked and in what ways, or an explanation as distinguished from a judgment about whether it worked (9).

To provide an appropriate framework to facilitate this realist review also requires specification of a set of factors, and relationships among those factors, that can be used to examine and explain the observed outcomes. As a PDSA/QI activity can be considered the implementation of a health care intervention, a relevant framework for a realist review could derive from *Implementation Theory* and those implementation constructs would provide that set of nuanced factors to explore (7).

Of the various implementation theories and frameworks that exist, the *Consolidated Framework for Implementation Research* (*CFIR*) was the particular framework chosen (10). Implementation theories have been regularly and successfully applied to health service outcomes research, but the CFIR is unique as it comprises "… common constructs from published implementation theories" and is "… 'meta-theoretical' – it includes constructs from a synthesis of existing theories, without depicting interrelationships, specific ecological levels, or specific hypotheses." (10, p. 2). As the CFIR was developed by coalescing constructs from over 19 different implementation models, its inclusiveness facilitates identification of what works where, and guides the discovery of why, in different contexts.

C. **Purpose of the Study**

My research questions are: 1.) What evidence is there that the proper use of PDSA, in a QI activity for resident clinical education, results in PBLI competence? and 2.) What environmental or context factors influence an educational PDSA/QI activity and demonstration of the outcome of PBLI competence?

To provide a context for this study, we will describe the educational origin of PDSA, as it provides the rationale for how a "business tool" could be used within the scientific environment of healthcare. Then, we will discuss how the ACGME mandate for resident competencies informed specification of the "components" of PBLI, to provide a

rationale for how I interpreted this complicated competency in order to guide the analysis and synthesis of the perspectives from the studies I reviewed.

D. **Significance of the Study**

In response to societal expectations that healthcare be efficient, effective, affordable and safe, at the level of the individual and in outcomes for populations, the ACGME in 1997 shifted its focus from demonstration of Graduate Medical Education (GME) processes to resident (and program) outcomes, within their framework of competencies (one of which is PBLI) (11). However, support for that initiative was threatened by lack of evidence of the validity of those competency constructs and their assessments (12).

Now, the ACGME has implemented its *Next Accreditation System* (*NAS*), which adds a timeline and benchmarks to those competencies that "describe the progression of resident competence during training and to culminate in achievement of independent practice" (1, p. 1). The NAS is accompanied by the *Clinical Learning Environment Review* (*CLER*) program. The intent of the CLER is "to generate national data on program and institutional attributes that have a salutary effect on quality and safety settings where residents learn and on the quality of care rendered after graduation." (2, p. 1054). The CLER program focuses on using site-teams to gather evidence within GME training sites, and specifically patient safety, health care quality, supervision, transitions in care, duty hours/fatigue management and mitigation, and professionalism (3).

Despite the clear rationale and necessity for such programs, ACGME's advancing to the NAS program does so without providing evidence to support the effectiveness of their prior mandates for competencies, milestones and assessment tools (10, 11). Similarly, concerns and questions exist about the NAS program itself where (1):

1.) Validity evidence for these milestones and assessments have neither been established nor the necessity for substantial faculty development appropriately acknowledged..

2.) Uncertainty about whether the current NAS reporting interval (six months) facilitates assessment or enhances validity of measurements.

3.) Uncertainty if the NAS milestones result in more efficient and effective assessments of resident performance.

4.) Concern that if evidence of the effectiveness of milestones is lacking, will political agendas direct rather than inform medical training?

While both the NAS and CLER programs require significant changes within existing GME programs and assessments, they both hinge on the pivotal need to develop resident life-long learning skills, a stated and perhaps the most important demonstrable outcome of PBLI competency.

Currently, activities that are believed to support or facilitate PBLI often take the form of a QI activity, which frequently incorporates PDSA methodology. Fundamental questions then arise as to whether there is evidence to support the belief that PDSA/QI facilitates the development of PBLI competence and to identify the environmental factors and contexts that contribute (or not) to their success. This study will address these questions by a review of the literature and by first identifying for what type of learner did the PDSA/QI activity work, in what contexts, to what degree and what could explain such patterns. If the activity was successful, then were life-long learning skills demonstrated that support the achievement of resident PBLI competence.

II. CONCEPTUAL FRAMEWORK AND RELATED LITERATURE

A. Educational Foundations of PDSA and its fostering of PBLI competence

The attributes and structure of PDSA (and how it could be used to develop PBLI competence) originates from the philosophical tradition of pragmatism, and specifically the form of pragmatism associated with the Natural Sciences, popularized in the twentieth-century by Charles Sanders Peirce, William James and John Dewey and referred to as *scientific method* or *logical empiricism* (13). Their operational version of pragmatism was the "historical outcome of the many attempts of philosophers, mathematicians, and experimental scientists to avoid sterile speculation, subjective intuitions, and unverifiable hypotheses" (14).

The aspect of pragmatism relevant to the conceptualization of PDSA was popularized by John Dewey and referred to as *experimentalism* or *scientific method*. Dewey believed that experimentalism contributed to the formation and development of the learner when incorporated into the curriculum by the teacher and applied to solving practical or "everyday" problems. However, there are important considerations: i) wherever experimentalism occurs it also influences and impacts upon more than the individual learner and ii) the philosophical view of *fallibilism* or the idea that there is no absolute certainty about knowledge. Fallibilism is our acceptance of the view that new or future evidence may require us to revise our previously held beliefs of both the process and interpretation of the outcome of an intervention (15). Since a chosen approach to address an issue may not provide "the" expected outcome, further attempts with varying approaches and iterations may be necessary and new information may change those earlier interpretations.

The use of real-life problems, the difficulty of separating an individual from their environment, and the realization that the "*instrument*" (action the learner will implement to address the problem) chosen may not lead to the desired result, Dewey believed, would foster learning, flexibility, and development of relationships between experiences and self-reliance. These features and outcomes all represent life-long learning as conceptualized by the PBLI competency.

The steps or activities that Dewey described an individual needing to attempt, when solving their problems through the use of his process of experimentalism, are summarized by Ozmon as (16, p. 123):

1. *A felt difficulty* - that occurs because of a conflict in one's experience or a hitch or block to ongoing experience.
2. *Its location and definition* - establishing the limits or characteristics of the problem in precise terms.

3. *Suggestions of possible solutions* - formulating a wide range of hypotheses.
4. *Development by reasoning of the bearings of the suggestions* - reflecting on the possible outcomes of acting on these suggestions, in short, mulling things over.
5. *Further observation and experimentation leading to acceptance or rejection*- testing hypotheses to see whether they yield the desired results.

Concepts of pragmatism and Dewey's concept of experimentalism were the foundation for a new methodology introduced in industrial manufacturing in the 20th century as a way to improve quality control by using statistical and scientific methods. Such a managerial process was introduced by Shewhart, but more fully developed in subsequent revisions by Deming, and currently known as the *PDSA cycle* (within the United States the *Shewhart cycle, Shewhart Cycle for Learning and Improvement, Deming wheel, Deming cycle, and Deming circle* are also used) (17). An important and critical aspect of this process was its cyclical nature. Its initial purpose was to serve as a managerial process that would maintain the quality of a manufactured product. However, since its introduction, the PDSA model has continued to evolve and now can incorporate predictions or theories as to whether introducing a change will result in improvement if conditions were to vary, but in a more fundamental way it supports learning; see ***Figure 1*** (18).

As expected, PDSA and experimentalism both show significant similarity to our current description of the scientific method that consists of a series of five steps: Ask and define a question *(Plan);* do background research *(Plan);*, form an hypothesis *(Plan);* test the hypothesis *(Do);* analyze the data *(Study);* draw a conclusion and finally decide if your hypothesis is correct *(Study)*. However, it is the *Act* component in PDSA (and its analogy in experimentalism) that is "missing" in the scientific method, yet serves to link the last-step (Study) back to the first-step (plan) and ensures that PDSA and experimentalism can become cyclical and iterative. Both Dewey's experimentalism and PDSA share this step, but this critical component or Act-step is absent in the scientific method.

The relationship between these stages/steps for experimentalism, scientific method and PDSA are further presented in ***TABLE I.*** Yet, one distinction from our current conception of scientific method needs to be made. The iterative aspect of PDSA (or experimentalism) or the *Act* step is not part of the scientific method. We can also characterize PDSA as an "applied science", as there is a specific problem or issue to be solved (assumed to be solvable with current accepted methodologies) and not the act of discovery when a "question is asked", as is the case with the scientific method. Creativity is a component of both, but the process of reflection in trying to clarify something you don't understand, better characterizes the scientific method.

So, the iterative aspect is a fundamental component of PDSA, while observable behaviors and outcomes provide evidence of whether the process of PDSA was understood and successful. Observations performed later help to identify whether PDSA is specific for just a particular context or generalizable and representative of life-long learning. This iterative component (*ACT* step) is critical for PDSA, as it both encourages and permits intervention(s) by learners, and by not necessitating that it be "the solution", facilitates their commitment to long-term participation.

TABLE 1.

COMPONENTS OR STEPS OF DEWEY'S CONCEPT of EXPERIMENTALISM, SCIENTIFIC METHOD AND PDSA.

Dewey's Experimentalism (16, p. 123)	Scientific Method	PDSA activity	
A felt difficulty, that occurs because of a conflict in one's experience or a hitch or block to ongoing experience	Ask a question	**PLAN**	Formulate objectives
Its location and definition, establishing the limits or characteristics of the problem in precise terms	Do background research	**PLAN**	Formulate questions and predictions Develop a plan to carry out the PDSA cycle (who, what, where, when)?
Suggestions of possible solutions, formulating a wide range of hypotheses	Form a hypothesis		
Development by reasoning of the bearings of the suggestions, reflecting on the possible outcomes of acting on these suggestions; mulling things over			
Further observation and experimentation leading to acceptance or rejection, testing hypotheses to see whether they yield the desired results	**Test the hypothesis**	**DO**	**Carry out the plan** **Document problems and unexpected observations** **Begin data analysis**
	Analyze the data **Formulate a conclusion** **Decide if your hypothesis is correct**	**STUDY**	**Complete the data analysis** **Compare data to predictions** **Summarize what was learned**
		ACT	**What changes need to be made?** **Next cycle?**

1. **Considerations in the use of PDSA**

Within business, the focus of a PDSA/QI outcome is the customer (so within healthcare this could be an individual or a population) not the practitioner (in our case the resident) and its goal is often maintenance, not improvement of outcomes. Were PDSA/QI to be incorporated into an activity to develop PBLI competence, success would be reflected as the outcome for that resident, but not necessarily, although usually, a similar positive outcome for their patient(s), the antithesis of PDSA/QI in non-healthcare fields. Whether a PDSA activity can produce an individual (healthcare or system) change is influenced by the same factors that influence any healthcare or system change that relates to dissemination or implementation of a change or innovation (19).

The *Act* step within PDSA appears to be critical, if it is to facilitate life-long learning, by requiring the learner to repeatedly develop a response to a problem that is itself being modified or changed by their prior actions. Iterative practice is a fundamental component in a PDSA/QI activity if it is to foster learning that leads to PBLI competence. This "repetition", or iterative practice, plays the same critical role as repeated practice with feedback, which facilitates the direct and generalizable outcomes of improved retention shown by *testing effects* (20, 21) or achieving mastery of material as demonstrated in deliberate *practice* (22).

One last aspect to consider when PDSA is used can be demonstrated graphically in **Figure 3** (23). When a PDSA activity becomes iterative, it may not follow a smooth and progressive linear course. There may be setbacks, false starts, new directions, the impact of one cycle on future cycles and the realization that each repetition of the cycle may not be complete or have the same significance or eventual impact on the outcome.

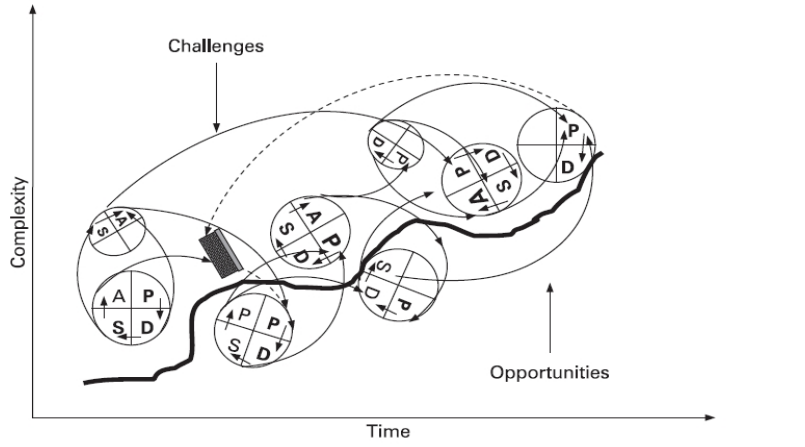


Figure 3. PDSA iterative cycles

Reproduced from [A Case Study of translating ACGME practice-based learning and improvement requirements into reality: System quality improvement projects as the likely component to a comprehensive curriculum. Tomolo AM, et al. Postgrad Med J 85:530-7, 2009] with permission from BMJ Publishing Group Ltd.

Tomolo et al (23) described this dynamic and more realistic representation of the nature of PDSA within their own process of developing a curriculum to teach PBLI to residents, ***See Figure 3***.

B. <u>Historical Foundations: How the development of the ACGME Competencies informs the 'Outcome' of PBLI</u>

1. A "pre-competency" period (24)

A pre-competency period within the United States began in the 1930s' when board certification was under the auspices of the *American Board of Medical Specialties* (*ABMS*) Member Boards to provide "assurance to hospitals and health plans, government and the public that the physicians identified as "board certified" have met specific criteria." In 1940, the idea of a "Time Limit on Certification" appeared in a report published by the Commission on Graduate Medicine as it became increasingly evident that initial certification was insufficient to assure that specialists maintained those competencies throughout their professional career. As continuing competence of physicians was demanded by the public, specialty boards introduced recertification; in 1969 the Boards of Family Practice and of Internal Medicine were the first to develop policies on recertification—the former mandatory, the latter voluntary. By 1995, there were 21 boards that proposed time-limited certificates which required recertification at intervals of 7 to 10 years.

2. The development of competencies

Over a period of time, a consensus emerged through the reports and summaries of six separate organizations (Council on Graduate Medical Education, Pew Health Professions Commission, Association of American Medical Colleges, Federated Council of Internal Medicine, Royal College of Physicians and Surgeons of Canada and the Association of Program Directors of Surgery), that within the current healthcare environment, patient needs and expectations weren't being adequately addressed in the preparation and training of specialist physicians (25).

At this same time, 1994, the ACGME began its own review of graduate medical education, recognized the same important issues of formulating physician-in-training competencies, and also contemplated a shift in their focus of accreditation from process to outcomes. In 1997, they announced this change in the accreditation process by stating, "The ACGME supports the increased use of outcomes assessment in the accreditation process and the development of an overarching model for outcomes assessment in accreditation that can be applied across specialties." (26, pg. 1).

What followed next was a systematic and repetitive process by the ACGME (and others) to identify general competencies for all physicians in training, with the expectation that they would serve as "evidence of residents'

attainment of these competencies as indicators of a residency program's educational effectiveness and quality" and eventually this initiative would become known as the *ACGME outcome project* (27). These groups reviewed the published documents of those 6 organizations and formulated an initial set of 13 competencies, chosen by two criteria: (a) multiple references to the competency across these documents and (b) competencies needed for practice in the emerging health care system as determined by GME organizations. Additional input from organizations, educators, healthcare workers and interest groups eventually led to further refinement, identification (*ACGME Outcome project*) and eventual approval by the ACGME board, of six general competencies expected of all residents in training and to be incorporated within their training programs: *patient care; medical knowledge; practice-based learning and improvement; interpersonal and communication skills; professionalism and systems-based practice* (27, 28).

The authors of the ACGME Outcome Project proposed specific timelines (phases) for integration of these competencies, education programs, and their assessments within GME, beginning in July 2001 (Phase 1 - Begin to identify specific objectives, teaching and assessment) to its culmination set for July 2011 (Phase 4 - Identify benchmark programs or models of excellence) (27, 29). A primary requirement for this initiative and timetable was the development of valid assessments. Difficulty in developing valid and reliable assessments (a persistent concern) led the ACGME to publish an outcome Web site for program directors (*Recognize Success Via implementation, RSVP*) as a forum to describe methods to teach and access these competencies (web page is no longer on the ACGME website; http://www.acgme.org/outcome/implement/rsvp.asp). Agreement between the ACGME, as an accrediting body for GME programs, and the American Board of Medical Specialties, as a certification body for graduates, in regards to the relevance of competencies and outcome assessments was critical to ensure the success of this entire initiative. In 1999, the ABMS approved their *Description of the Competent Physician* that stated "the competent physician should possess the medical knowledge, judgment, professionalism and communication skills to provide high-quality patient care which encompasses the promotion of health, prevention of disease and diagnosis, treatment and management of medical conditions with compassion and respect for patients and their families." (25)

This common set of six competencies was embedded within a recertification process that became known as the *ABMS Maintenance of Certification® (ABMS MOC®)* where certificates are time-limited and physicians must achieve a series of requirements during their recertification cycle. The ABMS MOC® consists of four essential components to maintain certification: i) evidence of professional standing; ii) evidence of commitment to lifelong learning and

involvement in a periodic self-assessment process; iii) evidence of cognitive expertise; and iv) evidence of evaluation of performance in practice (24). This agreement had its own socio-cultural underpinnings and raised the "concern that the competencies have been defined by a political process, rather than an empirical one", but it is not clear how such an undertaking and outcome would have otherwise been possible (30; 31, p. 51). Perhaps of more fundamental importance was the transition of GME to an outcomes model and that concepts of "performance" (role based outcomes are now part of the NAS and linked to behaviourism) and "production" (emphasizes standardization and the end-product) would "inform" the instruction as well as the assessment of competence (32).

C. Practice-Based Learning and Improvement in Competency

1. Definition

PBLI is one of the six competencies identified by the ACGME as a necessary and demonstrable outcome of graduate medical education. It is defined as a capability where "*Residents must demonstrate the ability to investigate and evaluate their care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and life-long learning. Residents are expected to develop skills and habits to be able to meet the following goals:"* (4, p. 9).

- *Identify strengths, deficiencies, and limits in one's knowledge and expertise;*
- *Set learning and improvement goals;*
- *Identify and perform appropriate learning activities;*
- *Systematically analyze practice using quality improvement methods,*
- *Implement changes with the goal of practice improvement;*
- *Incorporate formative feedback evaluation into daily practice;*
- *Locate, appraise, and assimilate evidence from scientific studies related to their patients' health problems;*
- *Use information technology to optimize learning; and*
- *Participate in the education of patients, families, students, residents and other health professionals.*

However, the PBLI competency requires implicit, but unmentioned, pre-existing learner skills, infrastructure requirements, mentoring and environmental conditions to exist if this competency's specific outcomes are to be successfully achieved. These pre-existing conditions must be elucidated and their specific relationship to PBLI described so, my first step is de-constructing the PBLI competence into its "components" and then defining what pre-existing conditions apply.

2. ” Components” of the PBLI competency

To clarify implicit pre-existing conditions necessary for PBLI competence, the “three” components of PBLI competency were separated and further characterized: *Practice Based*, *Learning* and finally, *Improvement*. Deconstructing the PBLI competency was my approach to uncover and examine the underlying constructs related to these three components. While this characterization could facilitate identification of what needs to be taken into account when using a PDSA activity to learn or assess PBLI competency, it will not capture all of the social and dynamic relationships, characteristics, skills or environmental issues associated with development of PBLI competency. In fact, these three PBLI components may be inseparable from one another. However, the rationale of making more explicit the underlying assumptions of PBLI competency by this deconstruction was the hope of providing clarity and direction for my later analysis of a PDSA outcome.

a). “Practice-Based component”

While in part driven by the needs of managed care, changes in health care delivery and clinical practice require residents to develop skills that facilitate a shift in their focus from the care of a patient to the health of a population within their community (33). These skills encompass knowledge that Lurie (34) suggested fell into eight domains, but in an increasingly managed-care environment, required competence in each. The domains she identified were: epidemiologic thinking, human behavior, organizational behavior, information technology, health systems financing, economics and delivery, ethics, systems-based care and finally quality measurement and improvement (34). It is the last domain she identified, *quality measurement and improvement*, which is most relevant to a PDSA/QI activity. When that domain is linked to learning, a quality improvement activity becomes more analogous to a PDSA/QI activity whose goal is continuous quality improvement.

The milieu of clinical practice for health care providers includes problems and experiences they encounter in their day-to-day work. This environment ensures clinical and practical relevance in regards to any quality improvement question of what to measure and improve. However, other variables need to be taken into account, as a medical resident's clinical experiences occur in a practice setting that constitutes an education continuum defined by; to who or what kinds of patients and populations a resident will likely be exposed; when, or the timing of what is learned or experienced will vary with the level of residency training; and where, or the type of setting from which a resident's clinical practice is drawn (35).

These considerations (who, what, when and where) are important when implementing a PDSA activity as is the why, since "any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes" (36). However, quality improvement is meant or defined as an activity that will improve healthcare quality and outcomes through local innovations and adaptation of the processes and systems of care. A resident's clinical continuity clinic setting is clearly an appropriate site for PDSA to be used, but that resident's clinical practice environment needs to be defined.

b. "Learning component"

Learning implies change (not necessarily resiliency or its persistence), and for it to be successful, those internal and external factors that impact learning need to be identified. Yet, what contributes (or detracts from) learning, in general, and specifically within a clinical setting, is complex and may not be easily (if at all) determined or extracted from review of a PDSA/QI activity. Additional determinants of learning depend on the specific educational theory upon which the PDSA intervention is based; identification of all of these factors and "weighting" their impact on a PDSA outcome is not practical. However, identifying and exploring some of those factors is possible.

First, there are factors that are internal, or characteristics of the resident, and will influence their learning. Examples of Internal factors can include: the attribute of self-regulated or self-directed learning which "enable them to undertake realistic reflection on their own knowledge, conceptions, actions and behaviors, and these internal factors all underpin continued professional development" (37, p. 122); an education model, self-regulation, is appropriate to use in the planning and later incorporation into an activity that develops PBLI competence (38). In order to facilitate change, there first needs to be a "tension for change", an actionable alternative, knowledge and skill to do things differently and support for change (16). Effort is also an important consideration and needs to be distinguished from motivation, engagement or self-efficacy, although all are interrelated. By effort, I mean the time and energy a resident will use in addressing the formal requirements of an activity, which includes rule-oriented effort (compliance with basic rules), procedural effort (specific activities that need to be performed), and intellectual effort (time spent and cognitive skills used in understanding material) (39).

Next we need to consider those factors or conditions that are external to the resident; examples of External factors can include: support to be provided by opinion leaders and mentors to allow a PDSA activity to occur and to provide individual (and team) feedback on their performance. Institutional commitment and support is required for

any change, and as multiple participants will often be involved in a clinical setting, the needs and roles of all participants need to be considered (33). Regulatory or accrediting bodies, institutional goals and missions, evidence based guidelines, and the needs of the community, will result in limitations, and changes in the focus of the intervention and influence the role of a resident in a PDSA activity.

Contributing to both internal and external factors is the complexity of workplace learning conceptualized by experiential and sociocultural theories that attempt to define, understand and foster individual development within a clinical practice environment (40).

c. "Improvement component"

The outcome of PDSA is meant to be an improvement and we can expand upon this conceptual outcome by borrowing a definition from public health;

> *"Quality improvement in public health is the use of a deliberate and defined improvement process, such as Plan-Do-Check-Act, which is focused on activities that are responsive to community needs and improving population health. It refers to a continuous and ongoing effort to achieve measurable improvements in the efficiency, effectiveness, performance, accountability, outcomes, and other indicators of quality in services or processes which achieve equity and improve the health of the community."* (41, p. 6).

Yet, what are the quality improvement (QI) activities where PDSA can be applied? Empirical observations suggest that QI activities chosen by healthcare providers fall into major categories, some appearing to align best with PBLI, and others with the SBP competency, as demonstrated by these examples (42, 43):

- *Evidence and quality*
  - Example: Implement evidence based guidelines for diabetic foot care - SBP
  - Example: Create a standard set of ventilator weaning parameters for ICU patients - SBP
- *Competence development*
  - Example: Assessment of simulator training for CVP line placement maintenance of competence - PBLI
  - Example: Self-assessment module for hypertension management -PBLI
- *Proactive patient work*
  - Example: Lifestyle assessment among teenage mothers – PBLI or SBP
  - Example: School based asthma screening - PBLI
- *Organizational process*
  - Example: Designing and testing a change in the strategic management of people to improve organization within the institution - SBP
  - Example: Improving care processes for patients with congestive heart failure - SBP

- *Process technology*
    - Example: Implementation of Electronic Health Record for physician order entry (POE) - SBP
    - Example: Developing a rapid PTT blood test - SBP

By having deconstructed the PBLI competency into its three components, internal and external factors which impact that competency, by their influence on a PDSA/QI activity, can be more clearly identified. Now, using the Consolidated Framework for Implementation Research, we can ensure that these factors are included, as well as additional constructs the CFIR may provide with respect to implementation in general. The CFIR framework will provide further insight into the PDSA/QI activity as it describes the characteristics of those factors that support a favorable (or unfavorable) influence on the PDSA/QI activity and the development or recognition of PBLI competence (10).

III. METHODS

A. Review Purpose

Important and fundamental questions immediately arise when assuming that PDSA/QI facilitates the development of PBLI competence. This literature review will explore and clarify two primary assumptions, using the following questions to frame the review: (i) Is "success" in a PDSA/QI activity the same as demonstrating PBLI competence for that resident? and (ii) What other environment or contextual factors can be identified that influence an education PDSA/QI activity and the demonstration of PBLI competence? Ultimately, the relevance of these questions to health care derives from concerns of regulatory and oversight bodies who emphasize safe and effective patient care outcomes as fundamental learning objectives. In response, QI is increasingly implemented within residency programs, taught within a clinical setting, makes frequent use of PDSA as a tool, and success in the use of PDSA/QI is assumed to be a "surrogate" for PBLI competence. Understanding not only what works or doesn't with respect to PDSA/QI, but why, could constructively inform residency education programs in PDSA/QI and the outcome of PBLI competence.

The importance of identifying the environment or context of a resident's PDSA/QI activity becomes critical in understanding and interpreting its outcome. This could include identifying: a resident's characteristics or skills; the influence and limitations of the system or environment in which they practice; how effectively that environment was used in a PDSA/QI activity; and how their workplace dynamically defines and shapes the activities required of them to complete a PDSA/QI activity (44-46). Not taking into account characteristics of residents and their environment will obscure interpretation of a PDSA/QI outcome and may negate any potential benefits of resources, such as health information technology (HIT) (47). The use of the CFIR framework will ensure that these characteristics or constructs of that environment are captured.

While the first stage of this study was to review the characteristics of the PDSA/QI activities, residents and their outcomes, the second stage, using the framework provided by the CFIR, reviewed characteristics of the environment where the PDSA/QI activity took place and the learners. As no human subjects were involved in this study, IRB approval was not required.

B. Inclusion Criteria

Articles were identified focused on teaching or assessing PBLI competence in residency programs, but only those that incorporated PDSA within a QI activity were chosen for review (48, 49). The criteria used for inclusion

included: (i) involved residents or fellows, regardless of specialty or year of post-graduate education; (ii) activity involved quality improvement and incorporated PDSA; (iii) PDSA/QI activity could involve education or assessment; (iv) PDSA/QI activity was meant to foster or develop PBLI competence; (v) the authors' 'success' in demonstrating accomplishment of their study goals were not criteria for selection, (vi) did not require or presume any conceptual educational models that may have been used to inform the PDSA/QI activity (50-52). Finally, while informed by the CanMEDS competency framework (53), the focus of this study was on the current mandated physician competency based outcomes used within the United States as defined by the ACGME.

The *key-terms (and synonyms or related terms)* used to guide article selection include:

(i). ***Practice-Based Learning*** ("practice-based learning and improvement", "practice-based learning" and "practice based improvement").

(ii). ***Competency*** ("*competency", "general competencies", "competency based education" and "professional competence"*).

(iii). ***Self-assessment*** ("*self-assessment" and "self-monitoring"*).

(iv). ***ACGME*** ("*Accreditation Council of Graduate Medical Education" and "ACGME")*.

(v). ***PDSA*** ("*quality improvement", "Plan-Do-Study-Act,", "PDSA cycle,", "Deming cycle" and "Deming wheel*").

(vi). ***Graduate Medical Education*** (*GME*), ***Undergraduate Medical Education*** (*UME*), ***post-licensure physicians*** *(Continuing Medical Education, CME) and the term "medical education".*

Key term selection was chosen to be as broad as possible in order to capture articles that would most likely contain a PDSA/QI activity.

C. Search Strategy (54)

After consultation with a health sciences librarian, a search strategy was developed that used the Psychinfo, Eric and Medline databases. Despite the focus on Graduate Medical Education (*GME*), Undergraduate Medical Education (*UME*), post-licensure physicians (Continuing Medical Education, *CME*) and the term "*medical education*" were included to ensure inclusion of relevant articles that may have incorporated overlapping learner groups. An earlier literature survey helped to identify all key words or vocabularies that were specific to each database and used to inform this search strategy, but modified to ensure that each of those earlier papers would be retrieved in this current search.

The literature was originally searched, to include work from 1999 until September 2011 (later updated to July 2013) and restricted to English-language papers. The Grey literature (e.g., papers presented at professional meetings, doctoral dissertations) was not included. Assistance of a health sciences librarian (Loyola University Chicago, Stritch School of Medicine; Gail Hendler, MLS; ghendler@luc.edu) was used to guide this search strategy.

D. Study Selection

The specific key-word searches chosen used the following topic categories: Practice-Based Learning ("practice-based learning and improvement", "practice-based learning" and "practice-based improvement"), Competency ("c*ompetency", "general competencies", "competency based education" and "professional competence"*), Self-assessment ("*self-assessment" and "self-monitoring"*) and ACGME ("*Accreditation Council of Graduate Medical Education" and "ACGME")*. This search strategy was undertaken to be as broad as possible to capture articles that would most likely contain a PDSA activity. These search results became the *Primary database* from which PDSA/QI activities in GME would be identified ("quality improvement", "Plan-Do-Study-Act", "PDSA cycle", "Deming cycle" and "Deming wheel"). This *Primary database* then became the source of my *Final Review Database* of studies that included within their titles or abstracts a PDSA/QI activity meant to develop or access PBLI in a GME context.

Articles in this *Final Review Database* were placed into two categories. The first category (Category 1) included those papers that presented descriptions of instructional or assessment modalities used in specified groups, papers that explicitly stated that their aim was to develop an education program and/or test a PDSA/QI activity related to PBLI or papers that presented any kind of result with PDSA/QI based on previously unpublished experience in a specific sample. The second group (Category 2) consisted of opinion pieces, review articles and reports of consensus conferences. This second group assisted in identifying changes in the conceptualization of PDSA and PBLI, and instructional or assessment trends and provided another opportunity to identify original literature sources (by reviewing their bibliographies) that may have been overlooked by my search strategy. It also provided an opportunity to perform a separate cited-reference review using the *Web of Science*, for papers that cited them and papers they cited; the flow of study selection is shown in ***Figure 4*** (55).

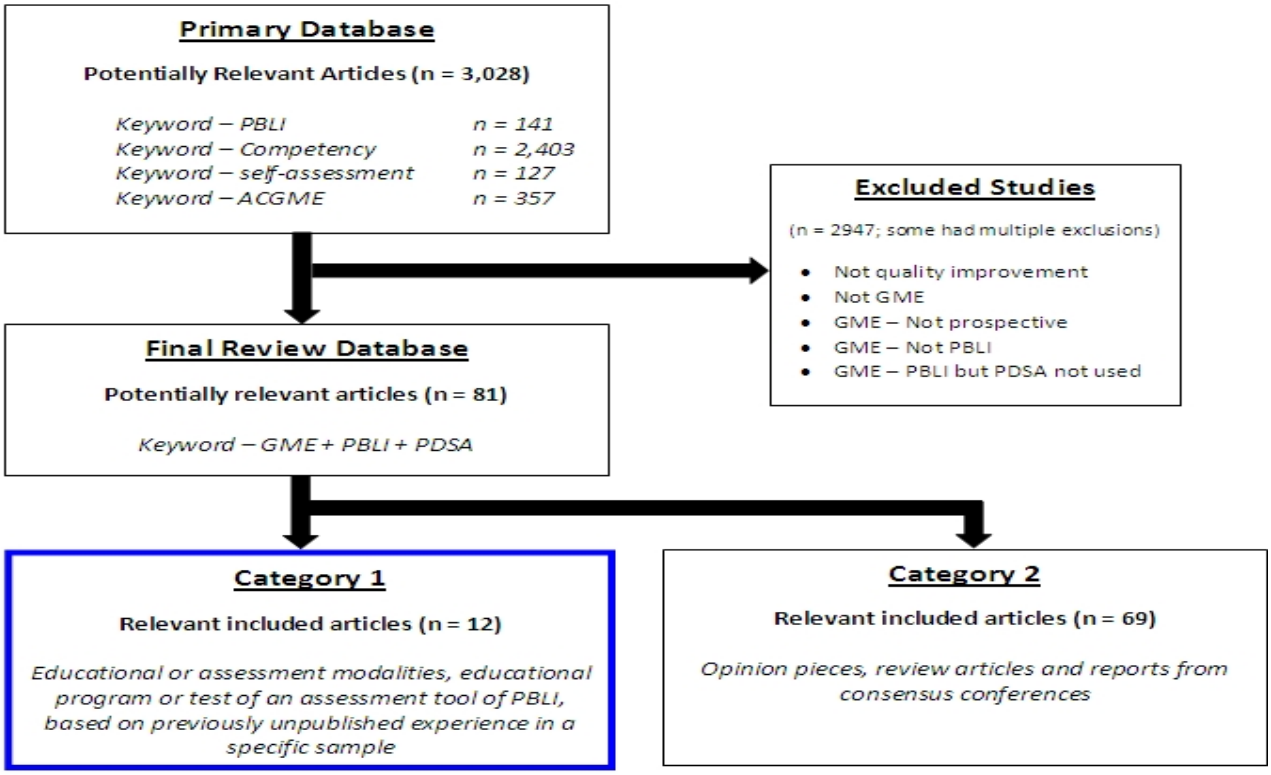


Figure 4. Study flow and article selection criteria for review

In order to maintain citations and abstracts, all search results were imported directly into the bibliographic management software Endnote® (Endnote Version X6; Thompson Reuters San Francisco, California, USA). This approach facilitated identification and elimination of duplicate references and the opportunity to enter information from a standardized data-coding sheet directly into customizable fields within this bibliographic database (56). The major source of articles and information identified was through the review approaches described. However, another potential source was the Accreditation Council for Graduate Medical Education website.

E. Data Abstraction

The references within Category 1 were each reviewed and the following information abstracted (***Figure 5***) and incorporated into ***TABLE III*** of the results section. Category 2 references were separately reviewed and served to provide additional background information concerning PDSA/QI and PBLI development, standardization and "state-of-the-art" developments.

FIGURE 5. Data abstraction template

1. Study name and year published
2. Setting
    a. Patient population (e.g., ambulatory or inpatient, insurance)
    b. Site (e.g., type of clinic setting, characteristics of resident training institution)
3. Learner
    a. Number of residents, year of training, specialty
4. Improvement activity
    a. Type of activity: Evidence and Quality, Competence Development, Proactive Patient Work, Organizational Process, Process Technology
    b. Iterative or non-iterative
5. Outcome evaluation method
    a. Individual Outcome (e.g., survey, pre/posttest, self-assessment)
    b. Clinical Outcome (e.g., controlled, uncontrolled, pre/ost chart review, patient survey
6. Outcomes
    a. Resident
        i. Brief, relevant and descriptive comment on resident outcome (stated within the article)
        ii. Effectiveness level
            1. Level 1 – Participation
            2. Level 2a – Modification of attitudes/perceptions
            3. Level 2b – Modification of knowledge/skills
            4. Level 3 – Behavioral change
            5. Level 4a – Change in professional practice
            6. Level 4b – benefit to patient/clients
    b. Clinical
        i. Patient – As identified within the study (e.g., beneficial)
        ii. Process – As identified within the study (e.g., beneficial)

The Category 1 articles were later reviewed again by using the Consolidated Framework for Implementation Research (CFIR) and a realist review methodology to address the "three components of PBLI" by asking the following questions: For what type of learner did the PDSA/QI activity tend to work, in what kinds of contexts, to what degree, and what could explain such patterns (57)? This synthesis was used to formulate the conclusions found in ***TABLE IV***.

F. <u>Analysis</u>

Study quality was accessed by using the M*edical Education Research Study Quality Instrument* (*MERSQI*) and summarized in **TABLE II** (58). Scoring was typically done to the highest possible level for each item, and in those studies where multiple residency activities were performed, only those that represented PDSA/QI were used to develop a score. However, for items 5-7 that dealt with *type of data* and the *validity of the evaluation instrument* used in each study, a more stringent scoring process was followed, when a score of 1 was applied. The item descriptions in MERSQI are based on the criteria formulated by Beckman et al and the score of 1 corresponds to their score of 2 (59). In

addition, the score assigned to those domains reflected that instrument's relationship to the characteristics or outcome expected of PBLI competence and the use of the instrument to capture that outcome, PBLI competence.

The descriptions of items 5-7 (based on Beckman et al, 59) are: *Internal structure (MERSQI score of 1)* – "Factor analysis confirming anticipated data structure, or multiple measures of reliability. Variation in response to specific items among subgroups (differential item functioning) can support or challenge internal structure depending on predictions"; *Content (MERSQI score of 1)* – "Well-defined process for developing instrument content, including both an explicit theoretical/conceptual basis for instrument items and systematic item review by experts"; and *Relationship to other variables (MERSQI score of 1)* – "Correlation (convergence) or no correlation (divergence) between assessment score and theoretically predicted outcomes or measures of the same construct. Such evidence will usually be integral to the study design, and anticipated a priori".

Each study was first reviewed with regard to the characteristics and outcomes of the residency PDSA/QI activities and tabulated as shown in ***TABLE III***. Next, each study was reviewed using a realist methodology approach to assess outcomes that occur in a complex (healthcare) environment and where those outcomes are sensitive to variations in the context of that environment. The realist review is not intended to determine 'if something works or not', but rather 'what works, for whom, and in what circumstances'. Those conclusions were used to generate the summary that comprises ***TABLE IV***. The five steps used in a realist review can be summarized as (9):

Step 1- Clarify the scope and identify the review question*:* (i) Is "success" in a PDSA/QI activity the same as demonstrating PBLI competence for that resident? and (ii) What other environment or context factors can be identified that influence an educational PDSA/QI activity and the demonstration of PBLI competence?

Step 2 - Search for evidence: Described in sections IIIB, C and D above.

Step 3 - Appraise primary studies and extract data: *Assessment of relevance and rigor of their conclusions*.

A realist review is typically conducted by a group of investigators where each could be conceived as representing a different, but relevant, stakeholder with respect to the topic under review. Recognizing the limitation of a single investigator conducting a review necessitates further transparency in both the method used to reduce bias and random error in data abstraction and justification for my data extraction form.

To incorporate an appropriate framework, a PDSA/QI activity was considered implementation of a health care intervention and so, Implementation theory was chosen to provide the review framework.

Implementation theories have been regularly and successfully applied to health service implementation research and these implementation constructs provide a more nuanced set of questions to explore the PDSA/QI environment. This specification of this set of constructs, and relationships among them, could then be examined and used to explain the observed outcomes.

Of the various implementation theories and frameworks that exist, the *Consolidated Framework for Implementation Research* (*CFIR*) was the framework chosen for this review (10). The CFIR is unique, as it was developed by coalescing constructs from over 19 different implementation models, so its inclusiveness facilitates identification of what works where and guides the discovery of why in different contexts. The CFIR is also unique as it comprises "common constructs from published implementation theories" and it is "'meta-theoretical' – it includes constructs from a synthesis of existing theories, without depicting interrelationships, specific ecological levels, or specific hypotheses." (10, p. 2). This inclusiveness of the CFIR helps to overcome any pre-existing bias that could result from choosing a more restricted or focused framework to perform this review.

To address the issue of bias and random error, when a single investigator uses the *CFIR* constructs (see **Appendix A** (10)), articles were reviewed and information extracted for entry into **TABLE IV** in two separate steps. First, each study was individually reviewed to develop a perspective in regards to its 'success' in addressing each of the constructs listed within the CFIR. Second, after a period of time, the articles were again individually reviewed, but now with respect to one CFIR construct at a time. This second step not only served to further clarify the interpretation of each construct with respect to all of the studies, but also helped to ensure that these interpretations were consistently applied across all of them. To guide my judgment, further clarification and examples of each construct were available within the publication by Damschroder, et al (11) as well as within their expanded appendix; a brief description of these CFIR constructs are provided in **Appendix A**. Only the results of this second review were used to arrive at the decision for entries in **TABLE IV.**

An additional approach to address the limitations of a review by a single investigator led to a decision to 'color code' the responses in **TABLE IV** rather than attempt to assign each a value that would 'suggest' a quantitative assessment, and this decision was based on the following rationale. First, I realized that many constructs could be effectively (or ineffectively) addressed by several different mechanisms or actions, and it would be difficult for a single investigator to determine equivalency or ranking among them and then

determine an appropriate methodology to individually assign each a weight and then summarize them. Normally a more quantitative process would occur through discussion among a group of investigators in a realist review. Second, it was still necessary to display some sort of 'summary opinion' of the effect (or lack) of any intervention on a specific construct. A decision was made to use a color to visually highlight the degree to which the study authors' successfully addressed (or not) that particular CFIR construct. The color scheme chosen was elementary in that green indicated a favorable, yellow an intermediate and red an ineffectual response to that construct. If information provided within the study was inadequate to develop an opinion, or perhaps nothing was done, then this was symbolized by the color grey. However, colors were not meant to indicate equivalency with respect to how the same construct was addressed across all studies, but rather to provide a *representation of the effectiveness* of those interventions for that particular construct in that specific study.

Step 4 - Synthesize evidence and draw conclusions: *Determine what works for whom, how and under what circumstances.*

Step 5 - Disseminate, implement and evaluate*: Recommendations and conclusions, e.g., compare official expectations with actual practice.*

IV. RESULTS

A. Trial Flow

The number of articles retrieved from each database and the search terms/strategy used are described in **Figure 4**. The original search was subsequently updated to July 2013 and yielded no additional articles in Category 1, but four additional articles in Category 2. A total of 12 articles were included in Category 1 that fulfilled this study's primary search criteria: incorporated a PDSA/QI activity to prospectively address the development or assessment of PBLI competency within a residency-training program.

B. Study Characteristics

The studies were all reported over a short interval of time, 2003 to 2008, despite a search strategy that extended from 1999 until July 2013. There is no evidence to suggest that this earlier publication 'surge' signifies a current lack of use or interest in promoting, implementing or training in PDSA/QI in healthcare. Current healthcare initiatives and regulatory reports continue to support acceptance of its relevance and methodologies of instruction. While it is only a conjecture, lack of similar publications since 2008 could signify the acceptance of the current instructional methods to learn QI using PDSA and the belief that PBLI competency is developed in those who successfully participate in PDSA/QI activities. However, there still remains a possibility that relevant publications may still have been missed despite the search strategy employed.

C. Study Quality

Total MERSQI scores among the 12 studies ranged from 6.5 to 13, with a mean (SD) of 7.83 (1.98). Mean domain scores were highest for sampling (2.04), data analysis (1.58) and study design (1.38); they were lowest for validity of the evaluation instrument ($\sim$ 0.0) and type of data (1.17) (**TABLE II**). Of the 12 studies, 10 used single group cross-sectional or single-group pre- and posttest designs (**TABLE II**), 2 included a comparison group and none were randomized. Only one study was multi-institutional.

Study quality was further appraised with respect to demonstration of resident PBLI competence and regardless of achieving education or patient care outcomes. Scoring in the domain of *validity of evaluation instrument* was based on identification of an instrument that could measure PBLI competence and whether the relevant information concerning its internal structure, content and relationship to other variables was explicitly stated. Different instruments were used

or developed, but the most relevant was based on the Theory of *Commitment to Change,* used by Holmboe et al to develop a resident questionnaire from which a qualitative review of resident comments was performed (60). Three studies (Varkey et al, 2006; Ogrinc et al, 2004; and Oyler et al, 2008) used the *QI Knowledge Application Tool (QIKAT,* revised as the *QIKAT-R)* which is a three clinical case scenario test which assesses the application of QI knowledge (61). Scoring is subjective and it has not been validated using psychometric testing, "but certainly holds up well in practical application" (62). Nuovo et al (2004) used an assessment survey tool that "was developed and tested as part of a *Robert Wood Johnson/Partnerships in Quality Education Care Initiative"*; while the survey was shown, no further information as to its development or properties was provided. Djuricich et al (2004) used their own assessment tool that was also used in a separate study by Canal et al (2007), but only partial details were provided with respect to the characteristics and validity of the instrument. Warm et al (2008) incorrectly referenced within their article the instrument they used, *Veteran Affairs Learners' Perception Survey* that was originally developed to serve as a quality indicator tool of residents' perception of VA training programs (63). The remaining studies (Coleman et al, 2003; Mohr et al, 2003; Frey et al 2003; and Ziegelstein et al, 2004) all used a self-developed resident survey that was meant to assess achievement of the learning objectives of a PDSA/QI education program and the resident's perception as to whether it was subsequently easier to implement such activities in their practice.

In summary, essentially all of the studies lacked evidence of a valid evaluation instrument that would identify resident PBLI competence; demonstrating a long-term change in their behavior by demonstrating that the skills of performing PDSA/QI were incorporated into their clinical practice and accompanied by sustained improvement in patient care outcomes. Instead, the instruments or survey tools focused on identifying the achievement of program objectives (knowledge and immediate patient care outcomes related to the associated clinical activity), resident perceptions of knowledge of PDSA/QI, and whether they felt they would be able to incorporate those skills into their practice.

TABLE II. STUDY QUALITY (Evidence for PBLI competency resulting from a PDSA/QI activity)

Domain	MERSQI item	Potential score	*Holmboe, et al (2005)*	*Varkey ,et al (2006)*	*Coleman, et al (2003)*	*Mohr, et al (2003)*	*Ogrinc, et al (2004)*	*Nuovo, et al (2004)*	*Canal, et al (2007)*	*Oyler, et al (2008)*	*Warm, et al (2008)*	*Frey, et al (2003)*	*Djuricich, et al (2004)*	*Ziegelstein, et al (2004)*
Study Design	***1. Study Design***													
	Single group cross sectional or single group posttest only	1			X	X					X	X		X
	Single group pretest and posttest	1.5		X				X	X	X			X	
	Nonrandomized, 2 groups	2	X				X							
	Randomized controlled trial	3												
Sampling	***2. No of Institutions studied***													
	1	0.5	X	X	X	X		X	X	X	X	X	X	X
	2	1					X							
	>2	1.5												
	3. Response rate, %													
	Not applicable													
	<50 or not reported	0.5												
	50 - 74	1												
	≥ 75	1.5	X	X	X	X	X	X	X	X	X	X	X	X
Type of data	***4. Type of data***													
	Assessment by study participant	1		X	X	X	X	X	X	X	X	X	X	X
	Objective measurement	3	X											
Validity of evaluation instrument	***5. Internal structure***													
	Not applicable				X	X					X	X		X
	Not reported	0		X			X	X	X	X			X	
	Reported	1	X											
	6. Content													
	Not applicable				X	X					X	X		X
	Not reported	0		X			X	X	X	X			X	
	Reported	1	X											
	7. Relationship to other variables													
	Not applicable				X	X					X	X		X
	Not reported	0	X	X			X	X	X	X			X	
	Reported	1												
Data analysis	***8. Appropriateness of analysis***													
	Data analysis inappropriate for study design or type of data	0			X	X					X	X		X
	Data analysis appropriate for study design or type of data	1	X	X			X	X	X	X			X	
	9. Complexity of analysis													
	Descriptive analysis only	1	X	X	X	X	X	X	X	X	X	X	X	X
	Beyond descriptive analysis	2												
Outcomes	***10. Outcomes***													
	Satisfaction, attitudes, perceptions, opinions, general facts	1				X					X	X		
	Knowledge, skills	1.5		X	X		X	X	X	X			X	X
	Behaviors	2	X											
	Patient/health care outcome	3												
	Total Score	18	13	8	6.5	6	9	8	8	8	6	6	8	6.5

D. Summary of results and outcomes of resident PDSA/QI activity

1. Characteristics and outcomes of residency PDSA/QI activities

TABLE III presents a list of the studies reviewed and includes the setting, learner, improvement activity and their immediate outcomes. In regards to the "Practice-Based component" of PBLI competence, all activities were predominantly conducted within an ambulatory setting of a resident's continuity clinic in an Academic Medical Center. This patient population may not be comparable to one encountered by a practicing physician in regards to payer or role (urban safety net), but appropriate in regards to a resident's exposure/experience within their residency program.

Resident continuity clinics serve as longitudinal clinical experiences that provide long-term patient care and allow health care outcomes to be observed and measured. To be effective, a PDSA/QI activity requires the activity to be iterative and, fortunately, a resident's continuity clinic provides the opportunity to document a change in a resident's behaviors (or attitudes) as demonstrated by persistence/improvement of their patient care outcomes or generalization of similar improvements to other healthcare outcomes. Patient healthcare improvement and its persistence supports the occurrence of "learning" by the resident and can indicate PBLI competence. However, none of the studies made use of this continuity clinic structure to incorporate the repeated use of their PDSA/QI activity or to document serial patient care outcomes that would support the development of PBLI competence. As the iterative nature of PDSA/QI is fundamental or critical if PBLI competence is to develop and demonstrated, it is unlikely that any of the observed outcomes could be considered as evidence of PBLI competence stemming from PDSA/QI activities. The education programs used in each study were effective in demonstrating that residents learned PDSA/QI methodology, consistent with the findings of Boonyasai et al (2007) in their systematic review of the teaching of quality improvement; education programs were effective in teaching PDSA/QI methodology (64).

The PDSA/QI activity most often implemented in these studies were in the category of *Evidence and Quality*, which is relevant to PBLI competency, while other activities chosen were more akin to those that would foster SBP competency. Only those activities designed to foster PBLI were included in this review and analysis. The PDSA/QI activities implemented in these studies while predominantly focused on Evidence & Quality, Process technology, Organizational process, Proactive patient work and Competence development were also used (43). All of these areas are appropriate for a quality improvement intervention since they could incorporate PDSA methodology. While the individual residency topics differed across studies, activities were chosen on an identified deficiency or need and that relevance was meant to encourage resident participation and incorporation of their specific PDSA/QI activity within that resident's clinical practice. The resident PDSA/QI activities undertaken were quite diverse and in some cases could be

placed within different categories or if modified, assigned to one specifically, but generally seemed to fit best into one of the mentioned groupings.

Activities within the category of Evidence & quality focused on integrating best practices or evidence based medicine into an organization and examples from these studies include: updating and keeping current patient medication lists, checking and then ordering appropriate immunizations for children, following clinical health care screening guidelines or evidence based standards, increased screening for depression in transgender patients, increasing use of sterile barrier precautions in the medical ICU to decrease catheter infections, ensuring effective rule-based management of anticoagulation, standardizing documentation of chronic care evidence based measures (diabetes monitoring metrics, vaccination documentation, colonoscopy screening, annual influenza vaccine administration)

Process technology would include introduction of a new process or methodology and examples from these studies are: enhance performance of outpatient medication reconciliation by developing a new outpatient medication history collection sheet, modifying processes to improve resident reconciliation and subsequent medication list dictation of dosage and frequency, modifying an existing office practice to ensure that diabetes quality of care interventions (checking for microalbuminuria) are instituted, implementing a new process to reduce needle stick injuries in students and residents, developing a heart failure database to improve quality of patient care, implementing a new process to ensure the recording of patient heights to allow BMI determination.

The focus of Organizational process is improving clinical pathways within or between organizational sections of an institution and exemplified by these resident activities: coordinating follow-up after admission for acute pain crisis from sickle cell disease, decreasing wait time for non-English speaking patients with biliary colic for their referral to a surgery clinic for cholecystectomy, improving the prescription refill process to streamline the transition from inpatient care to the ambulatory clinic and ensure medication list accuracy.

Proactive patient work involves supporting patients in self-care or life-style changes and exemplified by: assessing osteoporosis knowledge and risk factors for ambulatory patients, reducing barriers to discuss advance care planning discussion in the outpatient clinic.

Competence development refers to activities that involve training and education that increase knowledge and competence and exemplified by developing and using a resident learning portfolio (patient lists, procedural logs, learning objectives, goals, attendance at conferences) and later discussed during residency feedback sessions with their residency program director.

Review of the outcomes, presented in **TABLE III,** were separated into those that (a) focused on the resident and (b) focused on their patients' clinical outcomes. The majority of studies (8/12) did not describe a patient outcome, but when such outcomes were evaluated, improvements in the measured parameters were identified and described, supporting the immediate effectiveness of those PDSA/QI activities. There were also beneficial effects on patient care processes described in the majority of studies (9/12).

When assessing the effectiveness of the PDSA/QI activity for a change in knowledge, attitudes or behaviors of the residents, the outcomes achieved were a *Level 2b* (modification of knowledge/skills), but in three studies there was a suggestion that a behavioral change may have occurred or was noted (Level 3). Demonstration of PBLI competence requires the study outcome to demonstrate a persistent change in a resident's professional practice (Level 4a) or a consistent benefit to their patients (Level 4b). Assigning a Level 4a or 4b would have been possible if the study incorporated an iterative use of PDSA/QI in the resident's continuity clinic as this would have allowed serial patient healthcare outcomes to be measured, but this use of PDSA/QI was absent from all the studies reviewed.

TABLE III

CHARACTERISTICS OF RESIDENCY QUALITY IMPROVEMENT ACTIVITY OUTCOMES WHICH INCORPORATED PDSA

Study, year	Setting		# of Residents and specialty	Improvement activity[a]	Outcome evaluation method	Outcomes[b]	
	Patient population	Site				Resident[c]	Clinical
Holmboe, et al (2005)	Ambulatory Medicaid and uninsured patients	Resident continuity clinic Community based clinics	13 – PGY2 Primary Care Internal Medicine residents versus 13 – PGY3 Primary Care Internal Medicine residents	Evidence and Quality (Diabetes quality metrics) **NOT ITERATIVE**	Individual Survey Clinical Non-RCT Pre/post chart review	"modest improvement" LEVEL 3 (Not clear)	Patient – "modest improvements" (beneficial and null) Process - Mixed (beneficial and null)
Varkay, et al (2006)	Ambulatory	Preventive & Occupational Medicine clinic Academic Medical Center	5 – 2 Family Medicine, 1 Internal Medicine & 2 Preventive Medicine fellows	Process Technology (medication reconciliation) **NOT ITERATIVE**	Individual Survey Pre/post knowledge Clinical Uncontrolled Pre/post chart review	"confident they can improve health care locally" LEVEL 2b	Patient – Not clear Process - Only beneficial
Coleman, et al (2003)	Ambulatory	Resident training site (3 separate sites) Academic Medical Center	19 – residents placed into 3 teams	Process Technology (documentation; diabetes quality metrics) **NOT ITERATIVE**	Individual Survey Clinical Uncontrolled Pre/post chart review	"improved clinical practice" LEVEL 2b	Patient – Not clear Process - Only beneficial
Mohr, et al (2003)	Ambulatory Medicaid (54%) and uninsured (11%) patients	Resident continuity clinic Academic Medical Center	8 – PGY2 and PGY3 Pediatric residents	Evidence & Quality (immunization rate) **ITERATIVE?**	Individual - Not clear Clinical Uncontrolled Pre/post chart review	"Not clear" LEVEL 2b (Not clear)	Patient – Only beneficial Process - Only beneficial
Ogrinc, et al (2004)	Ambulatory and inpatient	Clinic & inpatient Academic Medical Center affiliate	11 – 3 PGY2, 7 PGY3 and 1 PGY4 versus 22 – "matched" Internal Medicine residents	Evidence & Quality (4 projects), Organizational Process (4 projects), Proactive Patient Work (2 projects) **NOT ITERATIVE**	Individual Self-assessment Pre/post exam Clinical Uncontrolled Pre/post chart review	"high satisfaction with curriculum goals" LEVEL 2b	Patient – Beneficial Process - Mixed (beneficial and null)
Nuovo, et al (2004)	Ambulatory	Resident continuity clinic Academic Medical Center	36 – Family Medicine residents	Evidence & Quality (Medication lists) *Proactive Patient Work (Not a Learner PDSA)* *Process Technology (Not a Learner PDSA)* **NOT ITERATIVE**	Individual Pre/post knowledge test Survey Clinical - Not clear	"more meaningful care, treatment, management of patients with diabetes" LEVEL 2a	Patient – Not clear Process - Only beneficial

[a] **Improvement activity category**: Evidence and Quality, Competence Development, Proactive Patient Work, Organizational Process, Process Technology

[b] When possible a brief, relevant and descriptive comment of resident 'outcomes' stated within the article is shown, but statistical significance of resident outcomes in general were not assessed

[c] **Resident outcome effectiveness level**: Level 1 – Participation; Level 2a – Modification of attitudes/perceptions; Level 2b – modification of knowledge/skills; Level 3 – Behavioral change; Level 4a – Change in professional practice; Level 4b – Benefits to patient/clients

TABLE III

CHARACTERISTICS OF RESIDENCY QUALITY IMPROVEMENT ACTIVITY OUTCOMES WHICH INCORPORATED PDSA (CONT.)

Study, year	Setting		# of Residents and specialty	Improvement activity[a]	Outcome evaluation method	Outcomes[b]	
	Patient population	Site				Resident[c]	Clinical
Canal, et al (2007)	Ambulatory and Emergency Medicine Department	Clinic and Emergency room Academic Medical Center	15 – PGY3 surgery residents	Proactive Patient work *Organizational Process (Not a Learner PDSA)* **NOT ITERATIVE**	Individual Pre/post knowledge test Survey Clinical - Not Clear	"curriculum process was a good one" LEVEL 2a	Patient – Not clear Process - Not clear
Oyler, et al (2004)	Ambulatory	Resident ambulatory clinic Academic Medical Center	34 – PGY2 internal medicine residents	Evidence and Quality (Clinical preventive services) **NOT ITERATIVE?**	Individual Pre/post self-assessment Clinical Uncontrolled Pre/post chart review	"positive reaction to curriculum" LEVEL 3 (Not clear)	Patient – Not clear Process - Only beneficial
Warm, et al (2008)	Ambulatory (Urban Safety-Net practice)	Resident ambulatory clinic Academic Medical Center	108? – PGY1-2 and PGY2-3 Internal Medicine residents	Evidence and Quality (Evidence based medicine standards) **NOT ITERATIVE**	Individual Survey Clinical Uncontrolled Pre/post chart review Patient survey	"increased personal reward" LEVEL 2a	Patient – Predominantly beneficial Process - Only beneficial
Frey, et al (2003)	Ambulatory	Clinic Academic Medical Center affiliate	12 – PGY3 Family Practice residents	Evidence and Quality (Clinical guidelines) **NOT ITERATIVE**	Individual Post self-assessment Clinical Uncontrolled Pre/post chart review	"high level of physician confidence" LEVEL 2b	Patient – Not clear Process - Only beneficial
Djuricich, et al (2004)	Ambulatory	Resident ambulatory clinic Academic Medical Center	42 – PGY3 Internal Medicine + PGY2 Pediatric residents	Evidence and Quality (Not clear) **NOT ITERATIVE**	Individual Pre/post knowledge test Clinical – Not clear	"knowledge and self-efficacy improved" LEVEL 2b	Patient – Not clear Process - Not clear
Ziegelstein, et al (2004)	Ambulatory	Resident continuity clinic Academic Medical Center affiliate	44 – Internal Medicine residents	Evidence and Quality (Clinical guidelines) Competence development (learning portfolio) **ITERATIVE?**	Individual Retrospective pre/post self-assessment Clinical Uncontrolled Pre/post chart review	"improved their proficiency in PBLI" LEVEL 2b	Patient – Not clear Process - Not clear

[a] **Improvement activity category**: Evidence and Quality, Competence Development, Proactive Patient Work, Organizational Process, Process Technology

[b] When possible a brief, relevant and descriptive comment on resident 'outcomes' stated within the article is shown, but statistical significance of resident outcomes in general were not assessed

[c] **Resident outcome effectiveness level**: Level 1 – Participation, Level 2a – Modification of attitudes/perceptions, Level 2b – modification of knowledge/skills, Level 3 – Behavioral change, Level 4a – Change in professional practice, Level 4b – Benefits to patient/clients

2. Implementation analysis (CFIR) of residency PDSA/QI activities

This next review was performed by using a framework derived from implementation theory, the *Consolidated Framework for Implementation Research* (*CFIR*). The CFIR was developed by coalescing items from over 19 different implementation models, so its inclusiveness facilitates identification of what works where and guides the discovery of why in different contexts (10). This inclusiveness of the CFIR helps to overcome any pre-existing bias that could result from choosing a more restricted or focused framework to perform my review. The CFIR is also unique as it is "'meta-theoretical' as it includes constructs from a synthesis of existing theories, but without depicting interrelationships, specific ecological levels, or specific hypotheses." (10, p. 2).

The CFIR is comprised of five major domains and each domain consists of several related constructs, a total of 26, each more fully described within **Appendix A**. The domains are:

- Intervention characteristics – descriptions or key attributes of the characteristics of an intervention.
- Outer setting –characteristics of the environment, external to the site or organization where the implementation will occur, but still influencing it.
- Inner setting – includes the actual environment or context (e.g. structural, cultural) where the implementation will occur.
- Characteristics of individuals –specific to the individuals who are involved with the implementation.
- Process - actual steps of the implementation, individuals as well as plan.

Using a realist methodology, each study was reviewed by following the process described in the methodology section, resulting in an assessment of their effectiveness in addressing each of the 26 individual constructs of the CFIR. ***TABLE IV*** summarizes those results and indicated by the use of a color: green – effective intervention(s); orange – partially or intermediately effective intervention(s); red – ineffective intervention(s); grey - information provided within the study was inadequate to develop my decision or if nothing appeared to be done. My final decision was often based on multiple factors identified within the study; all of them may not have been successfully addressed, but an overall impression was still possible. Similar colors do not indicate similar interventions across studies, but rather the author's ability to address the relevant factors for their specific site of implementation of their PDSA/QI activity. So, there was no "one-size-fits-all" statement or comment within or between studies to inform my decision, but the use of multiple sources of evidence to facilitate my decision as to whether that specific construct was successfully addressed.

TABLE IV

IMPLEMENTATION ANALYSIS (CFIR) OF RESIDENT QUALITY IMPROVEMENT ACTIVITIES THAT INCORPORATED PDSA*

	Study and Year											
	Holmboe, et al (2005)	**Varkey ,et al (2006)**	**Coleman, et al (2003)**	**Mohr, et al (2003)**	**Ogrinc, et al (2004)**	**Nuovo, et al (2004)**	**Canal, et al (2007)**	**Oyler, et al (2008)**	**Warm, et al (2008)**	**Frey, et al (2003)**	**Djuricich, et al (2004)**	**Ziegelstein, et al (2004)**
Intervention Characteristics												
Intervention source												
Evidence, strength & quality												
Relative advantage												
Adaptability												
Trialability												
Complexity												
Design, quality and packaging												
Cost												
Outer Setting												
Patient needs and resources												
Cosmopolitanism												
Peer pressure												
External policies and incentives												

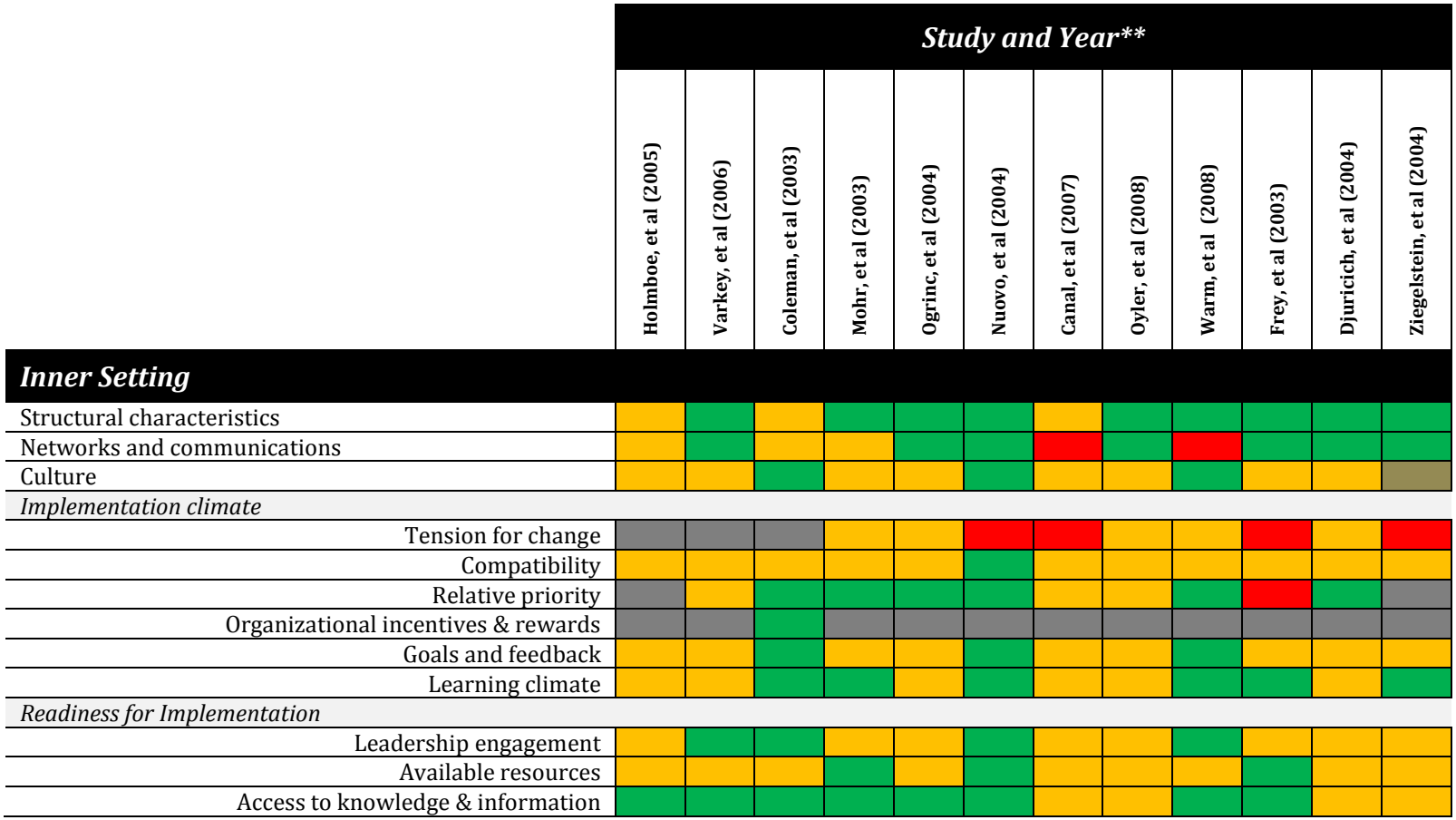
*These ***Consolidated Framework for Implementation Research*** (***CFIR***) constructs are further defined within Appendix A and more fully within the reference (Damschroder, et al; (10)).

** Appendix B provides each studies complete reference

Whether the construct was successfully undertaken/addressed (or not) was determined through a realist review of that particular study and coded using the following color scheme: ***Green*** – addressed in such a manner as to facilitate a successful outcome; ***Red*** – not addressed in a manner that would lead to a successful outcome; ***Orange*** – interventions were mixed, some were supportive and others not; ***Dark Grey*** – review of the study did not provide enough information to develop an opinion.

TABLE IV

IMPLEMENTATION ANALYSIS (CFIR) OF RESIDENT QUALITY IMPROVEMENT ACTIVITIES THAT INCORPORATED PDSA* (CONT.)



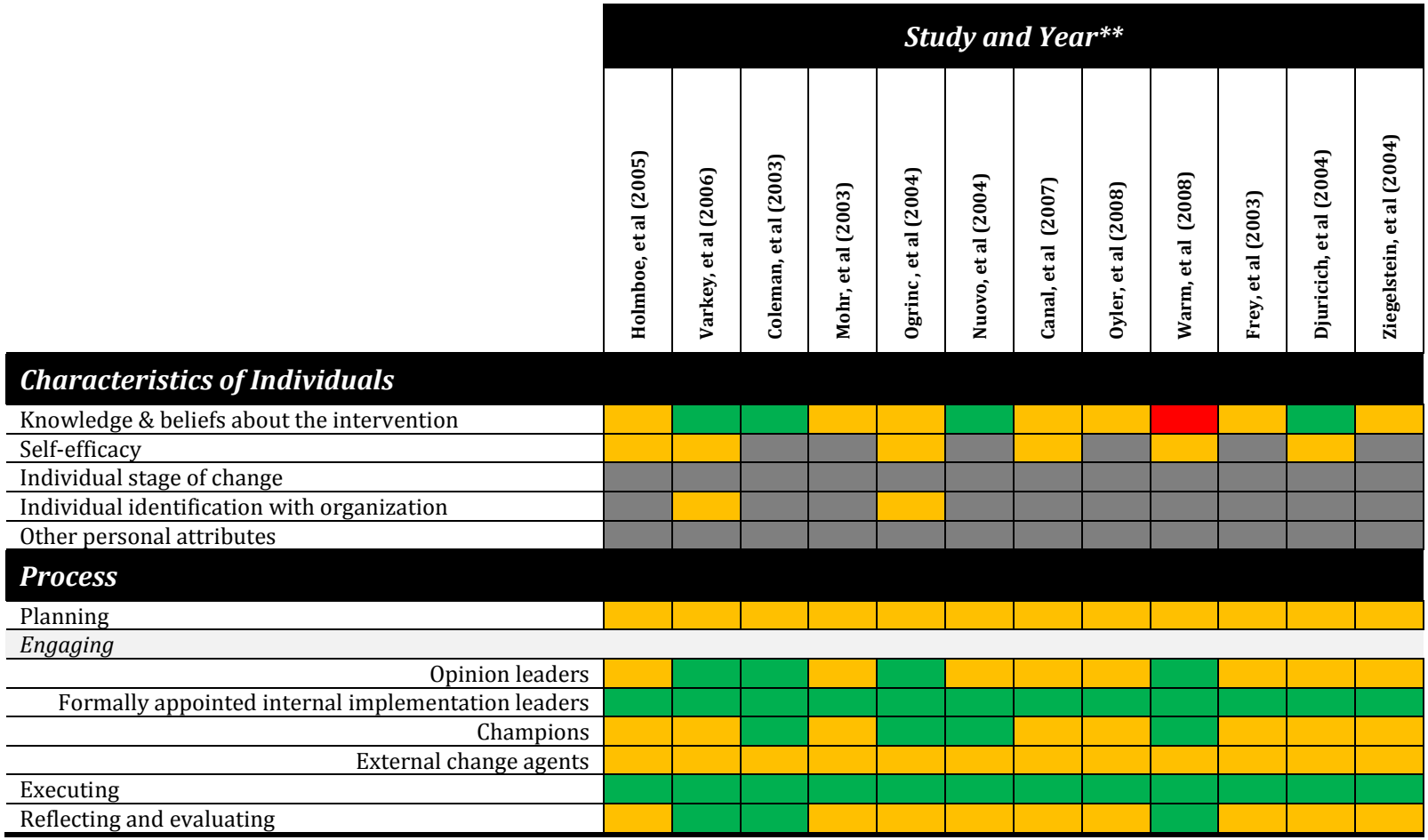
*These *Consolidated Framework for Implementation Research* (*CFIR*) constructs are further defined within Appendix A and more fully within the reference (Damschroder, et al; (10)).

** Appendix B provides each studies complete reference

Whether the construct was successfully undertaken/addressed (or not) was determined through a realist review of that particular study and coded using the following color scheme: ***Green*** – addressed in such a manner as to facilitate a successful outcome; ***Red*** – not addressed in a manner that would lead to a successful outcome; ***Orange*** – interventions were mixed, some were supportive and others not; ***Dark Grey*** – review of the study did not provide enough information to develop an opinion.

TABLE IV

IMPLEMENTATION ANALYSIS (CFIR) OF RESIDENT QUALITY IMPROVEMENT ACTIVITIES THAT INCORPORATED PDSA* (CONT.)



*These *Consolidated Framework for Implementation Research* (*CFIR*) constructs are further defined within Appendix A and more fully within the reference (Damschroder, et al; (10)).

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Whether the construct was successfully undertaken/addressed (or not) was determined through a realist review of that particular study and coded using the following color scheme: ***Green*** – addressed in such a manner as to facilitate a successful outcome; ***Red*** – not addressed in a manner that would lead to a successful outcome; ***Orange*** – interventions were mixed, some were supportive and others not; ***Dark Grey*** – review of the study did not provide enough information to develop an opinion.

To further clarify my decision making process and review of the results, examples from the studies are included in the summary that follows; final assessments are contained within ***TABLE IV***. Providing these specific examples further highlights how this realist review was informed.

a. **Domain of Intervention Characteristics**: As a major category, most of these individual constructs were effectively addressed in all the studies reviewed, but these particular constructs deserve further comment.

1. Evidence, Strength and Quality

Evidence, Strength and Quality refers to the likelihood of the intervention achieving its desired outcomes, but only considering the success of learning or demonstrating PDSA/QI. One potential limitation for all of these studies is that each is reporting a 'new' variation of a PDSA/QI intervention and evidence of similar interventions and successful outcomes or generalizability is lacking. Yet, evidence of a clear and well-defined intervention (e.g., Holmboe et al), external funding (e.g., Vareky et al) or an extension of a similarly successful activity (e.g., Djuricich et al) all constitute reasonable evidence to support the value of the activity and successful strategies used to implement them.

2. Relative advantage

Relative advantage refers to the perception of the stakeholders that not only is the chosen intervention more advantageous than an alternative, but the benefits are clearly visible to all stakeholders. Team meetings would achieve this benefit for all participants (e.g., Holmboe et al), as would development of a needs assessment (e.g., Djuricich et al) or ensuring active participation of faculty preceptors. In the same manner, negative perceptions of faculty concerning a hidden rationale or ulterior motive ("limiting exposure to subspecialties"; e.g., Warm, et al) are detrimental to developing a positive perception of the activity. Surveys can be used to identify the transformation of an initially negative perception (e.g., Frey et al) or information from surveys could be used to guide and further refine implementation strategies.

3. Complexity

Complexity refers to the stakeholder's perception and includes the scope or magnitude of the activity, duration and necessary reorganization of current processes (achieved by Warm et al in their reorganization of inpatient teams and increase in hospitalist coverage). To address this construct requires identification of barriers to implementation as well as the existing views of all of the participants (e.g., Frey et al.'s resident survey comments included it being a "burdensome exercise") since each needs to be acknowledged or addressed before the implementation is undertaken. One barrier identified in several studies overlapped with the next construct, cost, and

included both the lack of faculty with specific QI instructional experience as well as clear support for their own training and participation.

4. Cost

Cost is reflected at multiple levels that include limitations for clinical faculty participation (e.g., Coleman et al), personal and system deficiencies (e.g., Holmboe et al) and institutional commitment/support (e.g., Canal et al). Yet this same barrier could be addressed when senior leadership within the hospital and academic groups partnered to identify support and incorporated it within the implementation plan (e.g., Coleman et al).

b. **Domain of the Outer Setting**: Healthcare systems are organized within a hierarchy whose influences, explicit or implicit, can support or impede any intervention.

1. Patient needs and resources

Patient needs and resources is a fundamental construct and not only with regard to whether the intervention included input from patients, but whether patient needs were aligned with and carried the same meaning as those of the other participants in the PDSA/QI activity. Addressing patient needs by improving wait times for non-English speaking patients for surgical referrals (e.g., Canal et al) and developing education materials (e.g., Oyler et al) were examples where patient needs were being addressed. Picking a specific disease and developing clinical guidelines (e.g., Frey et al) or developing a project to improve clinical care (e.g., Coleman et al) are other examples of clinicians determining and addressing what they viewed as patient needs, but it is not clear whether patients participated in that decision. Directly involving the recipients (patients) in the development of education materials (e.g., Mohr et al) or having all healthcare team members meet with patients (e.g., Nuovo et al) are better examples of true patient centeredness that could more effectively overcome barriers to a new intervention.

2. Cosmopolitanism

Cosmopolitanism can best be conceptualized as those visible networks between individuals who are directly involved with the intervention, to external groups or organizations. These networks could be visualized by the implementation stakeholders as grant administrating groups, social/political organizations (e.g., Mohr et al, Varkey et al and Frey et al) or individuals who are known or recognized as a representative of the intervention or program now being implemented (e.g., Oyler et al). Successful interventions are examples of how social capital can help promote implementation by overcoming barriers and further establishing commitment of those involved.

3. Peer pressure

Peer pressure generated internally or externally was more difficult to ascertain from review of these studies as it was neither mentioned nor alluded to, but could be a facilitator of implementation or the decision to adopt an innovation (56). In an academic environment, peer pressure plays a role in stimulating the need to develop report, be recognized and in various ways be rewarded for new interventions.

4. External policies and incentives

External policies and incentives play a critical and decisive role in supporting the development of these PDSA/QI programs. Current changes within ACGME mandates and directives, such as the NAS and CLER, play a primary and decisive role in fostering these programs, but not necessarily establishing best practices.

c. **Domain of the Inner Setting**: These constructs are those we typically consider as comprising the environment or context in which an innovation is to be implemented.

1. Structural characteristics

Structural characteristics describe how people are clustered and how they will interact with one another with respect to the activity and not necessarily the organization as a whole. These relationships, with respect to the PDSA/QI activity, appeared to be defined within all the studies reviewed, but it needs to be recognized that these same characteristics can interact with other constructs, so the actual end result may or may not be favorable or similar in different groups.

2. Networks and communications

Networks and communications are difficult to comment upon but remain fundamental in healthcare as they bind groups together and help to eliminate errors. The importance of effective communication is to ""attenuate the "complex web of sources of power and covert and overt sources of influence" that all contribute to individual decisions about whether to cooperate"" (65). While evidence of effective communication was presented in all of these studies, the possibility of covert communication can't be excluded, and was identified in two of the studies. In Canal et al, it involved the inability of residents to effectively "communicate" patient related service needs (wireless phones) to hospital administration. In Warm et al, it was the perception of some faculty that curricular changes made to support the QI program were "an attempt to persuade residents toward careers in primary care by limiting exposure of residents to their subspecialties" (Warm et al, p. 925).

3. Culture

As a construct culture can have many meanings as well as attempts to measure it. Its importance emanates from the fact that individuals incorporate an organization's culture into their behavior and then manifest it by their work and how they relate to others. In this context, my focus is on how the culture is discerned within the QI activity and whether it was supportive. A relevant model to accomplish this task explores culture through its organizational effectiveness and based on contrasting value-based judgments, the C*ompeting Values Approach* (66). These contrasting values include the individual versus the organization, stability versus flexibility and process ("means") versus final-outcomes ("ends"). Four different effectiveness models can then be developed, but one is most relevant and aligns with these PDSA/QI programs, the *Human Relations* or *Team Based model* that uses cohesion and morale to develop the individual. As development, implementation and evaluation of an effective team and teamwork has evidence-based underpinnings or practical lessons, this model was used to facilitate review of this construct (58). Each study incorporated a team that included residents and staff, but Coleman et al, Nuovo et al and Warm et al explicitly extended their teams to become multidisciplinary and interprofessional by including staff, administrators, patients, etc., and then sought ways to develop and support them, which most effectively addressed the Team-based model.

4. Implementation Climate

Implementation climate can be conceptualized as *"'targeted employees' shared summary perceptions of the extent to which their use of a specific innovation is rewarded, supported, and expected within an organization.'"* (67, p. 2). The critical aspect of this statement is that the perceptions are those that are shared, not individual beliefs.

i. Tension for change

Tension for change is an important antecedent for successful implementation and *"can't be created if it doesn't exist"* (10). In light of the current broad healthcare initiatives to foster QI through various organizations, regulatory groups, programs, etc. this external tension for change exists. Within the studies reviewed, those individuals involved in the development or implementation of the PDSA/QI activity can be viewed as recognizing the need to change, but without clear input from the residents their willingness to participate is unknown. Residents' perceptions before the PDSA/QI activity was implemented would be most revealing, since if they were dissatisfied with the current system, it would facilitate their acceptance of a change in their current process. Nuovo et al, took an active step to develop this "tension" or desire for change by establishing small groups or one-on-one meetings before the

PDSA/QI activity was begun to establish "buy-in" among the group and address any ambivalence about its value. Warm et al, used interprofessional group team meetings to discuss findings and establish next steps when the PDA/QI activity began, building support for its acceptance. Djuricich et al, used a needs survey and made use of a high level of interest in the activity before they began and this interest remained high at its completion. In some cases, residents' perceptions may serendipitously have changed (e.g., Canal et al), without a clearly defined or active process by those directing the program, so mechanisms can't be defined. It may also be reasonable to assume that if residents were volunteers (e.g., Mohr et al), or the intervention was part of an elective (e.g., Ogrinic et al), that some pre-existing desire to change was present and hence they felt a need to change a current process. In the case of Frey et al, residents' perceptions before the program were negative ("*initially viewed as a potentially burdensome exercise"*) and improved at the end, but again without any specific intervention. As these examples demonstrate, the more that is known of residents' pre-existing perceptions, then the greater the likelihood that a plan could be developed or the program modified to ensure their buy-in and acceptance of the PDSA/Qi activity.

ii. Compatibility

Compatibility refers to how the stakeholders' own values, current workflows or systems align with the new innovation. Obtaining resident input, implementing within a known system (resident continuity clinic), limiting additional effort or providing support can serve as facilitators. Other possibilities for compatibility include using existing buy-in (e.g., Djurich et al), establishing and developing buy-in (e.g., Nurovo et al and Warm et al) when residents volunteer or take an elective that incorporates PDSA/QI, or if there is a self-directed aspect (Holmboe et al).

iii. Relative priority

Relative priority relates to the stakeholder' perceptions of the importance of PDSA/QI and perceived as a priority by them. While any educational intervention could be considered a priority, Organic et al, freed the residents from the majority of their clinical responsibilities in order for them to participate and Coleman et al, provided them academic credit to participate. Warm et al, used their residents' negative perceptions of the current structure of their ambulatory clinic, with the potential improvement in their clinical experience that the innovation would bring, to establish the importance of their specific innovation and support the implementation.

iv. Organizational incentives and rewards

Organizational incentives and rewards are extrinsic to the PDSA/QI activity and may take the form of a positive performance review, increased stature or respect and financial incentives, but the more types that are incorporated, the greater the likelihood of successful implementation. Coleman et al incorporate rewards by providing residents credit for participation in the PDSA/QI activity and each participating site of implementation received a certificate as well as a catered lunch.

v. Goals and feedback

Goals and feedback are important, but need to be clearly measured and the results communicated back to the participants. Leaders play a very critical role, as they need to demonstrate their own accountability, involvement and responsibility. Coleman et al, Nuovo et al, and Warm et al, demonstrated this by their broad involvement of individuals that included relevant leadership.

vi. Learning climate

A positive learning climate requires the participants to feel valued and safe in trying new methods and leaders who can freely express their fallibility. This is best accomplished by allowing sufficient time and opportunities to practice reflective thinking and evaluation as the innovation is being implemented. While each study demonstrated varying aspects of a positive learning climate, those studies where activities extended over time (e.g., Warm et al, Mohr et al and Ziegelstein et al), included multiple participants (e.g. Coleman et al and Nuovo et al) or interprofessional groups (e.g. Frey et al), were most effective in establishing a positive environment.

5. Readiness for implementation

Readiness for implementation includes that group of tangible and immediate indicators of an organizations' commitment to the decision to implement an innovation.

a. Leadership engagement

Leadership engagement relates to the depth and breadth of engagement beyond the immediate implementation groups and the tangible and immediate indications of an organizations' commitment to the decision to implement a PDSA/QI activity. Warm et al,s' initiative involved separating their ambulatory care from their inpatient service and required re-organization of the inpatient teams, an increase in hospitalist coverage, and engagement of senior leadership within the hospital and academic health center, to cover these new costs. Coleman et al, had the support of the department chair, the vice chair of clinical affairs, the residency program director and the training site directors. Nuovo et al, had multiple constituents that included the information service, billing service and health system leaders and then found ways to facilitate changes in workflow (e.g., offering staff continuing education credit through in-

services). Varkey et al, used presentations by their groups to key quality leaders of their academic medical center to engage leaders. However, Canal et al, were not as successful, as they were unable to obtain funding to purchase a wireless telephone to improve patient care communication, but their leadership commented that they would consider the possibility of such a purchase in the future.

b. Available resources

Available resources include time, people, infrastructure and financial resources that serve as a partial mediator between management support and implementation policy and procedures. Mohr et al were able to have patient charts relocated to a clinic building, which represented a substantial change in institutional policy, as well as having trained research assistants who performed the initial chart abstractions for their program. Coleman et al, used additional funds to provide CME for faculty to assume leadership roles in their improvement projects and Nuovo et al, ensured there would be no impact on resident duties or patient volumes related to the PDSA/QI activity. Funding through grants (e.g. Varkey et al, Mohr et al, Frey et al, Djurich et al, and Oyler et al) or through Offices of Academic Affairs, such as the Department of Veteran Affairs (e.g., Ogrinic et al), provided needed bridging resources. Warm et al, instituted a disease registry to track 20 processes, as well as outcome measures, and Ziegelstein et al's, initiative resulted in an infrastructure change within their organization for referrals, scheduling, tracking and patient access. Varkey et al, encountered numerous barriers to their interdisciplinary program, because of separate buildings, schedules, clinical/work time, differing instructional or administrative issues.

c. Access to knowledge and information

Access to knowledge and information refers to the intervention itself and assistance with its incorporation into current processes that necessitate the participation of experts, staff with experience, training or even computerized information systems. Examples of successful approaches include those reported by Coleman et al, who used librarians to teach residents how to improve literature searches related to their planned projects. Ogrinic et al, made use of an institutional culture of quality improvement for their activity and qualified faculty who were available to teach PBLI concepts and skills to their residents, while Nuovo et al, developed and trained their teams. Warm et al, developed and implemented a disease registry and embedded EBM guidelines into the daily work flow, but unfortunately found that their faculty practice did not readily adopt those interventions.

d. **Domain of the Characteristics of Individuals:** It is the interaction between individuals and the intervention that determines the eventual outcomes of the intervention and this group of constructs includes these

variables. While critical, this particular set of factors, with regard to the residents, was difficult to analyze and little information could be extracted from the studies, but the following can be surmised.

1. Knowledge and belief about the intervention

"How-to-knowledge" and use of the intervention appeared to be present in all of the studies, as evaluated by comments or exam/survey results. Developing an environment where affirmative opinions and beliefs are likely to be openly heard can prompt communication between participants either through work in teams (e.g., Varkey et al, Coleman et al and Nuovo et al) or the assumed validity provided by working on a "high priority initiative" for the institution (e.g., Varkey et al). When faculty comments were negative or not supportive, the activity was negatively affected (e.g., Warm et al).

2. Self-efficacy

Self-efficacy is important as it suggests whether residents will change their behavior, based on their own beliefs that they have the capability to do so. Djuricich et al, used their own assessment tool to develop a self-efficacy measurement and others attempted to assess self-efficacy at the end of their program (e.g., Holmboe et al) or document a change in a pre- and post-test measurement of the learning outcomes of the activity (e.g., Canal et al). However, in all of the studies, a validated tool to measure self-efficacy was not used.

3. Individual stage of change

Individual stage of change refers to the phase an individual is in as they progress toward sustained use of an intervention. No models of change or development were provided in any of the studies. However, one could surmise that if a resident volunteered to participate in a PDSA/QI activity, or takes an elective where PDSA/QI will be used, the resident has demonstrated that she/he has have moved beyond a stage of contemplation to one of commitment or action, but this remains an unsupported supposition.

4. Individual identification with the organization

Individual identification with the organization refers to how residents perceive their relationship with the organization that determines their willingness to put forth extra effort, and participate in or take risks in their organization, with the assumption of their "safety" in doing so. In one respect, all residents identify with their training program and fellow residents as they had selected or ranked for acceptance the residency program in which they are training. The difficulty is determining whether this identification generalizes to the organization within which the PDSA/QI activity is being implemented. This identification would appear to be more likely when residents interact

directly with key quality leaders in the organization (e.g., Varkey et al) or when there is already an active culture or reputation for similar innovations using QI (e.g., Ogrinic et al).

5. Other personal attributes

Other personal attributes include intellectual ability, motivation, innovativeness, learning style, etc. No such measures or comments in this regard were made in any of the studies.

e. **Domain of Process:** The various constructs included in this group are analogous to the steps of PDSA, but also with the inclusion of engagement that recognizes the importance played by key individuals strategically playing a role in the process.

1. Planning

Planning refers to the methods of implementing an intervention in advance and the quality of those methods. In one sense, the constructs of CFIR serve as a guide to facilitate planning, but those constructs or another implementation framework were not explicitly used or mentioned, in any of the studies. With respect to each of the studies and the education programs they developed, it was clear that significant planning took place. The rationale for scoring this construct as orange for each study was that none used any robust implementation guidelines or plans.

2. Engaging

Engaging refers to involving those individuals whose roles in the implementation allow them to use strategy and social marketing, personal characteristics and relationships to support the innovation and resist or minimize the negative effects of the innovations opponents.

i. Opinion leaders

Opinion leaders are those who are able to influence others' attitudes or overt behavior informally. This influence could be accomplished by engaging senior leadership (e.g., Warm et al and Coleman et al), linking with concurrent high priority institutional projects and hence those individuals (e.g., Varkey et al), or similarly by linking the activity to strong institutional cultural attitudes, identities or strengths (e.g., Ogrinic et al).

ii. Formally appointed internal implementation leaders

Formally appointed, internal implementation leaders can play a pivotal role in the successful implementation of a PDSA/QI activity, regardless of whether they have explicit time dedicated to the task. In general, such leaders were clearly identified in each of the studies, but the extent of their support (time, finances, etc.) was not clearly delineated in any of the studies.

iii. Champions

Champions are those individuals who are actively involved and dedicate themselves to supporting, marketing and facilitating the implementation of a PDSA/QI activity. They strongly believe in its benefits, willing to defend it and may develop an interdepartmental or interprofessional coalition within their organization to support it. In each study a champion could be identified, but in some studies it was easier to do so. The champion may have developed new processes and supports (e.g., Coleman et al and Nuovo et al), developed financial and administrative resources to support organizational structures (e.g., Warm et al) or further developed or linked the PDSA/QI activity to current organizational structure and culture (e.g., Ogrinic et al).

iv. External change agents

External change agents may formally influence or facilitate intervention decisions. In the majority of studies, the ACGME mandate for resident competencies was mentioned as a rationale for developing these innovations, but other healthcare related organizations, programs or the Institute of Medicine's report on health care issues, highlighted issues of patient safety, were also mentioned. In some cases, it was the residency program's affiliated professional organization that prompted PDSA/QI activities. The rationale for using orange for this facet, in all these studies, is that a specific external process, activity or agency was not identified and the process to develop a PDSA/QI activity was left up to that individual group.

3. Executing

Executing is the actual carrying out or accomplishing the PDSA/QI activity according to plan, facilitated by using trial runs or simulations, breaking the intervention into steps, and using early successes to build confidence and support. Each study appeared to have done a reasonable job in addressing this construct.

4. Reflecting and evaluating

Reflection and evaluation of the PDSA/QI activity can involve quantitative or qualitative feedback or even examples of prior success (or failures) to build an institutional memory. For example, this construct could be addressed by group meetings with an open discussion where all members feel safe to express their opinions. All of the studies reported making use of such meetings, but it was best exemplified within the interprofessional teams and reporting/communication process developed by some of them (e.g., Varkey et al., Coleman et al, and Warm et al).

E. Synthesis of Results

The most fundamental deficiency, identified in all of these studies, was in not requiring the iterative aspect of a PDSA/QI activity, despite the opportunity to do so, within their residents' longitudinal clinical learning environment, their continuity clinic. Not incorporating this iterative aspect of a PDSA/QI activity impacts the achievement and demonstration of the desired outcome of PBLI competence; demonstrated through a resident's active engagement in continuing attempts to improve their patient(s) health. This deficiency, across all of the studies, suggests this may be a symptom and not a sign of the actual problem, failure to properly consider all aspects of an implementation of a complex healthcare intervention, e.g. PDSA/QI activity.

The CFIR framework used to evaluate these studies provided a template that facilitated a systematic exploration of the environment of each PDSA/QI activity and identified which of those CFIR constructs were effectively addressed to support the implementation of their PDSA/QI activity. Reviewing the findings of this "CFIR review" (**TABLE IV**) also identified those constructs that would still need to be addressed, even if the PDSA/QI activity was iterative and occurred in the longitudinal clinical setting of a resident's continuity clinic. Reviewing **TABLE IV** provides an opportunity to develop general recommendations for the most relevant issues, and provides examples of what could be done to support an iterative rendition of the same PDSA/QI activity.

CFIR Domain of Intervention Characteristics: Successful implementation of a PDSA/QI activity requires all participants (especially the learners) to perceive its importance and benefits (patient and other participants) while specifying the amount of work involved. A needs assessment would be one step in identifying the perceptions of the participants and determining their willingness to support the "costs" (e.g. infrastructure modification, change in process, staff, facilitators, time, etc.) of the PDSA/QI activity. This type of information helps identify where interventions need to occur in order to favorably address the participants' concerns or issues. However, such an "assessment planning tool" was not routinely performed. If such an assessment were performed, then one example of an intervention, to address a negative perception and to encourage resident participation, is the important role that PDSA/QI activities play in their own professional development. An example of an intervention to overcome a programmatic or institutional lack of commitment is the necessity for residency program accreditation to document the achievement of the skills of PDSA/QI in their residents. What remains an important barrier, and difficult to address, is changing negative perceptions within a hospital's culture or environment with respect to PDSA/QI activities and ensuring that such programs have adequate support. The importance of determining whether an institution's culture will be supportive of PDSA/QI can't be overstated or overlooked, but in the majority of studies (9 of the 12) this support was not clearly identified (68).

CFIR Domain of Outer and **Inner Setting**: Healthcare organizations are assessed on their outcomes, at an institutional and individual level, that provide the justification to support PDSA/QI use and brings to the forefront the implications (e.g. financial, reputation) for neglecting to do so. There is an even more explicit source of motivation, the mission of the medical profession to ensure that their teaching hospitals fulfill societal expectations that healthcare be safe, effective and efficient. The resident as a care-provider also needs to demonstrate their commitment to continued professional development by participation in PDSA/QI activities. Now *Entrustable Professional Activities (EPA)* have begun to "replace" the competency nomenclature in documenting resident training outcomes. Patient safety and improvement (EPA 13: Identify system failures and contribute to a culture of safety and improvement) is one of those core EPAs and further serves as the "siren call" that PDSA/QI needs to become a high priority in resident (and faculty) education and an outcome for their institutions (69). So, how can all these "needs" be addressed?

The current network of relationships, and formal (or informal) communication, in a healthcare organization can support the priority of quality improvement initiatives, but needs to be explicitly modeled not only by word, but through action and at all levels of organizational leadership. Then, the potential implications (positive as well as negative) of faculty and staff efforts to develop and implement PDSA/QI require clear, visible and sustainable support. While the issue of cost (e.g., people, time, resources) needs to be acknowledged, PDSA/QI initiatives are justified by the greater cost and sequelae of inaction. Effectively communicating the importance of quality improvement initiatives, and making explicit the need for their implementation, requires persistent efforts from leadership and through all levels of the organization.

Resident education remains experiential in its core structure and skills translatable into patient safety and QI are experiential as well. The potential to incorporate a PDSA/QI component into a resident's workplace is the most appropriate way to foster learning, change behavior, modify attitudes and also provide secondary benefits (e.g. cost sensitivity and population health). It is imperative that PDSA/QI activities continue to occur in the resident's workplace, adjusted to their patient population, and at the same time prioritized by securing patient input as to their needs and their priorities. There is also an additional benefit in requiring these activities to occur in the workplace, as opportunities for interprofessional interactions and these collaborations are best learned when there is a common interest and tension to change.

CFIR Domain of Characteristics of the Individual: An effective curriculum begins with an assessment of the learners and not just their knowledge, but their willingness and comfort to change and their perceptions of the support their learning environment will provide. The learning environment (or culture) refers to the physical, social, and

psychological context. Their perception of that environment impacts their sense of well-being, academic achievements and behavior (70, 71). Since attitudes influence behavior, as they "determine what people see, hear, think and do", the learning environment will be a significant determinant of learners' attitudes, knowledge, skills, academic progression and behaviors (68, 72). Attention needs to be paid to improving or addressing problems in the learning environment.

CFIR Domain of Process*:* A specific action to effectively address this domain is through the use of a systematic process that explores issues, perceptions, realties, etc. This process requires a framework to gather information that informs discussion and then facilitates interventions based on appropriate conceptual frameworks (theories, models or best practices) that can also inform and be used to advance scholarship (50).

The Consolidated Framework for Implementation Research (CFIR), used in this study, provides a non-biased way to explore and catalogue information. Use of the CFIR sets the stage for further action or research on any construct by providing relevant background information. That information can facilitate an intervention in a specific environment, but is not prescriptive in regard to what conceptual framework is used or if several are believed to be equally useful. The CFIR can be considered a planning tool, and the role of implementation can be more broadly considered as applicable to any educational interventions.

If this study had not incorporated a realist review using the CFIR framework, its primary conclusion would be correct; an iterative aspect of PDSA/QI programs needs to occur, and long enough to demonstrate a consistently positive change in patient outcomes. If different clinical situations exist, then this activity could generalize to them and provide further evidence to support PBLI competence. The logical conclusion would be that fulfilling this single condition (make it iterative) would allow the resident to learn PDSA/QI and provide an opportunity for them to demonstrate competence in PBLI. However, the realist review process demonstrated that this reasonable single intervention, i.e., making the PDSA/QI program iterative, was too simplistic. The environment or context for this PDSA/QI activity would likely continue to impede the success of making it iterative until those barriers, identified by an implementation framework like the CFIR, were addressed (73).

V. DISCUSSION

A. Summary of findings

Programs which can effectively teach the relevant concepts of quality improvement, using the methodology of PDSA, currently exist (64). The structure of all GME residency programs not only include, but require, a longitudinal continuity clinic that offers both variability and similarity of the patient population to allow programmatic and resident specific PDSA/QI activities to be supported. The increasing implementation and sophistication of electronic medical record systems provide a platform that would allow patient care outcomes to be more effectively captured and address the burden of manually collecting this information (47). ACGME programs, such as NAS and CLER, are now implemented within GME training programs and provide a clear external incentive to ensure that residents not only know, but have integrated PDSA/QI into their practices. Finally, physicians have time limited medical licenses (10 years) that require fulfillment of Maintenance of Certification (MOC) requirements, some of which necessitate PDSA/QI activities. Yet, despite all of these synergies, there remains a deficiency in all of the studies reviewed, because they did not fulfill, at least based on these studies, their ultimate goal of appropriately using PDSA/QI to foster the development of PBLI competence.

Based on a review of the literature, it is unclear if a resident's successful participation in a PDSA/QI activity results in development and demonstration of PBLI competence, despite evidence that programs can achieve the knowledge outcomes of PDSA/QI. In the framework offered by Implementation theory, and through a realist review of the literature, evidence for PBLI competence was sought in the literature reviewed and the impact of the environment or context influencing PBLI outcomes was explored. A fundamental flaw was identified in all of the studies reviewed, as they did not integrate the residents PDSA/QI activity into a longitudinal experience within a resident's continuity clinic. This flaw prevented use of the iterative methodology required for PDSA and thereby impacted a resident achieving or demonstrating the desired outcome, PBLI competence. A subsequent realist review of the literature, using the CFIR framework, provided an explanation as to why these activities were not integrated into a resident's continuity clinic as aspects of their environment/context, institution and culture, were the most frequently identified barriers.

B. Limitations

Contrary to what is usually recommended as part of a realist literature review, I limited the databases chosen, restricted my search to the English language literature, and did not review the Grey literature (generally referring to materials not published commercially or indexed by major databases e.g., theses, conference proceedings, meeting

minutes, annual reports). The process used appears more akin to a conventional systematic review, with a defined and focused search strategy, but was "necessitated" by the limitations imposed by only having a single investigator. By contrast, a realist review of the literature is iterative and open-ended. During the article review, additional searches may be performed to further understanding, drawn from other bodies of knowledge (e.g., non-medical or healthcare literature), frequently using snowballing (pursuing references for references) and the Grey literature as they may be more informative in clarifying mechanisms (9).

Using traditional bibliographic sources, and manual searches of the literature, the review was iterative in the style of a realist review, but likely did not identify all of the relevant studies. With regard to identifying additional constructs not present within the CFIR, it is less likely that important constructs were missed, because of the formulation of the CFIR framework and the reason it was chosen for this study. The CFIR is a framework developed by coalescing constructs from over 19 different implementation models and that inclusiveness and theory 'neutrality' facilitated review and extraction of information from each study.

A limitation for this study, but not the process followed (8, 74), is that a realist review typically includes multiple investigators, each providing different perspectives and the necessary checks and balances that help to ensure an appropriate and balanced analysis. To address the issue of bias and random error when a single investigator performed a review, led to my decision to review the studies in two temporally separated steps. First, each study was individually reviewed with respect to developing a decision in regards to its "success" in addressing each of the constructs listed within the CFIR framework. Second, after a period of time, the articles were again reviewed, but now for one CFIR construct at a time. This second step further clarified interpretation of each construct, with respect to the same construct in all the studies, and helped to ensure that interpretations were consistently applied across all of them. Only the results of this second review were used to form a decision with respect to each individual CFIR construct.

An additional action taken to address potential bias and random error was to color code the decisions made, rather than assign each construct a numerical or letter value since that would suggest a more quantitative assessment was made. This decision was based on the following rationales. First, was the realization that many constructs could be effectively (or ineffectively) addressed by several different mechanisms or actions, and it would be difficult for a single investigator to determine equivalency or ranking among them and then determine an appropriate methodology to assign each a weight so they could be summarized. Normally such a "quantitative" process would occur through

discussion among a group of investigators in a realist review. However, it was still necessary to display some sort of summary opinion of the effect (or lack) of the actions taken within a study for a specific construct. Colors were chosen to provide that opinion and reflect the degree to which the study's authors interventions successfully addressed (or not) that particular CFIR construct. The color scheme chosen was elementary, so green was used to indicate a favorable action(s), orange if interventions were mixed as some were supportive and others not, red indicated an ineffectual response. If the information I extracted after review of the study was inadequate to develop an opinion or if nothing was done, this was symbolized by the color grey. These colors were not meant to indicate equivalency with respect to how the same construct was addressed across all studies, but provide a representation of the effectiveness of those interventions, for that particular construct, in that specific study.

Various methods of performing a qualitative analysis exist and whether a realist review was the most effective for this study could be called into question. However, a realist review allows synthesis of evidence by its focus on explaining why (or why not) an intervention (PDSA/QI) works, and in what ways, or an explanation as distinguished from a judgment about whether it worked (8, 75). It required the use of a relevant framework (CFIR for this study) to clarify those factors and then used to provide further insight as to how that intervention had its effect. With respect to healthcare and health policy, a realist review is increasingly used and a reasonable methodology to use for a review (76). Finally, the choice of using the CFIR framework was based on its development though a synthesis of constructs from existing implementation theories. This resulted in a comprehensive framework, and a consistent taxonomy and terminology for assessment of an implementation process (10). Whether the conclusions I reached with the use of the CFIR framework in this study will prove to be useful or inform similar or alternative methodologies will await similar applications.

C. Integration with other work

Of the six ACGME competencies, PBLI is the most relevant for a resident as it facilitates development and maintenance of those clinical practice skills which support their continued provision of safe, effective and efficient patient (population) care (47). Successful education programs that teach quality improvement have been identified by systematic reviews, similar to this study, often accompanied by immediately favorable patient or clinical process outcomes (64). Despite the success of these education programs, the characteristics of the learners still impact program outcomes, so using appropriate learning theories would suggest interventions not only for the learner, but the program and environment itself (77, 78). An example of one such learning theory, that provides a framework to

facilitate reflection and improve clinical practice; Transformative Learning can support the development of PBLI competence (79). Further research could incorporate existing change theory models to develop behaviors that facilitate individual (or team) change and used in industries outside medicine to promote evidence-based practices (80). One model, Pathman model, is applicable for facilitating behavioral changes that can result in PBLI competence (81). This model addresses participant beliefs, reinforces or enable appropriate behaviors, facilitate adaption to practice change and help in adherence to these new practices. With regard to assessment instruments for PBLI, more effective models need to be explored as they serve to inform the needs of the learner, but also assist in program development (82, 83).

The expansion of electronic medical records, and their search capability, allows resident specific patient demographic databases to be developed that identify focused areas that a PDSA/QI activity can address (47). As emphasized in human-centered systems engineering (HSE), learning objectives and assessments need to be aligned with the actual work and involve practical problem solving in that local context (84). Identifying relevant and specific healthcare issues for each resident, encourages engagement and those specific outcomes that need to be followed (52). As we now transition into residency program outcomes that are defined by EPAs', PDSA/QI activities may prove to effectively address some of these EPA outcomes and at the same time signify PBLI competence (69). However, one issue related to support is often not considered and that is the sustainability of these PDSA/QI programs, but applicable to study by implementation science (85).

Neglecting a prospective and thoughtful plan of implementation of a PDSA/QI activity precludes the opportunity to identify and address barriers that can obscure or prevent success and gives due diligence to the fact that implementation is "the Achilles heel of innovation." (86). There remains a critical need to first determine and understand stakeholder perceptions, as they can be used to form a strategy that guides them to consensus, leads to cooperation and fosters team development. The formation of teams, supported by the professional culture of the organization, allows stakeholder perceptions to be openly discussed and eventual agreement or conformity achieved (87). Sociocultural theory can be used to inform issues of relevance for the environment, team and individual that further encourages effective team development (77, 88).

Finally, one major advantage of the CFIR framework, and its implementation constructs, is that while its constructs are specific, they are not meant to be directive, but serve an organizing role for approaches to address them. Since these constructs are theory and measurement tool neutral, existing theories, as well as assessment tools, could be used to inform and develop specific implementation plans for a PDSA/QI activity (73, 89).

D. Next steps

There is a clear relevance and rationale for physicians to become proficient in the use of PDSA/QI as a means to improve their clinical practice and ultimately patient care and safety. While there are currently multiple programs that can successfully teach these skills, some fundamental components still need to be incorporated (chance for repeated practice and feedback, different patient conditions and contexts, etc.) that can only occur within an appropriate and relevant longitudinal clinical experience. That experiential site of clinical learning has been available for some time within each resident's continuity clinic, but not fully utilized because of differing environmental, cultural or learning context barriers. While valid and reliable instruments that measure changes in resident behavior (supporting a change in their attitude) also need to be developed, "surrogate" measures (e.g. improving patient care outcomes or generalization to other patient care outcomes) may fulfill that role, so the current lack of such instruments should not impede effective program development (90).

It seems reasonable that future PDSA/QI programs begin with the insights provided through implementation theory as it can identify and then allow an opportunity to address any barriers prospectively. Routinely incorporating such a step can save time, money and effort, while facilitating the generalization of such programs to different learners and within their different healthcare environments (86).

Appendix A – Characterization of constructs within the CFIR framework (Damschroder, et al; 10)

Intervention Characteristics

- Intervention source - Perception of key stakeholders about whether the intervention is externally or internally developed
- Evidence, strength & quality - Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.
- Relative advantage - Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.
- Adaptability - The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs.
- Trialability - The ability to test the intervention on a small scale in the organization [8], and to be able to reverse course (undo implementation) if warranted.
- Complexity - Perceived difficulty of implementation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement
- Design, quality and packaging - Perceived excellence in how the intervention is bundled, presented, and assembled
- Cost – Costs of the intervention and costs associated with implementing that intervention including investment, supply, and opportunity costs.

Outer Setting

- Patient needs and resources - The extent to which patient needs, as well as barriers and facilitators to meet those needs are accurately known and prioritized by the organization.
- Cosmopolitanism - The degree to which an organization is networked with other external organizations
- Peer pressure - Mimetic or competitive pressure to implement an intervention; typically because most or other key peer or competing organizations have already implemented or in a bid for a competitive edge.
- External policies and incentives - A broad construct that includes external strategies to spread interventions including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.

Inner Setting

- Structural characteristics - The social architecture, age, maturity, and size of an organization.
- Networks and communications - The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.
- Culture - Norms, values, and basic assumptions of a given organization.
- Implementation climate - The absorptive capacity for change, shared receptivity of involved individuals to an intervention and the extent to which use of that intervention will be rewarded, supported, and expected within their organization.
    - Tension for change - The degree to which stakeholders perceive the current situation as intolerable or needing change.

    - Compatibility - The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.
    - Relative priority - Individuals' shared perception of the importance of the implementation within the organization.
    - Organizational incentives & rewards - Extrinsic incentives such as goal-sharing awards, performance reviews, promotions, and raises in salary and less tangible incentives such as increased stature or respect.
    - Goals and feedback - The degree to which goals are clearly communicated, acted upon, and fed back to staff and alignment of that feedback with goals.
    - Learning climate - A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.
- Readiness for implementation - Tangible and immediate indicators of organizational commitment to its decision to implement an intervention.
    - Leadership engagement - Commitment, involvement, and accountability of leaders and managers with the implementation.
    - Available resources - The level of resources dedicated for implementation and on-going operations including money, training, education, physical space, and time.
    - Access to knowledge & information - Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.

<u>Characteristics of Individuals</u>

- Knowledge & beliefs about the intervention - Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.
- Self-efficacy – Individual belief in their own capabilities to execute courses of action to achieve implementation goals.
- Individual stage of change – Characterization of the phase an individual is in, as he or she progresses toward skilled, enthusiastic, and sustained use of the intervention.
- Individual identification with organization - A broad construct related to how individuals perceive the organization and their relationship and degree of commitment with that organization.
- Other personal attributes – A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

<u>Process</u>

- Planning - The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and the quality of those schemes or methods.

- Engaging - Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modeling, training, and other similar activities.
    - Opinion leaders - Individuals in an organization who have formal or informal influence on the attitudes and beliefs of their colleagues with respect to implementing the intervention
    - Formally appointed internal implementation leaders - Individuals from within the organization who have been formally appointed with responsibility for implementing an intervention as coordinator, project manager, team leader, or other similar role.
    - Champions - "Individuals who dedicate themselves to supporting, marketing, and 'driving through' an implementation, overcoming indifference or resistance that the intervention may provoke in an organization.
    - External change agents - Individuals who are affiliated with an outside entity who formally influence or facilitate intervention decisions in a desirable direction.
- Executing - Carrying out or accomplishing the implementation according to plan.
- Reflecting and evaluating - Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Appendix B – Resident Practice-Based Learning and Improvement activities

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PROFESSIONAL MEMBERSHIPS (CURRENT)	American Academy of Neurology (Fellow)
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Certification Council; United Council for Neurologic Subspecialties; UCNS (Chairman)

American Neurological Association (Fellow)

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Introduction to Clinical Neuroanatomy and Neuroscience, 6th Edition, Editors, MJ Turlough Fitzgerald, Gregory Gruener and Estomih Mtui., W.B Saunders Elsevier, London, 2012

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