Key characteristics of successful quality improvement curricula in physician education: a realist review

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ABSTRACT

Purpose Quality improvement (QI) is a common competency that must be taught in all physician training programmes, yet, there is no clear best approach to teach this content in clinical settings. We conducted a realist systematic review of the existing literature in QI curricula within the clinical setting, highlighting examples of trainees learning QI by doing QI.

Method Candidate theories describing successful QI curricula were articulated *a priori*. We searched MEDLINE (1 January 2000 to 12 March 2013), the Cochrane Library (2013) and Web of Science (15 March 2013) and reviewed references of prior systematic reviews. Inclusion criteria included study design, setting, population, interventions, clinical and educational outcomes. The data abstraction tool included categories for setting, population, intervention, outcomes and qualitative comments. Themes were iteratively developed and synthesised using realist review methodology. A methodological quality tool assessed the biases, confounders, secular trends, reporting and study quality.

Results Among 39 studies, most were before–after design with resident physicians as the primary population. Twenty-one described clinical interventions and 18 described educational interventions with a mean intervention length of 6.58 (SD=9.16) months. Twenty-eight reported successful clinical improvements; no studies reported clinical outcomes that worsened. Characteristics of successful clinical QI curricula include attention to the interface of educational and clinical systems, careful choice of QI work for the trainees and appropriately trained local faculty.

Conclusions This realist review identified success characteristics to guide training programmes, medical schools, faculty, trainees, accrediting organisations and funders to further develop educational and improvement resources in QI educational programmes.

BACKGROUND

Stemming from the Institute of Medicine's reports, *To Err Is Human* in 2000 and *Crossing the Quality Chasm* in 2001, improvement in patient outcomes and reduction in medical errors are foci for healthcare institutions around the world.[1] In 2003, the Accreditation Council for Graduate Medical Education (ACGME) and American Osteopathic Association responded by integrating systems-based practice (SBP) and practice-based learning and improvement (PBLI) as two of the six core competencies of medical education.[2] Quality improvement (QI) teaching encompasses content of both SPB and PBLI. However, uncertainty remains about which methods are the most effective, and in what circumstances, for improving educational and clinical outcomes.[3–5]

Reviews of QI teaching in undergraduate and graduate medical education have found some improvement in educational outcomes but little effect on patient outcomes.[6–8] Wong *et al*[9][10] identified three categories of QI education, most of which fall into the first category: (1) formal curricula that teach concepts or methods intended to facilitate trainees' participation in QI activities; (2) educational activities that impart specific related skills and (3) QI initiatives that involve trainees as active or passive participants. Many others worldwide have developed clinical teaching of QI, aiming to engage physician trainees to improve the care of the patients they serve and the function of the system in which they practice.[10]

Although helpful in summarising the novel approaches to QI education, prior systematic reviews have been limited. They appropriately sought to answer the

question of whether or not QI educational interventions had an impact on physician trainees' ability to gain knowledge and sought to identify themes associated with successful QI curricula, but did not assess the specific mechanistic and contextual factors that predicted success, especially for improvement of patient care and system performance outcomes. The realist review approach offers one approach to deconstruct such complex interventions to assess key success characteristics and develop recommendations.[11 12]

In this study, we define key characteristics of successful QI curricula in medical education. This realist review determines how the teaching of QI in the clinical setting enhances patient care and system performance while increasing trainee knowledge and skills.

METHODS

Review framework

A realist review is based on the premise that complex interventions are successful when certain characteristics facilitate the optimal functioning of a system to produce a particular outcome when a complex intervention is applied.[11] In a realist review, an iterative approach is used to identify the characteristics of complex interventions in the following categories: 'what works,' 'for whom,' 'under what circumstances' and 'to achieve what outcomes'.[11] The realist review begins with the articulation of candidate theories that may explain the characteristics required for interventions to be successful.[11] Next, identification and selection of studies is achieved through standard systematic review approach.[11] Once relevant studies are chosen for inclusion, data are systematically abstracted from the studies and the studies are read and reread to identify themes.[11] An iterative approach is used to identify data, quotations, tables and figures that either support or refute the candidate theories articulated at the outset. Theories are refined as more data are gathered from the articles.[11]

We began by searching the literature for existing theories which explained teaching of QI in the clinical setting. We evaluated the prior systematic reviews on the topic of QI medical education,[7–9 13] spoken with experts in the field,[7 9] and prepared a candidate conceptual framework (see online supplement 1) and accompanying theory for review.[7 14] Our candidate theory hypothesised that the process of educating physicians begins with a curriculum and is impacted by characteristics of the learner, teacher, community and others, all encompassed within the educational context. From within the educational context emerges engaged learners and teachers, who produce improved educational and clinical outcomes. The combination of these successes produces physicians who are capable of and believe that it is their job to do their work and improve their work.

The second step of the realist review is development of inclusion criteria, search strategies, a data abstraction tool and methodological quality assessment for review of the literature and analysis of included studies. Throughout the above process, the candidate theories were tested and refined and new theories added. As the studies were evaluated, themes emerged that were based on the predetermined theories. Each theme was assigned a code and linked to a quotation in the study. As a new theme emerged it was assigned a new code; we then searched for this theme in all the included studies in the review. New and revised candidate theories were synthesised into the set of candidate theories to test in our realist review.

Study eligibility criteria

Included studies had the following criteria:

- Study design—original journal articles (no commentaries, letters to the editor, editorials or position pieces).
- Setting—medical schools, residency and fellowship programmes worldwide.
- Population—physician trainees (medical students, residents and/or fellows).
- Interventions—whether clinical or educational—that engage trainees in QI work, where they are involved in changes to the delivery of care to patients within the clinical setting.
- Reporting of clinical outcomes (patient care outcomes and system performance improvements) as the primary outcome measure.

Search methods

In collaboration with a professional librarian, one reviewer (ACJ) developed search strategies for the following databases: MEDLINE (2000 to 12 March 2013), Cochrane Library (2013) and Web of Science (15 March 2013). To locate potentially relevant studies in MEDLINE, we used exploded Medical Subject Headings terms and key words to generate sets for the themes of *QI* and *medical education*. We then used the Boolean term 'AND' to find their intersection. This basic approach was modified as necessary to search each electronic database. No language restriction was applied. Time limit was applied to obtain articles published after 2000, which corresponded with the publication of the *Institute of Medicine* reports *To Err Is Human* and *Crossing the Quality Chasm*. We excluded commentaries, editorials and letters. The full search strategy is available upon request. Reference reviews of the four earlier systematic reviews[7–9 13] were performed by obtaining all references cited and searching forward using Web of Science to find all papers which cited these reviews and including them in title and abstract review.

Study selection

One reviewer (ACJ) independently screened each title and abstract for eligibility. Then, two non-blinded reviewers (ACJ and GO) independently assessed the

eligibility of each full text record. Discrepancies were resolved by consensus between both reviewers after full text review.

Data collection

One reviewer (ACJ) abstracted data from the full text articles. A standardised data collection tool was used to capture identifying information, intervention summaries, details of study protocol, all primary and secondary outcome data and a section to extract quotations from the articles for the realist review (see online supplement 2).

Analysis

Analysis of interventions and outcomes

Anticipating that the QI interventions and outcomes would be complex and different depending on the training programme, we used an iterative approach to categorise the different types of interventions and outcomes described in each study. We focused on any qualitative or quantitative reports of change in clinical outcomes. If outcomes were reported quantitatively, we determined whether statistical analysis was performed, either in the form of enumerative statistics or analytical statistics using statistical process control, a method of time-ordered analysis for QI.[15] For the secondary outcome, we noted the findings of the educational outcomes such as knowledge, skills and attitudes.

Assessment of methodological quality

The Medical Education Research Quality Instrument[16] is a validated instrument for methodological quality assessment of the medical education literature, but does not allow assessment of the methodological quality of the QI education literature specifically. Thus, we developed a set of criteria based upon the Cochrane Risk of Bias Tool and the Standards for Quality Improvement Reporting Excellence publication guidelines.[17][18] Criteria were based on attention to quality factors in three major categories: the population, intervention and outcome reporting (see online supplements 3 and 4). Each study was assessed on all the criteria for quality, taking into account bias, confounding and study quality.

A final methodological quality score was given to each study, based on a scale ranging from 'fair,' if almost none of the criteria were met, to 'good,' when minor flaws were found, to 'very good,' when high-quality reporting was achieved in at least one criterion each for population, intervention and outcome reporting, and 'excellent,' when high quality was achieved for all criteria (see online supplement 5).

The realist review

After completing the methodology of a systematic review, we used the realist review methodology to rigorously test the conceptual framework. We iteratively identified relevant themes, and through continuous data collection and rereading the articles, we tested the conceptual framework. Specifically, we looked for examples of when the curriculum was developed at the outset of the intervention to support the educational context of the candidate theory. We also looked for examples of successful completion of QI curricula and examples of physicians who are capable of and believe that it is their job to do their work and improve it.

RESULTS

Results of search

We included 39 studies for our final review (figure 1; excluded studies after full text review is available upon request), most of which were before–after studies or case reports in internal medicine or family medicine residency programmes (table 1). Less common were controlled trials, studies with medical students or reports from subspecialty resident programmes. Of the 29 studies that reported a sample size, the mean sample size was 5.6 trainees (SD=102), the median sample size was 24 trainees and the range was from 3 to 510 trainees.

Among the interventions, 21 were primarily clinical interventions in which the goal was clearly to improve patient care or system performance in the clinical setting with education of the trainee not the primary focus of the intervention; 18 studies primarily had educational interventions, in which the goal was to deliver a curriculum to trainees focused on learning about improvement of which a component was to improve patient care and system performance in the clinical setting. The mean intervention length was 6.6 months (SD=9.2).

Twenty studies reported system performance outcomes (e.g., improved documentation) while three reported only patient care outcomes (e.g., haemoglobin a1c, blood pressure) and 16 reported both patient care and system performance outcomes. Among the clinical outcomes, 28 studies reported successful improvements, two of which were not sustained. Ten studies demonstrated improvement in some measures and two clinical outcome reports were equivocal. No studies reported clinical outcomes that worsened.

Nineteen studies reported educational outcomes, using various measures of knowledge, skills and attitudes such as the Quality Improvement Knowledge Application Tool (QIKAT),[19] satisfaction surveys or objective structured clinical examinations.

Description of studies

The most common types of interventions were team projects and involvement in an existing clinical QI team (table 2). Among the team project interventions, trainees worked together to make improvements in the clinical setting; these studies had varied methodological quality scores. Seven of these studies demonstrated significant
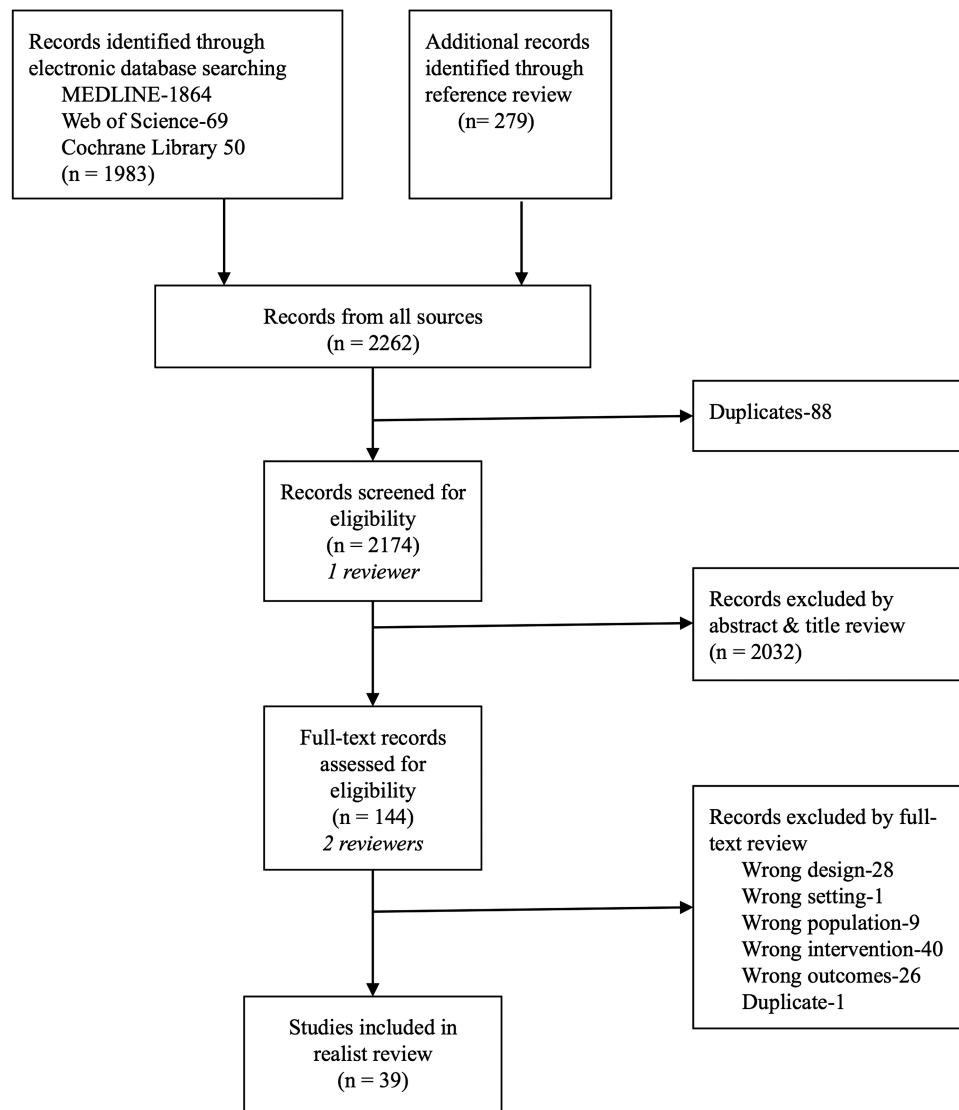
Figure 1 Study selection flow diagram.

improvement in documentation, critical care measures and medication adherence[20–26]; six studies showed no significant clinical outcomes.[4 27–31]

Of the interventions that involved trainees taking a role within an existing clinical interprofessional QI team, most were of 'good'[32–41] methodological quality. Most showed no significant clinical outcomes,[33 35 37 40–43] but some showed statistically significant improvement in diabetes measures, vaccination rates, chronic care measures and critical care measures.[32 34 36 38 39]

The third most common type of intervention used a chart audit. Most of these had 'good' methodological quality. About half these studies showed statistically significant outcomes, specifically in improved diabetes care, preventive care measures, documentation and critical care measures[44–48]; and the other half did not show statistically significant outcomes.[49–52]

The least common intervention used individual projects in which the trainee worked independently. Most

of these studies were rated 'good,'[53–56] and one received a 'fair'.[57] Most of these studies showed no significant clinical outcomes,[53 55–57] while one study showed significant improvement in care for heart failure patients.[54]

Methodological quality

A majority of studies (30) had 'good' methodological quality. Six were 'fair' studies and 3 were 'very good'. There were no 'excellent' studies.

Among the included studies, all but three studies described the intervention in sufficient detail so that it could be replicated. Although all the studies had, by our inclusion criteria, trainees participating in QI work within the clinical setting, only 14 studies articulated educational objectives for trainees. There were five studies which described a clinical intervention rather than an educational intervention and reported no educational outcomes (table 2).

Table 1 Baseline characteristics of included studies

Characteristic	n
Study design	
Controlled trials	2
Before–after studies	18
Case reports	10
Time series	7
Interrupted time series	1
Qualitative	1
Population	
Residents only	27
Medical students only	3
Fellows only	3
Residents and fellows	3
Medical students and residents	2
Medical students, residents and fellows	1
Specialty	
Internal medicine	10
Family medicine	7
Psychiatry	4
Paediatrics	3
Critical care	2
Surgery	2
Neonatology	1
Preventive medicine	1
Radiology	1
Various specialties	5
Medical schools	3
Clinical setting	
Outpatient	
Primary care	15
Psychiatry	2
Paediatrics	1
Inpatient	
General medical unit	2
Adult intensive care unit	2
Neonatal intensive care unit	1
Paediatric emergency department	1
Radiology	1

It is notable that three studies took steps to minimise bias and confounding. Holmboe et al[45] matched each second year resident in the intervention track to a third year control. Dysinger and Pappas[21] enrolled the entire fourth year medical school class in a required month-long clinical QI rotation over 3 years, resulting in 510 students completing the curriculum, and allowing for comparison over 3 years of data collection to observe and account for secular trends. Asao et al,[49] in addition to enrolling only second year residents in the chart audit curriculum intervention, completed a multivariate analysis to account for the trainee's experience as an auditor, the duration of exposure to the curriculum independent of training level and number of comorbidities in the resident's patient sample.

Synthesis of results and realist review

We identified several major themes through realist review. These themes are organised by 'what works,' 'for whom,' 'under what circumstances' and 'to achieve what outcomes' (table 3). After synthesising the range of interventions, clinical and educational outcomes, the methodological quality and realist review of the 39 studies, we tested the candidate theory and conceptual framework by iteratively analysing the major themes which emerged from the data. Specifically, we looked for evidence of a predetermined curriculum and educational context, as we hypothesised at the outset. However, we failed to find evidence of these mechanistic and contextual factors as important determinants in producing physicians who are lifelong learners and improvers. Thus, we revised the candidate theories and developed a conceptual framework (figure 2).

Many different types of curricula are described in the included studies, some of which are distinct educational interventions and some of which involve trainees in existing clinical QI in their practices. Among the included studies, these interventions fell into four categories, and we found examples of statistically significant improvements in clinical outcomes in each category. Those studies with 'fair' methodological quality scores did not report significant results or failed to report numerical results with statistical analysis. Therefore, the higher-quality studies suggest that, with certain contexts and mechanisms, significant improvement in clinical outcomes is achievable when trainees are exposed to QI within the clinical setting.

Several success characteristics were common to different contexts of clinical QI education (table 3; for illustrative quotes see online supplement 6). As noted by Sockalingham et al[56] 'residents identified workload as a major barrier to (doing QI work).' Successful QI teaching programmes were consistently clear about the time required for trainee work-hour rules, competing demands and for faculty involvement. Success of specific programmes will also depend on whether it makes more sense to train all faculty members in QI principles or to have a dedicated select faculty group in charge of the QI curriculum. The availability of data through information systems is also a facilitator to trainee satisfaction and engagement. The sustained improvement reported by Halverson et al[36] was achieved through the use of timely regular data feedback to all providers, including trainees, about the care of patients with diabetes in the practice. Two studies also highlighted the challenges that occur when trainees must abstract their own data, such as is the case in a practice which has not implemented an electronic medical record, or when data feedback is not timely enough for continuous QI.[34 44] Choice of the project topic is also important for trainees. QI educators need to consider the needs of the clinical setting as well as level of trainee; however, no consensus emerged as to the best approach.

Table 2 Summary of interventions, outcomes and methodological quality

Author and year	Population (n)	Intervention description	Clinical setting	Clinical outcomes		Educational outcomes	Quality assessment†
				Finding	Statistically significant*		
Chart audit							
Gould et al 2002[44]	2nd year medical students (77)	Learners audited random sample of diabetes charts using Qualidigm, before and after 'Project in a Box'	Outpatient primary care clinic	Improved rates of Hba1c, foot exam and eye exam documentation	Yes	Improved knowledge, skills, attitudes; poor learner satisfaction	Good
Paukert et al 2003[48]	FM residents (36)	Self and peer audits done at several time points	Outpatient primary care clinic	Improved, but unsustained, composite 'preventive' score	Yes	NR	Good
Holmboe et al 2005[45]	2nd year IM residents (26)	Learners audited sample of their own diabetes patients using Qualidigm	Outpatient primary care clinic	Improved patient care (Hba1c, LDL) and system performance (monofilament testing documentation)	Yes	Improved perceived value and motivation	Very good
Kaddan et al 2006[46]	Residents and medical students (NR)	Structured session every 24 hrs of all X-ray and culture reports among ED patients	Paediatric emergency department	Decrease in chart requiring attending comment and change in treatment course	Yes	High learner satisfaction	Good
Krajewski et al 2007[51]	Residents (NR)	Performed audit on self-identified problem in radiology reporting; presented at M&M conference	Radiology department	Multiple system improvements implemented	No	NR	Fair
Asao et al 2009[49]	2nd and 3rd IM year residents (80)	Peer audit performed; feedback and motivational plan proposed by learner	Outpatient primary care clinic	Improved composite measures for COPD, CHD, DM, HTN, LVF	No	NR	Very good
Carek et al 2009[50]	FM residents (20)	Chart audit before and after educational session	Outpatient primary care clinic	Improvement in oral and mental health, care of underserved populations, antibiotic use, elderly care, preventive services	No	NR	Good
Kirschenbaum et al 2010[47]	CC fellows and residents (NR)	Team audit and analysis of all transfers from GMU to MICU	MICU	Improvement in number of cardiac arrests and deaths, number of times MET called	Yes	NR	Good
Smith et al 2012[52]	IM residents (20)	Peer RCA on near-miss cases, presented at M&M conference	Various departments	Multiple system improvements implemented, some successful	No	High learner satisfaction	Fair
Participant on clinical QI team							
Coleman et al 2003[34]	FM residents (NR)	Participation at training site QI team; learner chose projects and improvement approaches	Outpatient primary care clinic	Improved microalbuminuria screening, medication list completion, data summary sheets	Yes	NR	Good
Mohr et al 2003[38]	Peds residents (8)	Resident team chose project for interprofessional practice team improvement	Outpatient paediatric clinic	Improved vaccination rates for the practice	Yes	NR	Good
Landis et al 2006[37]	FM residents (126)	Residents involved in statewide learning collaborative to improve diabetes care	Outpatient primary care clinic	Improved ACIC scores	NR	NR	Good

Continued

Table 2 Continued

Author and year	Population (n)	Intervention description	Clinical setting	Clinical outcomes		Educational outcomes	Quality assessment†
				Finding	Statistically significant*		
Halverson et al 2007[36]	FM residents (NR)	Resident served on committee to improve diabetes care	Outpatient primary care clinic	Improved percentage of patients at goal for Hba1c, LDL, BP	Yes	NR	Good
Stapleton et al 2009[42]	Peds senior residents (NR)	RPIW on improving senior resident rotation	Paediatric inpatient service	Improved system performance measures	NR	NR	Fair
Buckley et al 2010[32]	CC fellows and residents (NR)	Mandatory participation on MICU improvement team	MICU	Improved iatrogenic pneumothorax rates, sepsis-specific mortality, sepsis bundle compliance	Yes	NR	Good
Fischman et al 2010[35]	IM residents (4)	Controlled trial with involvement on clinical QI team	Outpatient primary care clinic	Improvement in no-show, continuity measures, doctor-patient relationships	NR	NR	Good
Stevens et al 2010[39]	IM, FM, peds residents (NR)	Involvement in statewide collaborative for diabetes care	Outpatient primary care clinic	Improved ACIC scores	Yes	High learner participation	Good
Yu et al 2010[41]	FM residents (6)	Resident participation in statewide collaborative to improve diabetes care	Outpatient primary care clinic	Improved ACIC scores	NR	Improved % of residents reviewing performance reports, demonstrating improved behaviours	Good
Vidyarthi et al 2011[43]	Fellows and residents (NR)	Financial incentive (US$1200 per trainee) for involvement in improvement work at medical centre	Various departments	Several system performance measures improved	NR	NR	Fair
Stueven et al 2012[40]	Residents and medical students (249)	Residents surveyed for relevant patient safety and QI improvement issues, attended retreats	Various departments	Several system performance measures improved	NR	NR	Good
Carey et al 2013[33]	Neonatology fellows (3)	Fellows participate on Q and S committee, chair working group when issues arise	NICU	Improvement in broncho-pulmonary disease, catheter-associated bloodstream infections	NR	Learner self-reflections about QI, presentations at conferences	Good
Team project							
Varkey et al 2006[31]	Fellows, residents, medical students (7)	Multidisciplinary trainee teams in training hospital	Various departments	Improvement in documentation of medication reconciliation	NR	Improved QIKAT scores	Good
Oyler et al 2008[23]	2nd year IM residents (34)	Mandatory project while on ambulatory rotation	Outpatient primary care clinic	Improvement in documentation of height, weights, BMI	Yes	NR	Good
Varkey et al 2008[30]	Preventive medicine, endocrinology fellows (9)	QI project taught jointly by medicine and engineering faculty	Various departments	Improvement in patient understanding on treatment	NR	Improved QIKAT scores, learner satisfaction	Fair

Continued

Systematic review

Table 2 Continued

Author and year	Population (n)	Intervention description	Clinical setting	Clinical outcomes Finding	Statistically significant*	Educational outcomes	Quality assessment†
Tomolo et al 2009[29]	IM residents (42)	QI project while rotating on inpatient medicine service	Various departments	Multiple sustained system performance measures improved (i.e., missing lab values)	NR	High learner satisfaction	Good
Varkey et al 2009[26]	Preventive medicine fellows (19)	Fellows develop and implement projects over 4-week rotation	Various departments	Multiple system performance and patient care measures improved	Yes	Improved QIKAT scores, OSCE performance, learner satisfaction	Good
Diaz et al 2010[20]	2nd and 3rd year FM residents (61)	Clinical scholars curriculum delivered over 1 year of residency	Outpatient primary care clinic	Multiple system performance and patient care measures improved	Yes	Increase in number of publications and presentations	Good
Shiner et al 2010[25]	Psychiatry residents (12)	Aiming to improve care for major depressive disorder	Outpatient psychiatry clinic	Improved percentage of patients seen within 6 weeks of starting MDD treatment	Yes	NR	Good
Clark et al 2011[28]	General surgery residents (33)	Team completed needs assessment and improvement in signout process by template	Inpatient surgery service	Improvement in signout processes	NR	NR	Good
Dysinger et al 2011[21]	4th year medical students (510)	Required rotation, putting students into practices focused on improvement	Various departments	Improved documentation	Yes	Some improved learner satisfaction	Very good
Laiteerapong et al 2011[22]	IM residents (10)	Team project to improve documentation	Outpatient primary care clinic	Improvement in height, weight, BMI documentation	Yes	Improved learner satisfaction	Good
Ogrinc et al 2011[4]	2nd year medical students (22)	Health Leadership Practicum Elective brings student teams into clinical settings in need of improvement	Various departments	Multiple reported improvements (i.e., urine samples screened in pregnant women)	NR	NR	Good
Oyler 2011[24]	IM residents (64)	Required rotation encouraging teams to develop projects	Outpatient primary care clinic	Improvement in ASA use, documentation on BMI and smoking history	Yes	NR	Good
Arbuckle et al 2013[27]	3rd year psychiatry residents (12)	Longitudinal QI curriculum over 37 weeks, including longitudinal project	Outpatient psychiatry clinic	Improvement in monitoring of depression symptoms, screening	NR	Improved QIKAT scores	Good
Individual project							
Weingart et al 2004[57]	2nd and 3rd year IM residents (26)	RCA/QI project on voluntary elective	Various departments	Improvement in system performance and patient care measures	NR	Improved learner satisfaction	Fair
Canal et al 2007[53]	3rd year general surgery residents (15)	Mandatory QI project on research time	Various departments	Improvement in several system performance measures	NR	Improved QI curriculum pre/post test	Good

Continued

Table 2 Continued

Author and year	Population (n)	Intervention description	Clinical setting	Clinical outcomes		Educational outcomes	Quality assessment†
				Finding	Statistically significant*		
Sockalingham et al 2010[56]	2nd and 3rd year psychiatry residents (40)	Mandatory QI project while on rotation	Various psychiatry departments	Improvement in consult/referral services	NR	Information by focus group and questionnaire	Good
Oujiri et al 2011[54]	3rd year IM residents	Learners chose QI project as part of elective rotation	Outpatient primary care clinic	Improvement in several patient care and system performance measures for heart failure patients	Yes	NR	Good
Reardon et al 2011[55]	Psychiatry residents (16)	Learner assigned to unit and completed mandatory project	Various departments	Improvement in consult processes	NR	Improved QIKAT scores	Good

*If 'Yes' the majority of findings in the results of the study had to be shown to be statistically significant, either by p value or statistical process control (SPC) analysis.
†We modified methodological quality assessment of these studies to take into account the important factors of educational literature: clear accounting for systematic bias, clear description of the intervention, learning objectives articulated for educational interventions, minimisation of other exposures which could have impact on the outcome, minimisation of bias and confounding.
QI, quality improvement; ACIC, assessment of chronic illness care; ASA, aspirin; BMI, Body Mass Index; BP, blood pressure; CC, critical care; CHD, coronary heart disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; ED, emergency department; FM, family medicine; GMU, general medical unit; Hba1c, haemoglobin a1c; HTN, hypertension; IM, internal medicine; LDL, low density lipoprotein; LVF, left ventricular failure; M&M, morbidity and mortality; MET, medical emergency team; MICU, medical intensive care unit; N, no; NICU, neonatal intensive care unit; NR, not reported; QIKAT, quality improvement knowledge assessment test; OSCE, objective structured clinical examination; RCA, root cause analysis; RPIW, rapid process improvement workshop; Y, yes.

DISCUSSION

How can our findings inform a comprehensive model of teaching, learning and doing QI in medical education? Our realist analysis and conceptual framework (figure 2) suggest that clinical education, whether providing care to an individual patient or doing QI work, does not begin with the curriculum. It begins with the trainee and patient at the centre of a healthcare system that encompasses many institutional levels. The trainee exists within two overlapping worlds: educational and clinical. The educational world is comprised of teaching faculty and together they exist within the training programme. The clinical world is made up of the patient and family at the centre of an interprofessional care team, of which the trainee is one part. The outcome of the educational world is improved trainee knowledge, skills and attitudes. The outcome of the clinical world is improved patient care and system performance. While these are often seen as separate, QI is one key area that exposes the inter-related complexities of the educational and care-delivery systems. In order to produce physicians who are capable of and believe that their duty is to do their work and improve their work, we should rethink the conventional wisdom

Table 3 Relevant themes from realist review

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What works	Accurately account for the time it takes to deliver QI education in the clinical setting due to competing demands, existing work load of trainees, and work-hour rules Identifying educational and clinically relevant project topics is challenging Consider having trainees choose their own project Choose topics of clinical importance Use near misses as a way to identify system errors
For whom	Medical students can, and should be expected, to contribute to quality of care in the clinical setting Residents are front-line providers and have deep insights into the clinical processes and the knowledge for improvement within the system
Under what circumstances	Successful QI teaching in the clinical setting requires support from both educational and care delivery leaders and the work of the trainees Data are critical. The availability of data, especially through health information technologies, has a direct positive impact on learner satisfaction and engagement Opportunities for interprofessional engagement and education can be found in teaching about QI within the clinical setting Programs can be successful by either engaging all faculty around QI or by having dedicated QI faculty for teaching QI within the clinical setting
To achieve what outcomes	There is lack of clarity around whether educational and clinical outcomes are of equal or relative hierarchical importance Sustainability is important for the clinical setting and the trainee. Sustainable projects can impact the culture of the clinical setting, but unsustainable projects may leave the trainee and other participants disheartened about improvement work

QI, quality improvement.
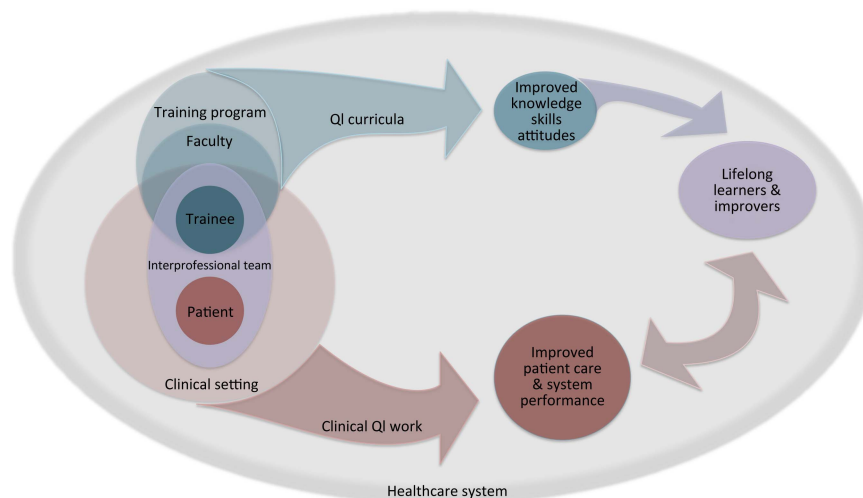
Figure 2 A conceptual framework describing the relationships between the contexts, mechanisms and outcomes for quality improvement (QI) in medical education.

around education and acquisition of improvement knowledge and skills. As Batalden and Davidoff[58] wrote, 'Learning how to do quality improvement and actually carrying out quality improvement are essentially one and the same; both are special forms of experiential learning.' In fact, medical education is currently embracing this culture in teaching clinical skills using Adult Learning Theory, which reminds us that professionals learn best when they see a *need* to acquire the knowledge and skills for fulfilment of goals.[59] If trainees see that faculty are asking questions of the process and *needing* to learn more to improve the system, then they have the opportunity to engage with them.[60] Interestingly, Asch *et al*[61] have demonstrated that within obstetrical residencies, it is possible and, perhaps beneficial, to rank obstetrical programmes based on overall performance on clinical rather than educational outcomes, representing yet another innovation for the future of the medical profession. The ACGME has acknowledged the importance of the clinical learning environment as an essential component of resident education and, accordingly, adopted the Clinical Learning Environment Review, 'to generate national data on programme and institutional attributes that have a salutary effect on quality and safety in settings where residents learn and on the quality of care rendered after graduation.'[62] Through the knowledge, skills and attitudes that trainees achieve during their educational programme while taking part in the improvement of the clinical care, we expect to nurture lifelong learners and improvers who will advance clinical improvements in patient care and system performance.

This realist review has limitations that begin with the known publication bias in this field. This bias was corroborated in our review, as none of the published studies described a clinical process that was *worsened*. Not sharing failed pilots and curriculum limits the learning that can occur across programmes. Also, although our search strategy allowed us to analyse *any* circumstance of trainees being involved in QI in the clinical setting, this may have caused us to falsely criticise studies with primarily clinical interventions, because they did not aim to prove that involving trainees made a difference in their clinical outcomes. The realist review process, however, helps to differentiate these studies and their important qualitative information about 'what works,' 'for whom,' 'under what circumstances' and 'to achieve what outcomes'.

Because a methodological quality tool does not exist for assessment of the QI education literature, we created a tool by combining elements of existing validated tools. Although we did not use a validated instrument, the tool we developed contains the specificity for the QI education literature and thus made the quality assessment more rigorous. We did not, however, identify any 'excellent' quality studies (see online supplement 5). Although we found that all the lowest-quality studies did not demonstrate significant results, there were no strong studies to show improvement in both clinical and educational outcomes. We identified many studies with minor weaknesses, and the realist review process helps to glean the notable characteristics from these data. More high-quality studies would take steps to minimise bias in the study population, clearly describe the intervention and educational objectives, minimise other exposures or secular trends that could have accounted for the results, analyse results with enumerative or analytic statistics, explain all biases and confounders and report funding sources. Among the studies in this review, many would have been improved by particular attention to minimising bias and confounding in the study population, and a clear articulation of educational objectives.

CONCLUSION

The studies in this review reported on many more clinical outcomes than had been described in previous reviews, in large part due to the development of clinically oriented QI programmes since the prior reviews. Using the realist approach allowed us the advantage of synthesising these data to not just update, but reconceptualise (figure 2) the current landscape of QI teaching. Advances in teaching and doing QI has made tremendous strides in the past decade, but further work is needed to determine the factors that reliably facilitate the development of physicians who will believe and are capable of doing their work and improving their work—ultimately, physicians who are lifelong learners and improvers.

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Supplement 1. Candidate Conceptual Framework
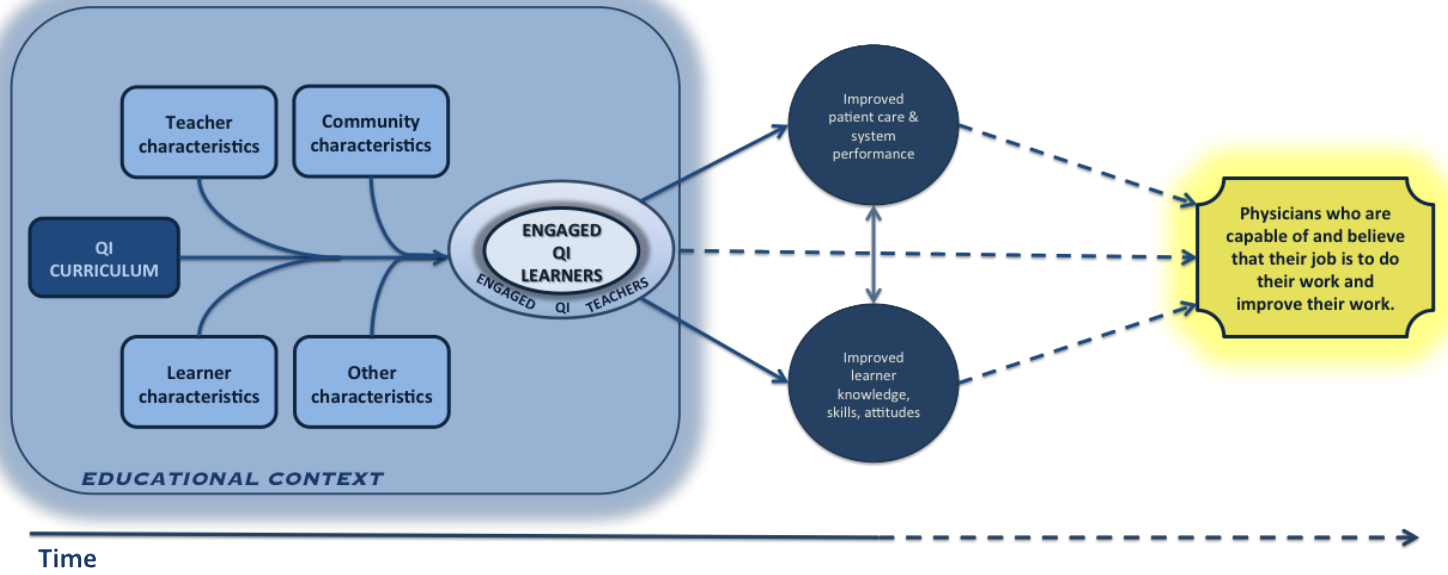
Supplement 2. Realist Review Data Abstraction Tool.

Author	
Year	
Study Design	
Setting (name of school or training hospital)	
Population/Participants (medical students, residents, fellows)	
Specialty	
How participants were selected	
N (Trainees, not patients)	
Length of study	
Specific clinical setting	

Intervention type Clinical OR educational	
Intervention details (chart audit, rotation, continuous project, etc)	
Length of Intervention	
Comparison (if applicable)	
CLINICAL OUTCOME Patient care OR system performance	
Improvement? (Y/N)	
Measure Type	
Outcomes	
LEARNER/EDUCATIONAL OUTCOME	
Improvement? (Y/N)	
Outcome	
Comments & Quotations	

Supplement 3.   Tool for Assessing Methodological Quality of Included Studies

BIAS	SPECIFIC QUALITY CRITERION
Sampling Bias	*Was there clear articulation of the group from which the study population was sampled?*
Selection Bias	*Was the process for selection of study participants clearly articulated?*
	Was the study population itself clearly articulated?
	Was a control/ comparison group used?
	If yes, was the composition of the comparison group clearly articulated?
	If yes, were the groups in fact comparable?
Performance Bias	*Was the intervention clear articulated?*
	Is it clear WHY the intervention was chosen?
	Is it clear WHAT was done?
	Is it clear BY WHOM?
	Is the timing of the intervention clearly articulated?
	If a secular trend was identified or suspected, did the study attempt to minimize or account for it?
	If applicable, were educational objectives clearly articulated?
Detection Bias	*Were the study participants (learners) aware that their performance was being assessed?*
	If applicable, were the study participants (learners) aware that their performance was being compared to another group?
	Were patients aware that an improvement intervention was being conducted on them or their process of care?
Attrition Bias	*Was it clear when participants (learners) left the study and why?*
	Was it clear when patients were being evaluated?
Reporting Bias	*Were clinical outcomes reported numerically?*
	Was statistical significance of clinical outcomes considered? (either p-value or SPC analysis)
	Were educational outcomes reported numerically?
	Was statistical significance of educational outcomes considered? (p-value)
	Were confounders or effect modifiers accounted for and discussed?
Funding Bias	*Was a funding source specified?*
	If yes, is it likely that the funding source has no interest in outcomes of the study?
Other Quality Considerations	*Sample size?*
	Validated outcome measurement?
OVERALL	**Excellent – Very good – Good - Fair**

Supplement 4. Methodological Quality Criteria

METHODOLOGICAL QUALITY ASSESSMENT CRITERIA	
Category of Quality	**Criteria**
Excellent	Systematic bias is accounted for and minimized in the study population. Intervention is clearly described (who, what, when, where, why). If an educational intervention is proposed, learning objectives are clearly articulated. Efforts are taken to minimize exposures that could have accounted for the outcomes of the study other than the intervention itself (i.e. secular trends, other educational interventions, training level of the learner, length exposure to intervention). Results are reported numerically with appropriate comparison group; includes statistical analysis (p-value or SPC analysis). Biases that were present in the study were thoroughly explained and addressed. No apparent funding bias was evident.
Very good	Systematic bias is accounted for and minimized in the study population. At least one of three criteria describing the intervention are met. At least one of three criteria describing the outcome are met.
Good	Intervention is described but not with sufficient detail. If an educational intervention is proposed, learning objectives are articulated but are inadequate or unclear. There are minor systematic biases in the study population. There is an exposure that could account for the outcomes of the study other than the intervention itself but imposes minor biases. Results are reported numerically, but no statistical significance is reported. Major biases that were present in the study were explained and addressed, but minor biases were present and unaddressed. No probable apparent funding bias was evident.
Fair	Intervention is not described. If an educational intervention is proposed, learning objectives are not articulated. There are major systematic biases in the study population. There is an exposure that could account for the outcomes of the study other than the intervention itself and it imposes major biases. Results are reported non-numerically. Major biases that were present in the study werenot explained and addressed. Funding bias was evident.

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Supplement 5. Methodological Quality of Included Studies

Author & Year	Unbiased study population?	Intervention described in sufficient detail?	Educational objectives specified?	Other exposures or secular trends accounted for?	Numerical clinical outcomes with statistical analysis?	Biases explained and addressed?	Funding source disclosed?	Overall Assessment
CHART AUDIT								
Gould *et al.* 2002	No	Yes	No	No	Yes	Yes	Yes	2
Paukert *et al.* 2003	No	Yes	No	No	Yes	Yes	No	2
Holmboe *et al.* 2005	Yes	Yes	No	No	Yes	Yes	No	2+
Kaddan *et al.* 2006	No	Yes	No	No	Yes	Yes	No	2
Krajewski *et al.* 2007	No	Yes	Yes	No	No	No	No	3
Asao *et al.* 2009	Yes	Yes	No	Yes	Yes	Yes	No	2+
Carek *et al.* 2009	No	Yes	No	No	Yes	Yes	Yes	2
Kirschenbaum *et al.* 2010	No	Yes	No	No	Yes	Yes	Yes	2
Smith *et al.* 2012	No	Yes	No	No	No	Yes	No	3
PARTICIPANT ON CLINICAL QI TEAM								
Coleman *et al.* 2003	No	Yes	Yes	No	Yes	No	No	2
Mohr *et al.* 2003	No	Yes	No	No	Yes	Yes	Yes	2
Landis *et al.* 2006	No	Yes	No	No	No	Yes	Yes	2
Halverson *et al.* 2007	No	Yes	No*	No	Yes	Yes	No	2
Stapleton *et al.* 2009	No	No	No	No	No	No	No	3
Buckley *et al.* 2010	No	Yes	No	No	Yes	Yes	Yes	2
Fischman *et al.* 2010	No	Yes	No*	No	Yes	Yes	No	2
Stevens *et al.* 2010	No	Yes	No	No	No	Yes	Yes	2
Yu *et al.* 2010	No	Yes	No	No	No	Yes	Yes	2
Vidyarthi *et al.* 2011	No	No	No*	No	No	No	No	3
Steuven *et al.* 2012	No	Yes	No*	No	Yes	Yes	Yes	2
Carey *et al.* 2013	No	Yes	Yes	No	No	No	No	2
TEAM PROJECT								
Varkey *et al.* 2006	No	Yes	Yes	No	No	Yes	No	2
Oyler *et al.* 2008	No	Yes	No	No	Yes	No	Yes	2
Varkey *et al.* 2008	No	No	No	No	No	Yes	No	3
Tomolo *et al.* 2009	No	Yes	Yes	No	No	Yes	Yes	2
Varkey *et al.* 2009	No	Yes	Yes	No	Yes	Yes	Yes	2
Diaz *et al.* 2010	No	Yes	Yes	No	Yes	Yes	No	2
Shiner *et al.* 2010	No	Yes	No	No	Yes	Yes	Yes	2
Clark *et al.* 2011	No	Yes	No	No	No	No	No	2
Dysinger *et al.* 2011	Yes	Yes	Yes	No	Yes	Yes	Yes	2+
Laiteerapong *et al.* 2011	No	Yes	No	No	Yes	Yes	Yes	2
Ogrinc *et al.* 2011	No	Yes	Yes	No	No	Yes	Yes	2
Oyler 2011	No	Yes	No	No	Yes	No	Yes	2
Arbuckle *et al.* 2013	No	Yes	Yes	No	No	No	Yes	2
INDIVIDUAL PROJECT								
Weingart *et al.* 2004	No	Yes	Yes	No	No	Yes	Yes	3
Canal *et al.* 2007	No	Yes	Yes	No	Yes	Yes	Yes	2
Sockalingam *et al.* 2010	No	Yes	Yes	No	No	Yes	Yes	2
Oujiri *et al.* 2011	No	Yes	No*	No	Yes	Yes	Yes	2
Reardon *et al.* 2011	No	Yes	Yes	No	No	Yes	Yes	2

Note: No*=Clinical interventions which would not be expected to report educational objectives.

Supplement 6.   Themes and Illustrative Quotes from Realist Review

Theme	Illustrative Quotes
What Works	
Accurately account for the time it takes to deliver QI education in the clinical setting due to competing demands, existing work-load of trainees, and work-hour rules.	"This multifaceted curriculum does not require a substantial time commitment by either the resident or the faculty member. For the resident, it is just four half-days over the course of four weeks with a modest amount of time needed for outside reading. The time commitment for a faculty member is just three hours spread over four weeks once the curriculum is in place." Holmboe 2005
	"Psychiatry residents identified workload as a major barrier to the QIPs...Residents emphasized the need for clearly allocated educational time to complete QIPs and offset the workload demands." Sockalingam 2010
	"Because residency is a period of training and career development, residents have many competing responsibilities including inpatient rotations, academic research, outpatient clinic, and education. These responsibilities make it challenging for residents to dedicate time to additional projects outside of requirements." Laiteerapong 2011
	"The Accreditation Council for Graduate Medical Education requires that residents be involved in patient safety and quality improvement, but this is a challenge given work hour restrictions and service-educational obligations....Residents also have difficulty allocating precious time for institutional goals that do not correspond to areas that they perceive as needing attention and improvement." Steuven 2012
Identifying educational and clinically relevant project topics is challenging.	"Substantial work needs to be done to give students good options for project themes. Ideally, there should be a mix of project themes that can stand alone, as well as those that can be repeated or followed up by the next group of students." Dysinger 2011
	"The greatest challenge was to identify meaningful projects that could be completed within 3 weeks. Several projects were not completed because the objective was too ambitious." Weingart 2004
Consider having trainees choose their own project.	"Informally, residents said that they liked working on problems that vexed them during their clinical rotations. Many found the elective to be an eye-opening window on hospital QI activities." Weingart 2004
	"Perhaps the optimal combination of curriculum in quality improvement would involve our curriculum in the first or second year of residency followed the next year by the opportunity to create a quality improvement project." Holmboe 2005
Choose topics of clinical importance.	"The factors that are considered in choosing a project include its relevance to preventive medicine, significance to patients and the learners, scope for improvement, and feasibility for completion within the duration of the rotation." Varkey 2009
Use near-misses as a way to identify system errors.	"Only with continuous academic teaching with feedback on near-misses and medical errors can residents and young physicians, however, learn to maintain protocols and a high work standard...by encouraging participants to report cases of error and weaknesses in the system, the findings had an effect on other services provided by the ED as well." Kaddan 2006
	"Our approach involved the house staff at many different levels and in different ways. Fellows learned to evaluate delivery of care on an institutional level and critique not only the care of junior house staff and nurses, but also themselves and their peers...As part of the process, they also gained exposure into root cause analysis of individual cases." Kirschenbaum 2010

Theme	Illustrative Quotes
For Whom	
Medical students can, and should be expected, to contribute to quality of care in the clinical setting.	"Our data show that medical students can successfully initiate CQI activities at practices in which they participate with positive effects on the quality of care delivered. The use of medical students to initiate these efforts may represent an underutilized resource in efforts to improve the quality of care afforded the public." Gould 2002
	"It [the 1-month QI required medical student rotation] is, however, an experience that is consistently valued and can lead to improvements in processes of care." Dysinger 2011
	"Some may question whether students—particularly those in the early years of their medical education—are capable of systematically analyzing and changing systems as early as second-year medical school. Our work clearly demonstrates that students can develop and use these skills early in their careers....The curriculum thus becomes a vehicle for learning and improving patient care." Ogrinc 2011
Residents are front-line providers and have deep insights into the clinical processes and the knowledge for improvement within the system.	"...in their role as frontline physicians, they [residents] often are the first to recognize and identify systemic problems in the delivery of care that lead to inefficiencies and diminish quality. As future leaders in academic and community settings, they represent a group that should be educated and empowered with new skills and knowledge." Weingart 2004
	"Resident practices, by their nature, facilitated practice redesign to implement the CCM. For example, residents, as frontline caregivers, were effective and active participants in redesign and CCM implementation. In addition, evidence- based practice was highly valued and readily adopted in these training settings. Similarly, residents are by nature competitive in their commitment to providing good patient care; hence, teams both competed and readily learned from each other as change strategies were adopted across the diverse Collaborative settings" Stevens 2010
	"Lastly, and most importantly, our residents took on a much larger role than passive recipients of the chronic illness training. Not only did they participate in all stages of planning and implementation of the diabetes clinic, but they also designed QI activities, performed population-based management, and became the physician champions for spreading change to other members of the residency program." Yu 2010
	"Residents are willing and effective participants in a QI program. As front line providers, their experiences are valuable and their willingness to share insights can be an impetus for change." Smith 2012

Theme	Illustrative Quotes
Under What Circumstances	
Successful QI teaching in the clinical setting requires support from both educational and care delivery leaders and the work of the trainees.	"The support of the department chair, the vice chair of clinical affairs, the residents program director, and the training site clinical directors was essential to making possible the changes in the clinical schedules that permitted team meetings." Coleman 2003
	"Patience, persistent education, and commitment from the administrative, academic, and clinic leadership is critical to fully engage faculty and to reach the tipping point of a cultural change in which mistakes, waste, and planning silos are eliminated." Stapleton 2009
	"Part of the process of discoveries was the recognition of other stakeholders/professions (medical and non-medical)." Tomolo 2009
	"Nursing and departmental support were important, particularly in those areas requiring changes in policies." Kirschenbaum 2010
	"In addition to these interventions, we found three factors to be critical to our success overall: leadership committed to change, increased involvement of clinic staff, and residents as change agents." Yu 2010
	"At our institution, this was not successful until both the administration and the resident staff met and discussed the important components of such a system and, in fact, made it a priority, which illustrates the strength of a combined "top-down" and "bottom-up" approach." Clark 2011
	" From the medical center perspective, there is now a cohort of trainees who have skills and are engaged in the quality and safety mission of the hospital. They can be called on to lead their peers and superiors into engagement." Vidyarthi 2011
Data are critical. The availability of data, especially through health information technologies, has a direct positive impact on learner satisfaction and engagement.	"Getting learners to embrace the process of quality measurement and improvement, however, will be challenging as long as data collection re- mains tedious. Creative approaches to data collection and measurement (use of available managed care organization claims data) and active involvement of students in the planning process will be necessary to improve student experiences. We recommend further efforts in this area." Gould 2002
	"The need for data collection without dedicated personnel or an electronic medical record necessitated limiting the frequency and volume of data collection." Coleman 2003
	"Advanced information systems were central to this effort. The diabetes registry and subsequent reports were dependent on the data stored in our electronic medical record. Modifications of our medical record were necessary to capture items of particular interest, such as diabetic foot exams. The reports measuring practice progress toward our goals were critical for committee guidance." Halverson 2007
Opportunities for interprofessional engagement and education can be found in teaching about QI within the clinical setting.	"Our core clinical team invluded appointment secretaries, accounting representatives, clinic administrators, nursing personnel, laboratory technicians, physicians, nurse practitioners, and resident physicians." Halverson 2007
	"Chief residents were involved in interdisciplinary interactions with nursing and evaluation of house staff care." Kirschenbaum 2010
	"If programs are teaching systems-based practice via QI curricula, then it makes sense to teach across specialties and professions with nursing, social work, and administration." Reardon 2011
Programs can be successful by either engaging all faculty around QI or by having dedicated QI faculty for teaching QI within the clinical setting.	"We believe several features of our program contributed to its success... all faculty had quality improvement knowledge and experience (which may be lacking in many settings)." Mohr 2003
	"To learn how to refine and continually improve the QI-based curriculum, the program directors attend medical education– and QI-themed sessions at several national meetings each year... All members of the division faculty attend education-themed conferences offered by our institution's school of graduate medical education. By doing so, they stay up-to-date with current teaching and assessment methodologies as presented in the context of the ACGME competencies. Their attendance record is reviewed annually by the program directors who make recommendations for future conference attendance when areas for improvement are identified. Although the time commitment for these activities at times may pose a challenge to our faculty, each member of our staff considers that the clinical outcomes and their own professional development (including performance in practice credit) are well worth the effort." Carey 2013

Theme	Illustrative Quotes
To Achieve What Outcomes	
There is lack of clarity around whether educational and clinical outcomes are of equal or relative hierarchical importance.	"What may be more pragmatic and effective is to focus on clinical outcomes and allow educational outcomes to follow. The education of trainees (and others) may come more from doing QI than from studying it." Buckley 2010
	"We hope that the educational benefits extend beyond simply identifying unstable patients and escalating care. The decrease in house staff errors of judgment suggest that this might be the case." Kirschenbaum 2010
Sustainability is important for the clinical setting and the trainee. Sustainable projects can impact the culture of the clinical setting, but unsustainable projects may leave the trainee and other participants disheartened about improvement work.	"An apparent limitation of several previously reported house officer QI initiatives is a failure to create a durable infrastructure for sustaining the initiative." Weingart 2004
	"Beyond sustainability, our curriculum creates an ongoing residency-level project with the potential to improve the care of patients over the long term." Holmboe 2005
	"The following were the common themes that residents noticed while evaluating their projects...QI initiatives which decreased burden in clinic were more likely to be sustained...Structural changes to the clinic, while positive for clinic workflow, often had unintended consequences that affected the sustainability of QI projects." Oyler 2011