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Use of quality circles for primary care providers in 24 European countries: an online survey of European Society for Quality and Safety in family practice delegates

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ABSTRACT

Objective: To identify and describe the core characteristics and the spread of quality circles in primary healthcare in European countries.

Design: An online survey was conducted among European Society for Quality and Safety in Family Practice (EQuiP) delegates. To allow comparison with earlier results, a similar survey as in a study from 2000 was used.

Setting: Primary Health Care in European countries.

Subjects: General practitioners, delegated experts of the European Society for Quality and Safety in Family Practice (EQuiP).

Main outcome measures: (1) Attendance in quality circles (2) their objectives (3) methods of quality improvement quality circles use (4) facilitator's role and training (5) role of institutions (6) supporting material and data sources quality circles use.

Results: 76% of the delegates responded, representing 24 of 25 countries. In 13 countries, more than 10% of general practitioners participated in quality circles, compared with eight countries in 2000. The focus of quality circles moved from continuous medical education to quality improvement. Currently, quality circles groups use case-based discussions, educational materials and local opinion leaders in addition to audit and feedback. Some national institutions provide training for facilitators and data support for quality circle groups.

Conclusion: The use of quality circles has increased in European countries with a shift in focus from continuous medical education to quality improvement. Well-trained facilitators are important, as is the use of varying didactic methods and quality improvement tools. Qualitative inquiry is necessary to examine why QCs thrive or fail in different countries and systems.

KEY POINTS

- Countries with already established quality circle movements increased their participation rate and extended their range of quality circle activities
- The focus of quality circles has moved from CME/CPD to quality improvement
- Well-trained facilitators are important, as is the use of varying didactic methods and quality improvement tools
- Institutions should provide supporting material and training for facilitators

Introduction

Quality circles (QC) are small groups of healthcare professionals who meet to reflect on and improve their standard practice. QC is used as an umbrella term to include practice-based small group work, peer review groups, problem-based small group learning, practicebased research groups, continuous medical education (CME) groups and continuous professional development (CPD) groups. QCs exist across Europe for CME, CPD and quality improvement (QI) using different locally adapted designations. A literature review suggests QCs may improve individual and group performance by reducing costs, encouraging professionals to order fewer but more appropriate tests, improving prescription habits, and reporting critical incidents. QCs help participants link evidence to everyday practice, deal with uncertainty

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KEYWORDS

Education, family practice; health services research; peer review groups quality circle; quality development; quality improvement

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and feel secure in their professional roles. Participation may strengthen team-based strategies for preventing errors, reduce burnout, and help practices retain practitioners [1].

Though many studies corroborate the role of QCs in CME/CPD and behaviour change, descriptions of the characteristics of QCs are inadequate [2–4]. A survey in 2000 by Beyer et al. [5] provided a partial overview of the characteristics of QCs, but there is limited information available on their contemporary objectives, facilitators and their roles, the didactic methods and QI tools QCs use and the support they can access. QCs exist in several European countries, and knowledge about their characteristics will provide an initial step towards better understanding their successes or failures.

We collaborated closely with the European Society for Quality and Safety in Family Practice (EQuiP), a European Organization of Family Doctors collaboration network aiming to promote and exchange knowledge and innovations in quality development and patient safety in Europe. EQuiP includes one or two delegates from each of its member countries [6]; policy-makers and stakeholders share development and experiences with QI tools. Our goal was to identify and describe the core characteristics and the spread of QCs in primary healthcare in European countries.

Methods

Survey design

Beyer et al. [5] permitted the use of their original questionnaire to inform a new standardised online version that allowed collection of data that could be compared with the findings from their 2000 survey. The present survey included additional questions concerning further properties of QCs that emerged during interviews with Swiss and other European stakeholders in preparation for a realist synthesis on QCs [7]. The survey questions covered:

- General practitioner (GP) employment conditions
- Spread of QCs
- Main objectives of QCs
- Facilitators' characteristics and training
- QI tools used in QCs.
- Support and incentives for QCs
- Evaluation of QCs
- Autonomy
- Financial compensation
- Institutional support
- Reasons for not using QCs (for members of countries who do not use this tool)

When EQuiP members addressed the main objectives and QI tool of QCs, they used working definitions from literature that is standard in our organisation [6]. Continuous medical education (CME) helps physicians acquire new knowledge from research and publications to keep up with research evidence [8]. Continuous professional development (CPD) helps professionals incorporate new medical knowledge so they can deliver better patient care [9]. Quality improvement (QI) is an organised, data-guided activity that improves delivery of care and addresses local problems like perceived inefficient, harmful or badly-timed healthcare [10]. Guidelines are statements that are systematically developed; they reflect current knowledge and support decision-making by physicians and patients for appropriate care for specific health problems [11]. In discussions, two or more people examine a specific topic and each side presents their arguments [12]. Educational material contains summaries of evidence-based information about a topic or a clinical situation [13]. When a team or an expert visits a clinic to discuss practice recommendations, local barriers to change, and potential solutions, this is called an outreach visit. Synonyms for outreach visits are academic or educational detailing [14]. Audit and feedback mean that health professionals receive feedback on performance and reflect on data from their routine practice. Feedback takes different forms and comes from different sources, and may affect behaviour change. Data sources can include their own records, electronic medical records, and statistical summaries of health insurance companies or governmental organisations [15]. Local opinion leaders are considered trustworthy and influential. They may influence QC participants' and change their behaviour [16].

The standardised questionnaire was piloted and tested to minimise the risk of misunderstandings (supplementary file). This had two phases. First, the questions were discussed and revised during a workshop with six EQuiP delegates at a meeting in Tallinn in May 2014. After revision, the questionnaire was sent by email to six Swiss (AR) and six Danish (UK) colleagues who were not EQuiP members; the resulting critiques and comments were incorporated into the final version of the questionnaire. Because English is the common language among EQuiP delegates for meetings, the questionnaire was written in English.

Survey implementation

In preparation for an open EQuiP conference in Fischingen in 2015 on the topic of QCs, a survey was

conducted among its members to map the characteristics of QCs, their spread and variety, and update the results of the previous survey [6]. EQuiP delegates were sampled because of their expertise in CME, CPD and QI. They also have local networks and connections, making them an excellent source of information on local CME/CPD and QI developments. The Danish survey software (SurveyXact, Rambøll Management Consulting, Aarhus) was used to guide national delegates through the questionnaire.

In a first round, the questionnaire was sent to each delegate between February and March 2015. This was scheduled before the EQuiP conference held in Fischingen in April 2015, where experts on QCs held talks and workshops about QCs in their countries. The preliminary results of the survey were reported in presentations and discussed in panel sessions among experts and participants at the conference. After the conference, new member countries and more delegates joined EQuiP; therefore, the survey was repeated between October 2015 and February 2016 to include response rate and confirm or correct the first answers. The UK delegates included a Scottish expert who could account for the situation specific to Scotland.

Data analysis

SurveyXact allowed data to be exported into MS Excel files, where they were coded by AR and UK and then sorted by country of origin. Beyer et al. [5] used a cutoff point of 10% GP participation to distinguish between countries with high QC activity and those with low/no activity. We chose to use the same cut off of 10% for signposting high QC activity as Beyer et al. [5] for comparability. Everett Roger argues that the decision to accept or reject an innovation is not spontaneous; it is a longer social process in which people take actions like learning about an innovation, persuading and deciding to use the innovation, implementing it, and finally confirming or refuting its advantages. To spread on its own, an idea must reach critical mass (around 15%). However, if 5-7% of the members of a social system have accepted an innovation, this accelerates the acceptance rate through word of mouth for subsequent adopters [17]. In the Beyer et al. [5] study, the objectives of QCs and methods used for QI were combined in a single category. In our survey, they were separated to clarify differences among countries. The results were entered into tables by the type of characteristic to allow comparability. Where two delegates provided answers, the differences were acknowledged and percentages averaged. Where delegates submitted a second set of answers during round two, the answers were compared and deviations from previous answers were clarified by email contact as needed. During the meeting in Fischingen, input on important characteristics of QCs (e.g. autonomy of the groups, facilitation and how that affected group dynamics, training of facilitators, didactic methods, QI tools and organisational support for groups) were summarised by AR and UK, and related to delegates' survey answers. Testing of associations of different variables with QC activity was judged inappropriate for this study because of the limited number of participants, although such tests were performed by Beyer et al. in 2000 [5].

Results

The first round generated a 69% response rate; that is, 22 out of 32 EQuiP delegates answered, corresponding to 18 of 20 countries. Six new EQuiP delegates representing Finland, Greece, Hungary, Portugal, Slovakia and Slovenia were appointed in August 2015. The second round generated six additional answers from these delegates, one new response from the Netherlands, and 20 confirmed answers corresponding a 71% response rate. When adding all answers from 2015 and 2016, this results in a 76% response rate, resulting in a total of 29 out of 38 delegates who responded at least once, with answers from 24 of 25 countries (Table 1). In four countries, two delegates answered the survey; those answers concurred and the difference in estimated percentages did not exceed 5%. Twenty delegates from 16 different countries answered the survey twice without changing their answers or estimations of percentages.

Self-employment is still the predominant type of employment. In addition to salary and fee-for-service, remuneration now includes capitation fees and payment for performance systems. Most European countries combine options to form an individual pattern of remuneration. Even the gatekeeper role has expanded from 'yes or no' to include 'yes with exceptions' that differ from country to country (Table 2).

In 2000, eight countries showed high QC activity, which increased to 13 countries in 2015/2016 (Table 3). Belgium, Denmark, Ireland and the Netherlands consistently showed high participation. The objectives of QCs increasingly focused on QI, rather than only CME/CPD. In these countries, QC participants extended the range of methods used from audits to case-based discussions, educational material

Table	1.	Survey	among	Europear	n Societ	y for	Quality	y and	Safety	/ in	Family	/ Medicine	delegates.

	Delegates	First round,	First round,	Delegates	Second round,	Second round,	
Country	2015	response	no response	2016	response	no response	Total
Austria	1	1		1	1 confirmed		1
Belgium	2	1	1	2	1 confirmed	1	1
Croatia	2	1	1	2	1 confirmed	1	1
Czech Rep.	2	2		2	2 confirmed		2
Denmark	2	2		2	2 confirmed		2
Estonia	2	1	1	2	1 confirmed	1	1
Finland		No delegate in March	2015	1	1		1
France	2	1	1	2	1 confirmed	1	1
Germany	2	1	1	2	1 confirmed	1	1
Greece		No delegate in March	2015	1	1		1
Hungary		No delegate in March	2015	1	1		1
Ireland	1	1		1	1 confirmed		1
Israel	1	1		1	1 confirmed		1
Italy	2	2		2	2 confirmed		2
Netherlands	2		2	2	1	1	1
Norway	2	2		2	2 confirmed		2
Poland	1	1		1	1 confirmed		1
Portugal		No delegate in March	2015	1	1		1
Slovakia		No delegate in March	2015	1	1		1
Slovenia	1	1		2	1	1	2
Spain	1	1		1	1 confirmed		1
Sweden	2	1	1	2	1 confirmed	1	1
Switzerland	1	1		1	1 confirmed		1
Turkey	2		2	2		2	0
The UK	1	1	0	1		1	1
Total delegates	32	22	10	38	27	11	29
Total countries	20	18	8	25	23	9	24

Delegates: each country appoints one or two experts as representatives of their professional organisation. Delegates in March 2015: all member countries and their delegates in 2015.

Delegates in 2016: all member countries and their delegates in 2016.

The UK was represented by a Scottish expert who answered on the situation specific for Scotland.

Total: total amount of answering delegates/total amount of countries.

in a workshop-like atmosphere and use of local opinion leaders.

In countries with low QC activity, CME/CPD persisted as the main purpose of QC (Table 4). QCs in Poland and Croatia mainly used discussions, a workshop-like atmosphere and local opinion leaders, rather than audit and feedback.

Representatives of countries with high QC activity provided data on several essential aspects of QCs: facilitation, supporting institutions, data sources, financial compensation, autonomy and evaluation. Facilitators were mostly GPs. Generally, facilitators led the group through the QI cycle as an equal among equals. Most facilitators had completed formal training. Professional institutions provided training and support, and licensed their facilitators to award CME credits. Detailed results are presented in Table 5.

The most frequent supporting materials used were educational materials discussed in a workshop-like atmosphere, guidelines and individualised feedback. Most popular data sources among QC participants were case discussions, followed by data derived from their own practice's medical records. Internal evaluation was more common than external assessment. QCs enjoyed a high level of autonomy with regard to topics, process and choice of facilitator. Financial compensation for QC participation appeared to be rare. A summary of these details is presented in Table 6.

The primary channels of communication between participants involved emailing and telephone calls (around half of the cases used each method). Online chat groups were used in Switzerland, whereas social media (e.g. Facebook) was preferred in Denmark and Germany. Countries with no QC activity indicated that this may be attributable to a top-down system of quality improvement in their countries.

Local experts' input at the conference in Fischingen confirmed the shifting objective of QCs towards Ql. During their talks and podium discussions, these experts verified the importance of facilitation and the significance of various didactic methods and Ql tools applied in QCs, as illustrated in a document published on the EQuiP website [6].

Discussion

Principal findings

Over the last 20 years, the practice organisation and the remuneration system in European PHC has changed. Self-employment is still the most common form, but remuneration includes combinations of salary,

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	Year	Country	Austria	Belgium	Denmark	Finland	France	Germany	Ireland	The Netherlands	Norway	Portugal	Scotland (UK)	Sweden	Switzerland
Attendance	2000	Participation: % GP	6	75	85	5	0	20	60	75	25	0	×	40	25
	2015/16		>30	60	85	10	10	60	85	75	45	30	25	15	85
Objectives	2000	Continuous medical education	>	`	>	`	×	>	`	`	>		×	>	`
		Continuous professional development					×			`	>		×		
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		Quality improvement	>		`>		×	>	`	`			×		`
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	2016	Continuous medical education		>	`>		`	>		`	>	>	`	>	`
		Continuous professional development	`	>	>	>	`	>	`	>	>	>	`	>	>
		Guidelines			>	>				>	>	>	`		>
		Quality improvement	>		`>	`	`	>		`	>	>	`	>	`
		Other objectives			>			>			>	>	`	>	
Methods of	2000	Audit and feedback	>	`	>	×		×	`	×	>		×	>	`
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improvement	2015/16	Discussion	>	`	>	>	`	>	`	`	>	>	>		`
		Workshop like atmosphere		>	>	>		>	`	>	>	>	>	`	`
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		Audit and feedback	>		>	`	`>		`>	`	>			>	`
		Use of local opinion leader		>	>	>			`		>	>		`	`
		Other methods			>		`				>			>	
Notes. 🗸 mean	s applicable	\sim (multiple combinations of \checkmark m	od be po	ssible becau	use of mul	tiple object	tives of th	e aroups):	x = missing	a data. Participati	ion: bold =	= indicates p	precise data ac	cordina to	experts in

lable 4. Count	Tries with IC	ow/non-identifiable quality circle act	tivity.											
	Year	Country	Czech Republic	Croatia	Estonia	Greece	Hungary	Israel	ltaly	Poland	Slovakia	Slovenia	Spain	Turkey
Attendance	2000	Participation: % GP	2	2	0	10?	0	30?	0	m	×	2	0	×
	2015/16		0	-	0	0	0	0	0	2	0	0	0	×
Objectives	2000	Continuous medical education	>	>		>		>		>			>	×
		Continuous professional development												×
		Guidelines	>	>		>						>		×
		Quality improvement	>	>						>				×
		Other objectives	>			>								×
	2016	Continuous medical education								>				×
		Continuous professional development		>										×
		Guidelines												×
		Quality improvement								>				×
		Other objectives												×
Methods of	2000	Audit and feedback	×	×		×				×				×
quality		Other methods	×	×		×				×				×
improvement	2015/16	Discussion		>						>				×
		Workshop like atmosphere		>						>				×
		Use of educational material												×
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		Audit and feedback												×
		Use of local opinion leader		>						>				×
		Other methods								>				×
Notes. Means ap	plicable (mul	tiple combinations of \checkmark may be possible	because of multiple	objectives o	of the group	x = mis	sing data. Par	ticipation:	i = que	stionable p	ercentage.			

capitation fees, fee for service, and pay for performance systems. The practice organisation shifted from individual practices to various group practices: the organisational pattern in PHC for each country depends on local context. QCs spread rapidly, since group work appears to meet GP expectations about CME, CPD and QI projects. Countries with already well-established QCs increased attendance and extended their range of activities. Facilitators are mostly GPs and have successfully completed training. Educational material, guidelines and individualized feedback are frequent supporting materials. Most popular data sources among QCs are cases/own patients followed by data derived from own medical records. QCs enjoy a very high level of autonomy which seems vital for their performance. Only a few institutions provide supervision and hardly any initiate QCs. Their main functions are providing supporting material and training of facilitators. Only 4 out 13 countries' organisations provide financial incentives. Their effect on QC activity is difficult to judge.

Strengths and weaknesses of this study

The limited number of participants is a limitation of this survey. However, by contacting local experts and using a standardised questionnaire, a large amount of information could be gathered from many different European countries. Another potential limitation may be that the survey was conducted in English. Some participants might not have understood subtleties of the questions, although English is the common language among EQuiP delegates. The return rate was extremely high and the standardised answers could be compared where more than one delegate from a country provided answers. However, 19 countries were represented only by one respondent, which may reduce validity. But we could corroborate the results through further comparison between completed questionnaires and discussions with local experts on QCs at the conference in Fischingen in 2015. Still, as seen in the tables, there are limited results that represent official statistics, for example, about the spread of QCs among GPs. The results represent the observations of EQuiP delegates and local QC experts. We could not ascertain the truthfulness of a respondent or how much thought a respondent gave their answers.

Findings in relation to other studies

Comparison of the present findings with Beyer et al. [5] showed that countries with high QC activity had

Country			Austria	Belgium	Denmark	Finland	France	Germany	Ireland	The Netherlands	Norway	Portugal	Scotland (UK)	Sweden	Switzerlanc
⁻ acilitators' role, profession	Facilitator's role	Equal	>	>	>	>	>	>		>	>		>	>	>
and Training		Leader			>	>		>	>	>	>	>		>	>
ı		Other			>	>					>			>	
	Facilitator's profession	მ	>	>	>	>	>	>	>	>	>	>	>	>	>
		Other			>	>					>		`>	>	
	Facilitator's training	Formal	>		>	>		>	>	>	>			>	>
)	Other				>	>		>			>	`>		
		None		>	>						>			>	
3ole of institutions	Training facilitators		No	No	Yes	No	No	Yes	Yes	Yes	No	No	Yes	No	No
	Support and licence		Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Votes. 🗸 means applicable	(multiple combinations of	🖌 may be	possible	because c	of multiple	objectives	of the gr	oups).	-	:					

the role Facilitator's role: 'Equal' means the facilitator is an equal among participants, 'Leader' means the facilitator may have

means formal training takes place, 'other' means another type than formal training is in use Facilitator's profession: GP means general practitioner; Other means other profession. Facilitator's training: + SCANDINAVIAN JOURNAL OF PRIMARY HEALTH CARE

increased the percentage of participating GPs and extended the range of activities. Compared with 2000, QCs now play an important role for CME/CPD and QI in France and Scotland. Israel and Greece were assigned high participation percentages in 2000, which could not be confirmed by new data in this survey or by personal contacts within EQuiP.

In Denmark, Ireland, Belgium and the Netherlands, numerous studies have shown that QCs have become an inherent part of QI [18-21]. QC activity increased in Scandinavian countries (e.g. Finland and Norway); the latter documented by Frich et al. [22]. In contrast, the participation rate in Sweden declined, which the delegate attributed to an increase in centrally-steered QI. QCs grew rapidly in German-speaking countries, where they are often a mandatory part of integrated contracts in healthcare, contrary to all other countries where QCs are not mandatory. Health insurance companies or public organisations provide financial compensation, which might have contributed to their successful implementation [23,24]. Scotland and Wales recently introduced QCs as a means of QI in primary healthcare and abandoned the pay-for-performance system [25]. In England, QI activities do not usually occur in QCs, but are organised in a top-down approach in which guidelines are implemented in a pay-for-performance system. Portugal's primary care system has developed rapidly over the past few years, with a corresponding development in QCs. Similarly, the QC participation rate in France increased from 'no QCs in existence' in 2000 to involving at least 10% of GPs in 2015, as recorded in studies and numerous projects [1,26]. The reasons for different development patterns in different countries are not fully clear.

Typically, facilitators were specially trained GPs, which was important for the acceptability of educational interventions [27]. Educational material, guidelines and individualised feedback were frequently used supporting materials. Own practice experience in the form of case-based discussions and data derived from own medical records were key in QCs. As shown in the literature, discussion of personal cases increased the sense of ownership, and helped participants understand how the topic mattered in the context of their everyday practice [28]. According to responding EQuiP delegates, QCs benefit from a high level of autonomy, which appeared to be vital for their performance. These findings were confirmed by local QC experts when reporting on local projects and discussing preliminary findings of the present survey at the conference in Fischingen. Few institutions provided supervision, and hardly any initiated QCs. Their main

lable o. Suppo	rt, autonomy and evaluation of quali	ity circles	in countri	ies with hi	gn activi	τy.								
	Country	Austria	Belgium	Denmark	Finland	France	Germany	Ireland	The Netherlands	Norway	Portugal	Scotland	Sweden	Switzerland
Supporting Material	Evidence based educational materials	`>	>	>		>	>	>	`	>		>	>	
	Feedback on individual and/or group performance from different data sources	>	>			>	>	>	`	>				>
	Guidelines	>	>	>		>	`	>	`		>			>
	Library resources		>			>		>		>				
	Evidence-based summaries		>			>		>	`	>	>	>		>
	Other supporting material			>	>					>			>	
	Not provided by institutions or organisations			>										>
Data Sources	Cases (own patients)	>	>	>	>	>	>	>	>	>	>	>	>	>
	video recordings of patient consultations			>						>	>		>	`
	Data from own medical records	>	>	>	>	>	>	>	`	>	>		>	>
	Data from external provider		>	>	>	>		>	>	>	>		>	>
	Other data sources			>			>			>			>	
Financial Support	Financial compensation		>			>			`					>
	Coverage of own costs		>					>	>			>	>	>
	Payment for facilitator			>			>			>				
	None	>		>	>	>				>	>	>	>	>
Autonomy	as to topic	>	>	>	>	>	>	>	\$	>	>	>	>	>
	as to didactic methods		>	>	>	>	>	>	>	>	>	>	>	>
	as to facilitator		>	>	>	>	>		`	>	>	>	>	>
	as to length and frequency of meetings		>		>	>	>	>	\$	>	>	>	>	>
	as to other characteristics				>					>		>	>	
Evaluation	Internal evaluation		>	>	>	>	>	>				>	>	>
	External evaluation			>	>			>	\$	>				
	No evaluation	>		\$						>	>		>	>
Notes. <pre> /means app</pre>	olicable (multiple combinations of \checkmark may be	e possible	because of	multiple obj	ectives of	the group	s).							

functions were providing supporting materials and training facilitators (e.g. as in Germany) [29].

Among countries with low QC activity, Croatia is attempting to re-establish the development of QCs. In 2016, they trained their first facilitators according to the principles of EQuiP, and are now forming a fostering organisation. Poland has stalled in what could be termed an 'establishment phase', and it is not understood why the implementation of QCs is so difficult there. QCs have disappeared in the Czech Republic, Greece and Slovenia. Estonia, Italy and Spain have prioritised other QI tools and are currently not using QCs.

Meaning of the study

The results may increase the understanding of QCs that allows stakeholders and policy makers to improve the effectiveness of QCs as interventions for behaviour change. The data and participants' comments for countries with an increasing percentage of QC participation show that a high level of autonomy and structured support are as important for successful QCs as well-trained facilitators and the use of varying didactic methods and QI tools. However, qualitative inquiry is necessary to examine how different aspects of QCs (e.g. training of facilitators, use of didactic methods and implementation of QI tools like use of internal or external data for audits) affect group performance to understand why QCs thrive or fail in different countries and systems.

Conclusion

Quality circles spread in European countries with a shift in focus from continuous medical education to quality improvement. Countries with already well established or emerging QC movements increased their participation rate and extended their range of QC activities. Well-trained facilitators are important, as is the use of varying didactic methods and QI tools. Institutions should provide supporting material and training for facilitators. Qualitative inquiry is necessary to examine these different aspects and provide explanations as to why QCs thrive or fail in different countries and systems.

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Ethics approval

The Swiss ethics committee classed involvement with QCs as service evaluation with no need for ethical approval. As the study results contribute to a PhD project at the University of Oxford, the project went through the Central University Research Ethics Committee's application process in Oxford and was approved (MSD-IDREC-C1-2015-002). This study ful-filled the requirements of informed consent, handling of personal information and confidentiality according to operational principles of the Declaration of Helsinski and adheres to the Belmont Report principles concerning respect for persons, beneficence and justice.

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