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DEVELOPING RESEARCH AND PRACTICE

Application of statistical process control in healthcare improvement: systematic review

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Objective: To systematically review the literature regarding how statistical process control—with control charts as a core tool—has been applied to healthcare quality improvement, and to examine the benefits, limitations, barriers and facilitating factors related to such application.

Data sources: Original articles found in relevant databases, including Web of Science and Medline, covering the period 1966 to June 2004.

Study selection: From 311 articles, 57 empirical studies, published between 1990 and 2004, met the inclusion criteria.

Methods: A standardised data abstraction form was used for extracting data relevant to the review questions, and the data were analysed thematically.

Results: Statistical process control was applied in a wide range of settings and specialties, at diverse levels of organisation and directly by patients, using 97 different variables. The review revealed 12 categories of benefits, 6 categories of limitations, 10 categories of barriers, and 23 factors that facilitate its application and all are fully referenced in this report. Statistical process control helped different actors manage change and improve healthcare processes. It also enabled patients with, for example asthma or diabetes mellitus, to manage their own health, and thus has therapeutic qualities. Its power hinges on correct and smart application, which is not necessarily a trivial task. This review catalogues 11 approaches to such smart application, including risk adjustment and data stratification.

Conclusion: Statistical process control is a versatile tool which can help diverse stakeholders to manage change in healthcare and improve patients' health.

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Quality improvement (QI) practices represent a leading approach to the essential, and often challenging, task of managing organisational change.¹ Statistical process control (SPC) is, in turn, a key approach to QI.² SPC was developed in the 1920s by the physicist Walter Shewhart to improve industrial manufacturing. It migrated to healthcare, first in laboratory settings (eg, Fisher and Humphries³) and then into direct patient care applications, along with other approaches to QI. Before we report on our systematic review of the literature on how SPC has been applied to QI in healthcare, there is a need to define SPC and its role in QI.

“Statistical process control (SPC) is a philosophy, a strategy, and a set of methods for ongoing improvement of systems, processes, and outcomes. The SPC approach is based on learning through data and has its foundation in the theory of variation (understanding common and special causes). The SPC strategy incorporates the concepts of an analytic study, process thinking, prevention, stratification, stability, capability, and prediction. SPC incorporates measurement, data collection methods, and planned experimentation. Graphical methods, such as Shewhart charts (more commonly called ‘control charts’), run charts, frequency plots, histograms, Pareto analysis, scatter diagrams, and flow diagrams are the primary tools used in SPC.” (Carey⁴, p xviii)

The terms “statistical *process* control” and “statistical *quality* control” are often used interchangeably,⁵ although sometimes the latter is used to describe a broader organisational approach to quality management that evolved into the concept of total quality management.⁶

One of the tenets of QI is that to improve healthcare performance we must change our way of working.⁷ But change does not always mean improvement. To discriminate between changes that yield improvement and those that do not, relevant aspects of performance need to be measured. In addition, measurement guides decisions about where improvement efforts should be focused in the first place. SPC may facilitate such decision making. Control charts, central to SPC, are used to visualise and analyse the performance of a process—including biological processes such as blood pressure homeostasis or organisational processes such as patient care in a hospital—over time, sometimes in real time. Statistically derived decision rules help users to determine whether the performance of a process is stable and predictable or whether there is variation in the performance that makes the process unstable and unpredictable. One source of such variation can be a successful intervention aimed at improvement that changes performance for the better. If the improvement is maintained, the process will stabilise again at its new level of performance. All of this can be easily determined by using SPC.⁴

Although there are theoretical propositions that SPC can facilitate decision making and QI in healthcare (eg, Berwick,⁸ Benneyan *et al.*,⁹ Plsek¹⁰) it is not clear what empirical support there is in the literature for such a position¹¹:

“The techniques of statistical process control, which have proved to be invaluable in other settings, appear not to have

Abbreviations: MRSA, methicillin resistant *Staphylococcus aureus*; PEFR, peak expiratory flow rate; QI, quality improvement; RCT, randomised controlled trial; SPC, statistical process control

realised their potential in health care. ... Is this because they are, as yet, rarely used in this way in health care? Is it because they are unsuccessful when used in this way and thus not published (publication bias)? Or is it that they are being successfully used but not by people who have the inclination to share their experience in academic journals?" (p 200)

The present systematic review aimed to answer these questions. We examined the literature for how and where SPC has been applied in QI of clinical/patient care processes and the benefits, limitations, barriers and facilitating factors related to such application.

MATERIALS AND METHODS

Drawing on the principles and procedures for systematic review of QI interventions¹² we searched for articles on the application of SPC in healthcare QI published between 1966 and June 2004 (see appendix A) in the following databases: Web of Science, Ovid Medline(R), EMBASE, CINAHL (Cumulative Index to Nursing and Allied Health Literature), PsycInfo, and the Centre for Reviews and Dissemination databases. We also included articles found by searching reference lists or from elsewhere which we were aware of, if they met our inclusion criteria: original empirical studies of SPC application in improvement of clinical/patient care processes in healthcare organisations, published in English. We excluded articles dealing with application of SPC in laboratory or technical processes (eg, film processing) and in surveillance/monitoring (unless they also contained empirical data about improvement efforts), as well as tutorials (unless they contained empirical case studies), letters, book reviews and dissertations.

We reviewed abstracts, when available, or else other information about the publication provided in the database (eg, publication type such as letters, book reviews or original articles). Articles that did not meet the inclusion criterion were excluded. We retrieved and read the full text of the remaining articles, again excluding the articles that did not meet the inclusion criterion.

We developed, pilot tested and modified a data abstraction form which we then used to consistently capture information of relevance to our review questions on reading the full text articles. The information recorded was: whether and how the article met the inclusion criterion; study objective(s); study design; whether the study empirically compared application of SPC with any other method for process data display and analysis; reported benefits, limitations, barriers and facilitating factors related to SPC; organisational setting; country where study was conducted; clinical specialty; unit of analysis; variables for SPC analysis; and other observations. Some questions in the form required a yes/no or brief response (eg, country where study was conducted) and others required answers in the form of direct quotes from the article or the a summary of the article written by the reviewer. Each article was read and data abstracted by one member of the review team (the coauthors of this review). Following this, all the data abstraction forms were reviewed by the first author, who solicited clarification and checked for any missing or incomplete data to ensure consistency in reporting across all articles reviewed. He also conducted the initial data synthesis, which was then reviewed by the entire team.

We determined the study design for each article and whether the investigators intended to test the utility of SPC application, alone or in combination with other interventions. In several articles, the study design or study objectives were not explicitly stated. Our determination of such intention in such cases was based on our reading of the full text papers.

Simple descriptive statistics—for example, the number of publications per year of publication or per country—were used to characterise the included studies. The qualitative nature of our research questions and of the abstracted data shaped our analysis and synthesis of findings regarding benefits, limitations, SPC variables, etc.¹³ The abstracted data was reviewed one question at a time and data from each article was classified into one or more thematic categories, each with a descriptive heading. Informed by our present understanding of QI and healthcare, we developed these categories as we reviewed the data, rather than using categories derived a priori from theory. For data that did not fit into an existing category, we developed a new one. Thus the categories emerged as we synthesised the data. We report the categorised data in tabular form, illustrated with examples, and give the references of all the source studies.

To strengthen our review through investigator triangulation,¹⁴ we sought feedback on an earlier version of this manuscript from two SPC experts: one was the most frequent coauthor in the included studies and the other was an expert on SPC application also in settings other than healthcare. Their comments helped us refine our data synthesis and distil our findings.

RESULTS

The database searches yielded 311 references. The initial review (abstracts etc.) yielded 100 articles which we read in full text form. Of these, 57 articles met the inclusion criteria and have been included in the review.^{15–71} To characterise the body of literature, figure 1 shows the year of publication and whether the studies were conducted in USA or elsewhere (further specified below); table 1 gives the study designs and objectives—whether or not to test SPC utility.

Most of the articles (45/57) concerned application of SPC in healthcare improvement in the USA.^{15–35 37–40 42 43 45 47 49–56 59 60 63 67–71} While the first US-based article was published in 1990, the non-US articles were published between 1998 and 2003: three articles were from the UK,^{61 62 66} three were from Switzerland,^{36 41 46} and one each were from Australia,⁵⁸ Finland,⁶⁵ France,⁵⁷ Indonesia,⁴⁴ Norway⁶⁴ and Spain.⁴⁸ The intention to test the utility of SPC is exemplified by a study aiming to reduce the rate of acquisition of methicillin-resistant *Staphylococcus aureus* (MRSA) on wards and units at Glasgow Royal Infirmary hospitals.⁶¹ Annotated control charts displaying data on MRSA acquisition were fed back monthly to medical staff, managers and hotel services. Sustained reductions in the rate of acquisition from the baseline, which could not otherwise

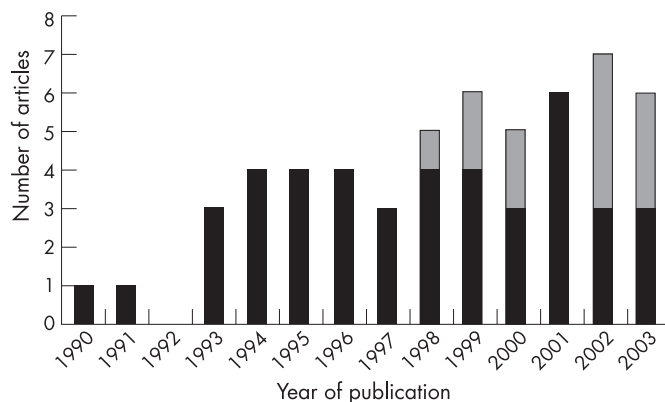


Figure 1 The number of included articles by year of publication. (A total of 55 articles were published in 1990–2003; the two articles from 2004 are not included in this graph since the database searches were conducted in June 2004.) Black bars: studies conducted in the USA; grey bars: studies conducted outside the USA.

Table 1 Study design and objectives of the studies included in the systematic review*

Study design	Number of articles	References	Number of articles in each study design category intending to test utility of SPC	References
Case study	28	16, 17, 19–21, 24, 26, 29, 33, 34, 36, 39, 41, 44–49, 53, 55, 57, 58, 61, 63–65, 67	16	16, 17, 20, 24, 26, 36, 41, 44, 47, 48, 57, 61, 63–65, 67
Tutorial with illustrative case study	23	15, 18, 22, 23, 25, 27, 30, 31, 35, 37, 38, 40, 42, 50–52, 54, 59, 62, 66, 69–71	3	22, 25, 30
Observational study of change in clinical procedure(s) using historical controls	2	43, 68	0	
Controlled before-and-after intervention studies	2	28, 56	1	56
Patient case reports	2	32, 60	2	32, 60

*The study designs are reported in order of frequency.

be accounted for, started 2 months later. In contrast, investigators at a paediatric emergency department used SPC to demonstrate a decline in the rate of contamination following the introduction of a new approach to drawing blood for culture specimens,⁶⁸ but the study had no intention to test the utility of SPC per se.

To characterise the content of the articles, we first present how and where SPC has been applied to healthcare QI. Tables 2–4 present the study settings (ie, hospital etc. where SPC was applied; table 2), the field of healthcare (ie, specialties or forms of care; table 3), and the units of analysis (table 4). Table 5 enlists the 97 distinct SPC variables that have been reported. Tables 6–9 convey our synthesis of the reported benefits, limitations, barriers and facilitating factors related to SPC application. For each category, we have given explanations or examples and references to the source articles.

DISCUSSION

SPC has been applied to healthcare improvement in a wide range of settings and specialties, at diverse levels of organisations and directly by patients, using many types of variables

(fig 1, tables 2–5). We found reports of substantial benefits of SPC application, as well as important limitations of, barriers to and factors that facilitate SPC application (tables 6–9). These findings indicate that SPC can indeed be a powerful and versatile tool for managing changes in healthcare through QI. Besides helping diverse stakeholders manage and improve *healthcare* processes, SPC can also help clinicians and patients understand and improve patients' *health* when applied directly to health indicators such as PEFr in asthma or blood sugar concentrations in diabetes. In healthcare, the "study subject" can thus also be an active agent in the process, as when patients apply SPC to their own health. Several studies indicated the empowering effects this may have on patients.^{35 38 40 50} SPC application thus has therapeutic potential as it can help patients manage their own health. We agree with Alemi and Neuhauser⁷⁰ that this potential merits further investigation.

Most of the included articles concerned application of SPC in healthcare improvement in the USA. Articles from other countries appeared only towards the end of the study period

Table 2 How and where SPC was applied: study settings*

Study setting	Number of articles	References
Hospital settings (total)	40	
Entire hospital	14	18, 21, 24, 25, 27, 31, 33, 37, 42, 44, 54, 56, 61, 69
Hospital department	12	17, 22, 28, 30, 39, 45, 47, 53, 57, 64, 68, 71
Hospital departments in collaboration	5	36, 41, 43, 46, 48
Hospital outpatient clinic	5	29, 32, 49, 60, 67
Hospital clinical chemistry laboratory	2	19, 58
Hospital outpatient clinics in collaboration	1	55
Hospital wards	1	65
Non-hospital outpatient settings (total)	12	
Outpatient single specialty clinic	5	35, 37, 40, 50, 70
Primary care centre	4	34, 52, 62, 66
Outpatient multispecialty clinic	2	15, 59
Ambulatory nursing centre clinic	1	23
Other settings (total)	6	
Healthcare system	2	26, 63
Nursing home	2	16, 51
Mental health residential facility	1	20
Not specified	1	38

*The study settings are divided in three groups, each consisting of several different settings. One article reported data from two settings, hence a total of 58 settings are reported.

Table 3 How and where SPC was applied: fields of healthcare*

Field of healthcare (specialty)	Number of articles	References
Anaesthesia—intensive care	12	22, 25, 33, 36, 39, 41–43, 46, 48, 57, 64
Family practice—primary care	7	34, 52, 55, 59, 62, 63, 66
Emergency medicine	6	19, 45, 46, 48, 53, 68
Cardiac (cardiothoracic) surgery	5	22, 30, 42, 47, 56
Cardiology	5	22, 32, 46, 48, 56
Internal medicine	4	15, 32, 37, 50
Surgery	4	42, 43, 49, 59
Asthma—allergy	3	35, 40, 70
Nursing	3	23, 24, 65
Clinical chemistry	2	19, 58
Nursing home	2	16, 51
Urology	2	36, 41
Endocrinology	1	55
Haematology	1	67
Mental health	1	20
Orthopaedics	1	28
Oncology	1	67
Otolaryngology	1	29
Paediatrics	1	59
Radiology	1	17
Rehabilitation medicine	1	60

*The specialties or fields of healthcare (eg, nursing homes) where SPC was applied are rank ordered according to the number of articles in which such application was reported. Whereas 11 articles did not specify a specialty or field of healthcare, several articles included more than one specialty.

Table 4 How and where SPC was applied: units of analysis*

Unit of analysis	Number of articles	References
Single patients (including patients using control charts themselves)	9	16, 22, 32, 35, 38, 40, 50, 60, 70
Single clinicians	4	37, 52, 62, 66
Outpatient clinic	3	29, 49, 59
An ambulatory nursing centre clinic	1	23
Primary care/family medicine centre	2	34, 63
Population(s) of patients in nursing home(s)	2	16, 51
Staff at mental health residential facility living areas	1	20
Hospital wards	5	26, 33, 56, 61, 65
Department process level	15	17, 19, 21, 25, 27, 30, 39, 42, 45, 53, 54, 57, 64, 68, 71
Hospital department and community-based orthopaedic surgeons	1	28
Microsystem(s)	6	15, 37, 43, 47, 50, 67
Process that involves more than one department	6	36, 41, 46, 48, 55, 58
Entire hospital	6	18, 21, 24, 31, 44, 69

*The units of analysis—the levels at which SPC was applied—are ordered according to the degree of aggregation (from individual patients to entire organisations). Some articles reported data from more than one unit of analysis. A microsystem is defined as “a small group of people who work together on a regular basis to provide care to discrete subpopulations of patients”.⁷² The distinction between microsystems and other categories is not absolute but a matter of judgment.

(fig 1). We have no explanation for this finding, but we speculate that it is related to differences between US and other healthcare systems with regard to QI awareness and implementation.⁷³

Only 22 studies included in the review were intended to test the utility of SPC (table 1). Of the four controlled studies, only one included a control chart in the intervention (as a minor component which did not fully exploit the features of SPC). In 35 articles we did not find an intention to test the utility of SPC application. In those cases, SPC was applied for other reasons (ie, to evaluate the impact of other interventions). Even though many articles thus did not address the utility of SPC, all studies offered information—to varying degrees—relevant to our review’s question of *how* SPC has been applied to healthcare. The utility of SPC is reflected in benefits reported regarding SPC application (table 6).

SPC has been applied in over 20 specialties or fields of healthcare, at a wide range of levels (tables 3 and 4), suggesting that SPC has broad applicability in healthcare. The dominance of anaesthesia and intensive care can be explained in large part by the fact that many studies included their services in conjunction with other specialties. This reflects the way in which anaesthesia has a vital supporting role in many clinical care processes. The 97 SPC variables reported (table 5) demonstrate a diversity of situations in which SPC has been applied, ranging from process indicators of patients’ health to health outcomes and many aspects of healthcare processes and organisational performance. This indicates that SPC is a versatile QI tool.

The benefits of SPC application (table 6) mirror those given in books and tutorials on SPC (exemplified by the quote in the Introduction to this review). As noted in a report from a top-ranked healthcare system which has applied SPC widely:

“Among the most powerful quality management tools that IHC [Intermountain Health Care, USA] has applied is statistical process control, SPC. Most notable among those

tools are control charts. Under optimal conditions, these graphical depictions of process performance allow participants to know what is happening within their processes as ‘real time’ data enable them to make appropriate decisions. The capability of truly understanding processes and variation in a timely manner has resulted in the most dramatic, immediate, and ongoing improvements of any management technique applied at IHC.” (Shaha,²⁶ p 22)

The limitations of SPC application (table 7) identified by this review are important, and yet perhaps less emphasised than the benefits in books and tutorials on SPC. SPC cannot solve all problems and must be applied wisely. There are many opportunities to “go wrong”, as illustrated by the case where incorrect application was highlighted by other authors (limitation number 5 in table 7). In several cases, our own understanding of SPC suggested that investigators had not used it correctly or fully (eg, standard decision rules to detect special causes were not applied to identify process changes). In the worst case scenario, incorrect application of SPC could lead to erroneous conclusions about process performance and waste time, effort and spirit and even contribute to patient harm. In the more authoritative studies we reviewed, co-investigators included experts in industrial engineering or statistics or authors who otherwise had developed considerable expertise in SPC methodology. On the basis of these observations, we conclude that although SPC charts may be easy to use even for patients, clinicians or managers without extensive SPC training, they may not be equally simple to construct correctly. To apply SPC is, paradoxically, both simple and difficult at the same time. Its power hinges on correct and smart application, which is not necessarily a trivial task. The key, then, is to develop or recruit the expertise necessary to use SPC correctly and fully and to make SPC easy for non-experts to use, before using it widely.

Autocorrelation is another limitation of SPC highlighted by this review. Our review, and published books, offer limited advice on how to manage it:

“There is no single acceptable way of dealing with autocorrelation. Some would say simply to ignore it. [Others] would disagree and suggest various measures to deal with the phenomenon. One way is to avoid the autocorrelation by sampling less frequently. ... Others argue against plotting autocorrelated data on control charts and recommend that the data be plotted on a line chart (without any centerline or control limits).” (Carey,⁴ p 68)

Just over a quarter of the articles reported barriers to SPC application (table 8). The three broad divisions of barriers—people, data and chart construction, and IT—indicate where extra care should be taken when introducing SPC in a healthcare organisation. Ideas on how to manage the limitations of and barriers to SPC application can be found among the factors reported to facilitate SPC application (table 9). They deal with, and go beyond, the areas of barriers we found. We noted the prominence of learning and also of focusing on topics of interest to clinicians and patients. The 11 categories under the heading “Smart application of SPC can be helpful” contain valuable approaches that can be used to improve SPC application. Examples include risk adjustment^{51 52 71} and stratification^{30 37 59} to enable correct SPC analysis of data from heterogeneous populations of patients (or organisational units). Basic understanding of SPC must be taught to stakeholders and substantial skill and experience is required to set up successful SPC application. Experts, or facilitators, in healthcare organisations can help, as indicated in table 9, and as we have described for other QI methods.⁷⁴

Table 5 SPC variables*

I Biomedical variables	
<i>Blood glucose and HbA_{1c} measures</i>	
1	HbA _{1c} level in groups of diabetic patients ⁵²
2	Blood glucose, as a daily group average, for intensive care patients on parenteral or enteral nutrition ³³
3	Average blood glucose levels among intensive care unit patients on total parenteral nutrition per week ²⁵
4	Standard deviation of blood glucose levels among intensive care unit patients on total parenteral nutrition per week ²⁵
5	Capillary blood glucose measurements of individual patients ⁵⁶
6	Individual patient blood glucose measurements ³⁸
7	Individual patient fasting blood sugar measurements ^{37, 50}
8	Average of five consecutive HbA _{1c} measurements in diabetic patients cared for by one clinician ⁵⁰
<i>Peak expiratory flow rates (PEFR)</i>	
9	Daily am (ie, morning) pre-bronchodilator PEFR in asthmatic patients (litres/min) ^{35, 40}
<i>Pain</i>	
10	Daily individual patient visual analogue pain scale recordings ⁶⁰
<i>Cardiovascular system measures</i>	
11	Blood pressure ^{22, 23, 32}
12	Heart rate ^{22, 32}
13	Central venous pressure ²²
<i>Urinary output</i>	
14	Urinary output (during intensive care) ²²
<i>Oxygen saturation</i>	
15	Oxygen saturation (during intensive care) ²²
II Biomedical measurement variable	
16	Blood pressure measurement error (mm Hg) ²³
III Other variables related to patient health	
17	Patient fall rate (number of patient falls/number of cases per month) ⁵¹
18	Days in between asthma attacks ⁷⁰
19	Nausea on day 3 after administration of chemotherapy, as reported by patients on a scale, displayed as the average in each sample of four consecutive patients ⁵⁷
20	Incontinence volume (of fluid) for individual incontinent patients (in "a change-program") on scheduled inspections ¹⁶
21	Volume of irrigation fluid absorbed during endoscopic renal pelvic surgery ⁴¹
IV Clinical management variables	
<i>Time to complete (part of) a clinical process</i>	
22	Time between patient check-in and interpretation of a preoperative radiograph ¹⁷
23	Door-to-needle time: "the time span between hospital admission and the initiation of thrombolytic therapy in patients with acute myocardial infarction" ^{46, 48}
24	Average length of stay for inpatients with congestive heart failure ⁵⁴
25	Length of stay after cardiac surgery (risk adjusted and transformed) ⁷¹
26	Average length of stay for total hip replacement patients ²⁸
27	Intensive care unit admission time ⁴²
28	Average postoperative (bowel surgery) length of stay (in days) per month ⁴²
29	Admission time (from "sign in" to "patient in room") ^{18, 31}
30	Duration of intravenous antibiotic treatment for patients with pneumonia ³⁷
31	Time to administration of antibiotic treatment for patients with pneumonia ³⁷
32	Average length of hospital stay for inpatients with pneumonia ³⁷
33	Time to extubation after coronary artery bypass grafting (CABG) surgery (hours) ⁴⁷
34	Length of stay in the intensive care unit after CABG (days) ⁴⁷
35	Total hospital length of stay after CABG (days) ⁴⁷
36	Laboratory turnaround time for blood tests ^{19, 27}
37	Average postoperative length of stay after non-emergent CABG surgery, per quarter ³⁰
38	Time from receiving a referral to first patient contact (days) ⁴⁹
<i>Time, or number of consecutive cases, between events</i>	
39	Time between deaths in chronic obstructive pulmonary disease ⁵⁴
40	Number of successful elective CABG surgeries between cases with mortality ⁴²
41	Number of successful CABG surgeries between cases with complications ⁴²
42	Number of successful bowel resection operations between cases with complications ⁴² (see also variable 18 for another example)
<i>Rate of events in a clinical process ("defect rate" or "success rate")</i>	
43	Percentage of chief complaints (of patients in an emergency department) charted in free text (as opposed to coded) in the medical record, per day ⁵³
44	Percentage of anaesthesia sessions with at least one "significant anaesthetic event" ⁵⁷
45	Mortality in patients with congestive heart failure ⁵⁴
46	Proportion of low birthweight infants ⁵⁴
47	Percentage of intravenous medication administration events associated with an error ²⁴
48	Occurrence of four intraoperative adverse events, of relevance to anaesthetic quality and safety: inadequate analgesia during brachial plexus block, emergence from general anaesthesia, intubation problems and medication errors ⁴⁴
49	Proportion of patients with excessive absorption of irrigation fluid during transurethral resection of the prostate ³⁶
50	Mortality after CABG ⁴²
51	Proportion of patients on enteral, or parenteral, nutrition with blood glucose levels outside a (clinical management) target range ³³
52	Daily percentage of satisfied requests for medical records at a paediatric outpatient clinic ¹⁸

Table 5 Continued

53	"Guideline non-adherence rate"; proportion of chemotherapy administrations in which guideline recommendations to prevent nausea were not followed ⁶⁷
54	Percentage of all blood cultures growing contaminants per month ⁶⁸
55	Proportion of intensive care unit patients on total parenteral nutrition with blood glucose values that were higher than the given target (>11.1 mmol/l (>200 mg/dl)) per week ²⁵
56	Percentage of all acute bronchitis visits during which a β -agonist was prescribed, per month ³⁴
57	Percentage of all acute bronchitis visits during which an antibiotic was prescribed, per month ³⁴
58	Percentage of outpatient surgical procedures per month (of all procedures) ⁴³
59	Proportion of cases where tests were delayed or not reported in a timely fashion ¹⁵
60	Proportion of incontinent patients (in "a toileting program") who were wet on scheduled inspections ¹⁶
61	Monthly percentage of emergency department patients who leave without being seen ⁴⁵
62	Percentage of inpatients on the ward in each of three acuity levels (low, medium and high) per day ²⁶
63	The quarterly incidence rate of eight variables among cardiac surgery patients: perioperative death, perioperative myocardial infarction; cerebrovascular accident; re-exploration for bleeding or tamponade; atrial fibrillation; leg wound; acute tubular necrosis; sternal infection; acute renal failure ³⁰
64	Rates of total and major complications per patient after cardiac surgery ³⁰
65	Proportion of first case starts each day in the operating theatres that are delayed due to the department of anaesthesia ³⁹
66	Proportion of cases in which the turnaround time between cases exceeded the given performance standard ³⁹
<i>Number of defects/events or occurrences in a clinical process</i>	
67	Number of medication errors, per month ²⁴
68	Number of out-of-hours "stat" (blood test analyses) requests received each week ⁵⁸
69	Number of MRSA cases per month ⁶¹
70	Number of diabetes patients (seen at office visits) with HbA _{1c} measurements, per month ²⁴
71	Number of patients (seen at office visits) at a department of family medicine with a recorded diagnosis of tobacco abuse, per month ³⁴
72	Total number of surgical procedures per month ⁴³
73	Number of patients with diarrhoea admitted to the hospital, per week ⁴⁴
74	Number of referrals per month for patients with diabetes from primary care to endocrinology ⁵⁵
75	Number of new referrals per work day ⁴⁹
76	Net number of new patients (=practice growth) ⁶³
<i>Clinical decision making</i>	
77	(Square root of) the number of cases per general practitioner (GP) diagnosed as having tonsillitis versus number of cases diagnosed as having any throat infection ⁶²
78	(Square root of) the number of GP patients diagnosed as having tonsillitis and non-tonsillar throat infection, who receive antibiotics ⁶²
79	(Square root of) the number of GP cases with any throat infection diagnosis who received antibiotics ⁶²
80	(Square root of) the number of GP cases with a diagnosis of sore throat in which antibiotics were not prescribed versus the number of cases in which antibiotics were prescribed ⁶⁶
V Financial resources variables	
<i>Cost of care</i>	
81	Average cost per procedure (total hip replacement) ²⁸
82	Staffing expense per shift, depicted as variance in US\$ from budget ²⁶
83	Staffing expense per 24-h period, depicted as variance in US\$ from budget ²⁶
<i>Productivity and efficiency</i>	
84	Relative value unit (RVU) production per provider FTE (full-time equivalent) (=provider productivity) ⁶³
85	FTE support staff per FTE provider (=practice efficiency) ⁶³
<i>Organisational financial performance</i>	
86	Net patient revenue per relative value unit (a primary care physician's practice) (=practice profitability) ⁶³
87	Provider cost as a percent of net revenue (=practice cost management) ⁶³
88	Non-provider cost as a percentage of net revenue (=practice cost management) ⁶³
VI Variables relating to the experience of healthcare	
<i>Patient satisfaction indicators</i>	
89	"Physician care scale score", which is the average of patient survey responses to 10 questions ⁵⁹
90	Patient satisfaction with (nursing) care ⁶⁵
91	Percentage of patients (who responded to a patient satisfaction survey) whose response was that the overall visit was excellent ²⁹
<i>Other experience with care</i>	
92	Patient rating of assistance in solving the patient's current health problem ⁶⁵
93	Staff satisfaction with (nursing) care ⁶⁵
94	Staff rating of assistance in solving patients' current health problems ⁶⁵
VII Variables related to clinical staff supervision	
<i>Clinical staff supervision</i>	
95	Active treatment monitoring index, based on observing staff performance in clinical encounters and assessing nine criteria ²⁰
<i>Completion of mandatory staff training</i>	
96	Percentage of employees who have completed mandatory safety training ²¹
VIII Other variables	
97	"A temperature signal" (of unspecified origin; it is probably not body temperature since it varies around 74°F or 23°C). "[T]he signal could just as easily have been bed occupancy, ED wait time, expense per equivalent discharge, or staffed care days." ⁶⁹

*The variables are divided into eight categories and then further subdivided under subheadings in a category. Several articles reported more than one SPC variable.

Table 6 Benefits of using SPC to improve clinical processes*

		Examples/explanations
<i>SPC facilitated and documented healthcare process improvement</i>		
1	SPC application helped people assess the impact of changes to the process ^{19 24 27 30 32-34 37 42 43 45 52 53 55 57 58 60 64 67 68}	Many articles reported a helpful role of SPC in determining the effects of interventions made to healthcare processes. Examples include successful effects, adverse effects or a lack of effect
2	SPC application contributed (led) to improvement of healthcare processes ^{16 17 20 26 28 30 31 36 37 46 53 56 65}	Several articles reported improvement of a healthcare process and attributed that improvement, more or less explicitly, to improvement efforts in general and SPC application in particular (the foundations for such attribution were methodologically weak—for instance, case reports without comparisons). For example, investigators evaluating the “door-to-needle-time” (DTNT) for thrombolytic treatment of patients with acute myocardial infarction (AMI) using control charts found that “in the beginning there was considerable variability of DTNT signifying that the process of in-hospital management of patients with AMI was out of statistical control. Shortly after the initiation of formal process analysis DTNTs were reduced significantly and remained within a narrow range, now showing a stable and statistically controlled pattern. Thus, process quality was significantly improved by our efforts” (Bonetti <i>et al.</i> , ⁴⁶ p 315)
3	SPC application helped people identify areas for improvement ^{21 26 40 42 47 49 58 70}	Several investigators identified process performance that was not satisfactory, and hence in need of improvement, using SPC. For instance, investigators applying SPC to the care of patients with asthma concluded that when the care process yields a range of breathing that “is clinically problematic, the care process should be redesigned and monitored to ensure that the problem has been corrected” (Boggs <i>et al.</i> , ⁴⁰ p 175)
<i>SPC was a useful tool for healthcare management</i>		
4	SPC application helped people distinguish special from common cause variation ^{15 30 35 38 39 41 42 45 49 51 54 59 64 70 71}	Reflecting one of the tenets of SPC, many articles reported how SPC helped people identify common cause and special cause variation, and understand the difference. Investigators applying SPC to surgical care, for instance, concluded that “plotting data over time and using control chart techniques will tell us whether the variation in a surgical process is stable and predictable or whether variation signals a significant change in the process” (Levett and Carey, ⁴² p 358)
5	SPC seen as a valuable QI tool which was easy to use ^{18 19 25 29 30 38 40 42 47 48 50 56 62 69 70}	Many articles report the usefulness of SPC as a tool in healthcare process management and improvement. Investigators at a cardiac surgery department, for example, designed a system for automated data collection and generation of control chart for critical pathway adherence, and concluded that it was “a cost effective method for providing timely feedback. The benefits of timely feedback with the control chart method are strongly suggested by this study” (Ratcliffe <i>et al.</i> , ⁴⁷ p 1821)
6	SPC enabled valuable prediction of future process performance ^{30 35 40}	A few studies reported the value of being able to predict future performance of stable processes. A predictable outcome was beneficial to the patient, doctor and insurer. ³⁰ In asthma care, such prediction enabled clinicians and patients to decide whether to maintain the current care regimen or alter it to improve future outcomes ^{35 40}
7	SPC helped describe and quantify process variability ^{22 23 35}	SPC allowed characterisation of process variability, including variability present in blood pressure measurement ²³
<i>SPC helped process stakeholders</i>		
8	SPC enabled patients to be partners in clinical management (and research) ^{35 38 40 50 60}	SPC enabled patients with chronic conditions to better understand and manage—alone or in partnership with clinicians—their condition, specifically, diabetes mellitus, ^{38 50} hypertension, ³⁸ muscular pain ⁴⁰ and asthma. ³⁵ SPC has also been proposed as a research strategy whereby patients can be active partners in data collection and analysis. ³⁸ In asthma care, for example, when patients control-chart their breathing function the benefits include “knowing each patient’s signals and their meaning; natural limits of the current care process; and having the ability to anticipate this patient’s future level of function given no change in his/her care process[. This] enhances both the patient’s and physician’s ability to meaningfully engage in the process of continuous quality improvement of asthma. [It] elevates the level of communication and dialogue between patients and physicians exponentially beyond that generated by traditional run chart information” (Boggs <i>et al.</i> , ³⁵ p 561)
9	SPC application improved communication between process actors ^{35 36 52 63 70}	SPC provided a common language and facilitated communication between managers and clinicians, or between clinicians and patients. See the example above
10	SPC application enabled (better) informed decision making ^{21 26 35 44 54 61 63 66}	SPC helped inform decision making in healthcare organisation governance and management ^{21 26 44 54 61 63} and in clinical decision making regarding—or in partnership with—patients. ^{35 66} Reporting on efforts at the Intermountain Health Care system to improve inpatient acuity level assessment, Shaha concluded that “control charts have given information to delivery-level decision makers which they have never before enjoyed. The system has helped nurse managers better understand the acuity on their units and plan more effectively for appropriate staffing to support patient care. Improved staffing has enhanced teamwork and the quality of work life on these units” (Shaha, ²⁶ p 30)
11	SPC empowered process stakeholders ^{15 21 26 35 50 54 61}	SPC had an empowering effect among—for example, patients, ^{35 50} nurse managers, ²⁶ a medical assistant, ¹⁵ healthcare workers and managers, ^{21 61} and board members ^{21 54}
12	SPC application helped stakeholders learn about their processes ^{40 63 68}	Stakeholder—or “organisational”—learning was facilitated by SPC application and involved patients, ⁴⁰ clinicians ^{40 63 68} and managers. ⁶³ “Both you and your patient are learners. Let the charts teach you and help you learn what is of practical value to your patients. You will find that learning together is a strong invitation of commitment to the [asthma care] process for both of you” (Boggs <i>et al.</i> , ⁴⁰ p 175)

*All articles reported benefits, and many reported several. The benefits formed 12 categories which are grouped into three broad areas.

We found more information on SPC benefits and facilitating factors than on limitations and barriers, and this may represent a form of publication bias, as indicated by the quote in the Introduction.¹¹ We did not find any study that reported failed SPC application. We can speculate that there have been

situations when SPC application failed, just as there must be many cases of successful SPC application that have not been reported in the literature. Studies of failed SPC application efforts, as well as studies designed to identify successful ways to apply SPC to manage change, would help inform future SPC

Table 7 Limitations of SPC application in improvement of clinical processes*

		Examples/explanations
<i>Limitations of the ability to improve clinical processes using SPC</i>		
1	Sharing performance data in control chart format does not automatically lead to improvement in healthcare organisations ^{1,5,67}	Even if control charts can help visualise the performance of a clinical process, and signal a need for improvement, there is no guarantee that such signals prompt improvement. For example, Mertens <i>et al</i> studied the effects of a number of interventions, including control chart format feedback, on oncologist prescribing patterns for the management of delayed chemotherapy-induced nausea and emesis. "In our study, these [control] charts effectively measured the degree of compliance with guideline recommendations, but they were not effective in improving physician compliance These findings indicate that statistically valid charting, although useful in measuring compliance, will not achieve improved compliance as a physician feedback tool. However, enhanced compliance may be achieved when adverse patient outcomes are coupled with evidence of poor compliance with evidence-based guidelines" (Mertens <i>et al</i> , ⁶⁷ p 1377)
2	Statistical control does not necessarily equal clinical control nor desired performance ^{27,35,63,64}	"It is important to note that a chart can be in statistical control, and [the patient can still] be at risk for severe asthma. So statistical control does not equate with clinical control. It simply reflects the absence of special cause variation" (Boggs <i>et al</i> , ³⁵ p 555)
3	Cause and effect relationships are not always obvious, even if a change is identified with statistical confidence ^{45,60,61}	"Although control charts can help detect when the [MRSA] rate has increased or decreased, they typically will not identify the specific cause of the change. Once a change is detected, the infection control team must use its skills to assess the situation, identify possible causes, and promote improvement in practices" (Curran <i>et al</i> , ⁶¹ p 16)
<i>Limitations of the applicability of SPC to clinical processes</i>		
4	Differences between patients may limit the appropriateness of combining data about their care onto one control chart ^{25,30,51,52}	"Unlike manufacturing, the health care industry deals with a variable input: Patients differ in their severity of illness on admission. This variability on admission affects care outcomes. ^[Ref] Therefore, it is imperative to adjust for patients' risk for adverse outcomes. ... Blindly applying methods of manufacturing to health care may be misleading" (Alemi and Oliver, ⁵¹ p 2)
5	The ability of stakeholders to apply SPC correctly may be limited ^{16,35}	Discussing an article which contains a methodological error—irrational subgrouping—Boggs <i>et al</i> emphasise that "the mathematics which defines the upper and lower control limits and the zone lines (from which signals are defined) is derived from the range between the values composing each subgroup. If the daily subgroupings are irrational—i.e., the AM pre- and postbronchodilator and PM pre- and postbronchodilator are included in the same subgrouping—the daily ranges are distorted, the mathematical calculations are erroneous, and the control charts these calculations produce are improperly constructed. An improperly constructed chart is by definition uninterpretable. This error of irrational subgrouping is fatal and invalidates both their analysis and conclusions" (Boggs <i>et al</i> , ³⁵ p 560). Another aspect of this limitation is when staff members lack sufficient knowledge of QI in general and SPC in particular. ¹⁶
6	Limitations regarding data for use in control charts ^{25,26,38,44,45,54,63-65}	Several articles highlight limitations related to the data needed for control charting: <ul style="list-style-type: none"> ● The sample size needs to be "big enough". A minimum amount of data are needed to produce reliable control charts.^{26,54} "If a control chart has too few data points, then it may appear that a special cause exists when it really does not" (Caron and Neuhauser,⁵⁴ p 31) ● Common types of control charts are not well suited to analysing infrequent events. Such events require special types of control charts⁶⁴ ● (Manual) data collection can be prohibitively demanding⁶⁵ ● Oversampling of patients whose values are out of control pulls the statistic in the direction of derangements²⁵ ● Choosing too long a sampling period may delay control chart signalling and delay decision making⁴⁴ ● (Retrospective) control chart interpretation can be difficult if charts are not annotated with interventions or other influences on process performance⁴⁵ ● Autocorrelation may limit the ability to analyse control chart data. "Autocorrelation is a phenomenon whereby the preceding observation predicts the next observation. ... If yesterday's blood pressure predicts today's blood pressure, there is autocorrelation" (Solodky <i>et al</i>,³⁸ p AS14) ● System-level aggregation of SPC data may prevent local sense making (if the data cannot be disaggregated). For example, performance measures of one primary care medical group practice "are computed on a group practice level. This level of aggregation means that the SPC charts cannot currently be used to evaluate the results of individual and team efforts within individual group practices" (Stewart and Greisler,⁶³ pp 258–9)

*We found statements regarding one or more limitations of SPC application in 22 articles. The limitations formed six categories which are grouped into two broad areas.

application efforts. On the basis of this review, we agree with the argument that "medical quality improvement will not reach its full potential unless accurate and transparent reports of improvement work are published frequently and widely (p 319),"⁷⁵ and also that the way forward is to strengthen QI research rather than to lower the bar for publication.⁷⁶

Methodological considerations regarding the included studies

None of the studies we found was designed to evaluate the effectiveness quantitatively—that is, the magnitude of benefits—of SPC application. This would have required other study designs such as cluster randomised trials or quasi-experimental studies.¹² Although the "methods of evaluating complex interventions such as quality improvement interventions are

less well described [than those to evaluate less complex interventions such as drugs]", Eccles *et al* argue that the "general principle underlying the choice of evaluative design is ... simple—those conducting such evaluations should use the most robust design possible to minimise bias and maximise generalisability. [The] design and conduct of quantitative evaluative studies should build upon the findings of other quality improvement research (p 47)."⁷⁷ This review can provide such a foundation for future evaluative studies.

An important distinction is warranted here: we believe that SPC rests on a solid theoretical, statistical foundation and is a highly robust method for analysing process performance. The designs of the studies included in this systematic review were, however, not particularly robust with regard to evaluating the effectiveness of SPC application, and that was not their

Table 8 Barriers to SPC application*

		Examples/explanations
<i>People related barriers</i>		
1	Lack of knowledge on how to apply SPC correctly ^{16 35 37 51}	Even though control charts, constructed correctly, may be easy to use, not all healthcare professionals and managers have sufficient SPC knowledge
2	At first, SPC may represent a new and challenging way of thinking ^{18 40}	"It is not at all surprising that many persons avoid involvement in statistical process control. The statistical procedures developed in industry to monitor production processes are somewhat different from those employed in biostatistics and social science applications. Many find it difficult to adjust to these procedures and to apply statistical process control techniques to situations in health care settings" (McKenzie, ¹⁸ p 81)
3	If SPC application is not perceived as helpful, it may not succeed ^{39 65}	"Whereas Finison <i>et al.</i> ^[Ref] claim that the mean and standard deviation are simple and easy for staff to understand, the staff involved in this study found them difficult to perceive. This is partly accounted for by the staff's resistance, as it seemed that they did not want to understand the results of the figures. The staff expected the investigators to tell them what to do and did not want to process the results and the issues underlying them" (Hyrkas and Lehti, ⁶⁵ p 186)
<i>Data collection and chart construction related barriers</i>		
4	Collection and attribution of data to different hospital units for SPC application can be difficult ⁶¹	In the case of hospital acquired infections, investigators found that it was hard to assign new cases to the correct ward or unit's control chart. "The few disadvantages of this approach primarily concern implementation. The ability to assign a new MRSA case to a specific ward rarely can be completely accurate. We attempt to minimize this imprecision by encouraging the input of ward staff in any discussions or debates as to where a patient acquired the MRSA" (Curran <i>et al.</i> , ⁶¹ p 17)
5	Finding the right level of aggregation of data for SPC application can be difficult and require trade-offs ⁶¹	Continuing with the example of hospital acquired MRSA infections, finding the best level of data aggregation was a barrier: "If the control chart includes too many wards, then staff may feel the responsibility lies elsewhere and they may not be inclined to use the feedback to alter their practices. Further, if the chart contains information from too many departments or units, it sometimes can mask local problems or out-of-control data. [Furthermore, monitoring] a large number of units on individual charts also can decrease the overall specificity and increase the false-alarm rate, especially if [2 sigma] warning limits are used as control limits" (Curran <i>et al.</i> , ⁶¹ pp 16–8)
6	Data collection and analysis can be time consuming and costly ^{17 19 37 39}	"Other real obstacles that challenge physicians are the time required for and the financial costs of data collection and analysis. ... Certainly, measurement may consume valuable resources" (Nelson <i>et al.</i> , ³⁷ p. 465)
7	Constructing the most appropriate control chart can be difficult ³⁰	"The most difficult task is deciding which probability distribution, and thus which control chart, is most appropriate for the data, and then choosing homogenous and rational subgroups to analyze" (Shahian <i>et al.</i> , ³⁰ p 1356)
8	Lack of access to reliable data in a timely fashion can be a barrier to real-time SPC application ⁴⁷	Discussing care pathways in cardiac surgery, one group found that "accurate process data are difficult and expensive to obtain. Data obtained from hospital and medical records data systems are often inaccurate, temporally inefficient, and not focused on daily patient events[.] Among the difficulties with optimizing outcome-based cardiac surgical care are the expense and problems with [multi-institutional] databases, including lack of standardization, cost of dedicated data entry/delivery personnel, and lack of timely feedback[.] Those] systems were not designed to provide rapid feedback of process data, which is necessary if individual practitioners are to effectively manage cardiac surgery pathways" (Ratcliffe <i>et al.</i> , ⁴⁷ p 1820)
<i>Information technology related barriers</i>		
9	Lack of computer power was a barrier to real-time SPC application ²²	"There are several reasons why control charts and other statistical process control techniques have to date not been introduced as tools to improve real-time clinical decision making. These include lack of computer power to perform calculations in real time, inability to interface medical monitors with computers and to produce clean measurement with an acceptable signal to noise ratio, and lack of statistical process control training for clinical decision makers" (Laffel <i>et al.</i> , ²² pp 76–7)
10	Software problems can hamper SPC application ²⁶	One study reported unspecified, and subsequently resolved, software problems as the only barrier to SPC application

*We found reports of barriers in 15 articles. They formed 10 categories which are grouped into three broad areas.

objective. This does not mean that SPC is not a useful tool for QI in healthcare, only that the studies reviewed here were more vulnerable to bias than more robust study designs, even if they do indicate many clear benefits of SPC application (table 6). Despite the studies not being designed to evaluate the effectiveness of SPC, many used SPC to effectively show the impact of QI or other change initiatives. In this way, SPC analysis can be just as powerful and robust as study designs often deemed superior, such as randomised controlled trials (RCTs).⁷⁷ The key to this power is the statistical and practical ability to detect significant changes over time in process performance when applying SPC.⁹ On the basis of a theoretical comparison between control charts and RCTs, Solodky *et al.*³⁸ argue that control charts can complement RCTs, and sometimes even be preferable to RCTs, since they are so robust and enable replication—"the gold standard" for research quality—at much lower cost than do RCTs. These points have been further elaborated in subsequent work.^{78 79}

A curious methodological wrinkle in our review is: can you evaluate the application of a method (eg, SPC) using that same

method for the evaluation? Several of the included studies used SPC both as (part of) an intervention and as a method to evaluate the impact of that intervention. For example, Curran *et al* used annotated control charts to feed information on MRSA acquisition rates back to stakeholders and used these same control charts to show the effectiveness of the feedback programme.⁶¹

Relationship between monitoring and improvement

When SPC is applied for monitoring, rather than for managing change, the aims are different—for example, to detect even small but clinically important deviations in performance—as are the methodological challenges.^{80 81} This review focused on the latter. Thus although studies on SPC application for monitoring healthcare performance were excluded from this review, we recognise the importance of such monitoring. The demarcation between monitoring and improvement is not absolute. Indeed, there are important connections between measurement, monitoring and improvement, even if improvement does not follow automatically from indications of dissatisfactory performance. "To improve performance, organizations and individuals need the

Table 9 Factors or conditions facilitating application of SPC*

		Examples/explanations
<i>Information technology and other tools facilitated SPC application</i>		
1	Easy-to-use tools and resources exist to aid with data management and control chart construction ^{22 30 31 35 45 47 69 70}	The evolution of information technology has brought many new possibilities for SPC data management, control chart construction and interpretation
2	Electronic clinical information systems with SPC capability facilitated data management and SPC application ^{19 25 28 30 34 47 49}	When designing a system which produced control charts for measures reflecting performance relative to a critical pathway for cardiac surgery, investigators found that a facilitating factor "was the existing electronic medical record, which requires that nurses enter a computerized progress note. ... Integration of the data collection with the generation of a nursing progress note clearly provides the motivation for the bedside nurse to use the system. Moreover, we were able to couple our data collection system with the requirement for an electronic progress note efficiently, so that ... the intranet-based system decreased by 50% the amount of time the nurses spent charting their progress note" (Ratcliffe <i>et al</i> , ⁴⁷ pp 1820–1)
<i>Feedback, training and learning may facilitate SPC application</i>		
3	User feedback guided changes to facilitate SPC application ⁴⁰	"In a focus group session with patients, we learned that many objected to plotting the exact PEFR values over time on a chart. The fear was misplotting – thereby ruining the chart. This insight led to a redesign of the chart in a manner that respected their concern yet did not compromise the chart's ability to provide the information needed" (Boggs <i>et al</i> , ⁴⁰ p 174)
4	Training users in SPC application may be helpful ^{15 26 44 50}	Reflecting on efforts to apply SPC at a provincial hospital in Indonesia, the author suggests that "(i) the process of data management should be performed by the hospital staff under supervision and with training they should be able to do it without supervision; (ii) a training session for staff on the creation and interpretation of the control chart should be carried out" (Purba, ⁴⁴ p 147)
5	Gradual introduction of SPC can allow learning and improvement to support subsequent application and spread ^{25 34 61}	At a family medicine clinic, the impact of QI including SPC application "had to be demonstrated through initial projects before there was more general support for the process by other residents and faculty within the department" (Ornstein <i>et al</i> , ³⁴ p 360)
6	Professionals in training led improvement efforts using SPC as part of a clinical scholars programme ³⁴	"Many of the ideas for patient care improvement projects [using SPC] have evolved from the work and leadership of a group of family residents, pharmacy residents, and faculty that is involved in a unique educational experience known as the clinical scholars program. The program was developed ... as a mechanism to provide the family medicine residents with hands-on opportunities to learn clinical research and quality improvement methods. ... Generally, the project leaders are residents in the clinical scholars program" (Ornstein <i>et al</i> , ³⁴ p 351)
7	SPC application to clinical topics captured the interest of clinicians ³⁴	"Clinical topics interest clinicians, and recognition of the potential personal benefits of a project will increase individual commitment and participation" (Ornstein <i>et al</i> , ³⁴ p 360)
<i>Patients can have a role in SPC application</i>		
8	The benefits of SPC application motivated and empowered patients to record and control chart the data ³⁵	"Adherence in our clinic population is better, both short-term and long-term, with [asthma patient operated control charts of PEFR] than for any PEFR monitoring method we have used in the past. ... It is our assessment that the reasons for high patient adherence with our method include (1) the PEFR measurement per se is simple and can be performed using inexpensive equipment; (2) the charts our patients use are easy to keep and understand; (3) the concepts of signals and not being at-risk are easily understood and appreciated by patients; (4) the chart plays a central role in each patient's follow-up visit and in telephone calls between visits; (5) because of the latter, patients know we will be monitoring their adherence; (6) patients understand that their chart provides information we need and will use to make decisions that will impact their care; and (7) the quality of the communication with patients is more substantive" (Boggs <i>et al</i> , ³⁵ p 561)
9	Patients as partners may be better at collecting data for SPC analysis than "human subjects" are in traditional research ³⁸	"For the control chart analysis used in the current study, the patient has been a partner (the first author of this article). Patients in RCTs usually are seen as 'human subjects.' Psychological theory suggests that partners are better data collectors than subjects" (Solodky <i>et al</i> , ³⁸ pp AS18–9)
<i>Literature and experts can guide SPC application</i>		
10	There is literature to guide SPC application ^{15 35}	"The statistical methods to be used in calculating control charts are well described in the literature. ^[Ref] " (Re <i>et al</i> , ¹⁵ p 395)
11	Local experts may provide technical assistance for SPC application ^{18 47}	"At the Indiana University Medical Center several persons from different hospital departments have volunteered to form a cadre of internal statistical process control consultants. The group has come to be known by some as the statistical process control 'think tank'. No doubt a small group of individuals who are interested in statistics, quality control, and computers can be found in most hospitals. While it is necessary that the large majority of managers and supervisors in any health care organization are knowledgeable about process management and control charts at the concept level of understanding, it takes a relatively few to understand and use such control charts. As internal consultants, these few persons can provide technical assistance when such aid is needed" (McKenzie, ¹⁸ p 81)
12	Collaboration with SPC experts may facilitate application ^{23 34}	Collaboration between scholars from nursing and experts in industrial measurement error research "has facilitated the conception and completion of a study [of blood pressure measurement error in a nursing clinic] that could not have been accomplished by either discipline alone" (Nelson <i>et al</i> , ²³ p 27)

Table 9 Continued

		Examples/explanations
<i>Smart application of SPC can be helpful</i>		
13	Freezing control limits and the centre line at pre-intervention levels helped decipher the impact of interventions ^{59 70}	"In [a figure], note that we have separated the plot into two periods: before and after the intervention. For calculating the [control limits], one should use only the data from before the intervention. In this fashion, the patient and the clinicians can decipher if the postintervention data exceeds their expectations from historical patterns" (Alemi and Neuhauser, ⁷⁰ p 99)
14	Data stratification or disaggregation helped disentangle performance problems and focus improvement efforts ^{37 59}	"The physicians at Site A needed to develop a theory about why their care was rated lower than at other sites. They theorized that the results might be different for the three service areas: family practice, pediatrics, and ambulatory surgery. Therefore, they developed a control chart to disaggregate the data by service. The results ... for each service were juxtaposed on the same control chart using a technique called <i>rational ordering</i> " (Carey, ⁵⁹ p 80)
15	Risk adjustment of SPC data revealed process changes that previously were hidden ^{51 52 71}	"Before risk adjustment, the process improvement was hidden by the variations in patient risk. Taking the patient risks into account by risk adjustment revealed the significant decrease in [length of stay] during the final 3 months of the 18-month period" (Hart <i>et al</i> , ⁷¹ p 115)
16	Annotations and feedback helped users interpret control charts ^{54 61}	"For anyone not familiar with the information presented in a control chart, annotations are essential. Annotations will aid in explaining observed variation and explaining changes in the underlying process" (Caron and Neuhauser, ⁵⁴ p 30)
17	Keeping control charts up to date increased their utility ⁶¹	"Because the infection control team updates the [control] charts frequently, they can respond more immediately to an increased rate and interact with the ward in a more timely manner" (Curran <i>et al</i> , ⁶¹ p 15)
18	Providing SPC information as locally as possible increased its accuracy and utility ^{26 61}	"A major reason for the system's success is that these data charts exist on the PCs at the patient care areas. The information is available to the caregivers and their manager. ... In the [Intermountain Health Care] model, the information is seen first by those who should care the most about its accuracy and reliability. They immediately seek legitimate and operational explanations for anomalies, genuinely showing a high degree of ownership and desire for data integrity" (Shaha, ²⁶ p 30)
19	Making SPC charts readily available to stakeholders may facilitate SPC application ^{34 65}	"Feedback to physicians and other providers is an important component of all the ongoing improvement projects. To facilitate this communication, monthly updates to the control charts used to monitor ongoing CQI projects are posted on a large bulletin board [and also distributed at meetings, and sent out by e-mail]" (Ornstein <i>et al</i> , ³⁴ p 353)
20	Knowing the clinical context helped in the interpretation of control charts ²⁵	Discussing the issue that blood glucose tests are taken more frequently from patients whose blood glucose level is deranged, investigators argue that they "interpret the charts in context, aware that points are weighted toward derangements" (Oniki <i>et al</i> , ²⁵ p 589)
21	Evidence of autocorrelation can be detected easily ³⁸	"Evidence for [autocorrelation—that the preceding observation predicts the next observation] is detected easily by correlating the value of the variable at time <i>t</i> with the value of the variable at time <i>t</i> + 1" (Solodky <i>et al</i> , ³⁸ p AS14)
22	Concurrent controls can help interpret variation detected using SPC ³⁸	"Control charts focus on change over time. Adding concurrent control patients can help monitor the effects of unknown exogenous factors that may influence outcomes" (Solodky <i>et al</i> , ³⁸ p AS17)
23	A key quality indicator helped reflect the functioning of a complex set of processes in a simple way ⁴⁶	"Overall process quality cannot be measured directly; we must resort to the use of quality indicators as easy to assess surrogate markers reflecting overall quality. DTNT [door-to-needle-time for patients with acute myocardial infarction who receive a thrombolytic drug] in our example, is a prototype of such an indicator, because it represents the result of a very complex set of processes but nevertheless is simple to measure" (Bonetti <i>et al</i> , ⁴⁶ p 314)

*We found reports of facilitating conditions or factors in 28 articles. The factors formed 23 categories which are grouped into five broad areas.

capability to control, improve, and design processes, and then to monitor the effects of this improvement work on the results. Measurement alone will not suffice (pp 1–35)."⁸²

Monitoring performance by way of control charts has been suggested as a better approach to clinical governance in the British National Health Service. Through six case studies, Mohammed *et al* demonstrate how control chart monitoring of performance can distinguish normal performance from performance that is either substandard or better than usual care. "These case studies illustrate an important role for Shewhart's approach to understanding and reducing variation. They demonstrate the simplicity and power of control charts at guiding their users towards appropriate action for improvement (p 466)."⁸³

Comments on the review methodology

No search strategy is perfect, and we may well have missed some studies where SPC was applied to healthcare QI. There are no SPC specific keywords (eg, Medical Subject Headings, MeSH) so we had to rely on text words. Studies not containing our search terms in the title or abstract could still be of potential interest although presumably we found most of the

articles where SPC application was a central element. We believe the risk that we systematically missed relevant studies to be small. Therefore, our findings would probably not have changed much due to such studies that we might have missed.

The review draws on our reading, interpretation and selection of predominantly qualitative data—in the form of text and figures—in the included articles to answer the questions in our data abstraction form. The questions we addressed, the answers we derived from the studies, and the ways we synthesised the findings are not the only ways to approach this dataset. Furthermore, each member of the review team brought different knowledge and experiences of relevance to the review, potentially challenging the reliability of our analysis. An attempt was made to reduce that risk by having one investigator read all data abstraction forms, and obtain clarifications or additional data from the original articles when needed. That investigator also conducted the initial data synthesis, which was then reviewed by the entire team and the two outside experts. Although other interpretations and syntheses of these data are possible, we believe that ours are plausible and hope they are useful.

The methods for reviewing studies based primarily on qualitative data in healthcare are less well developed than the more established methods for quantitative systematic reviews, and they are in a phase of development and diversification.^{13 84 85} Among the different methods for synthesising evidence, our approach is best characterised as an interpretive (rather than integrative) review applying thematic analysis—it “involves the identification of prominent or recurrent themes in the literature, and summarising the findings of different studies under thematic headings”.⁸⁶ There is no gold standard for how to conduct reviews of primarily qualitative studies. Our response to this uncertainty has been to use the best ideas we could find, and to be explicit about our approach to allow readers to assess the findings and their provenance.

The main limitation of this review is the uncertainty regarding the methodological quality of many of the primary studies. Assessment of quality of qualitative studies is still under debate, and there is no consensus on *whether* at all, or, if so, *how* to conduct such assessments.⁸⁴ We reviewed all the studies that satisfied our inclusion criteria and made no further quality assessment. Therefore our findings should be considered as tentative indications of benefits, limitations, etc to be corroborated, or rejected, by future research. The main strength of this review is our systematic and explicit approach to searching and including studies for review, and to data abstraction using a standardised form. It has helped generate an overview of how SPC has been applied to healthcare QI with both breadth and depth—similar to the benefits of thematic analysis reported by investigators reviewing young people's views on health and health behaviour.⁸⁷

In conclusion, this review indicates how SPC has been applied to healthcare QI with substantial benefits to diverse stakeholders. Although there are important limitations and barriers regarding its application, when applied correctly SPC is a versatile tool which can enable stakeholders to manage change in healthcare and improve patients' health.

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APPENDIX A

DATABASE SEARCH STRATEGY

Web of Science (1986 – 11 June 2004)

TS [topic search] = ((statistical process control or statistical quality control or control chart* or (design of experiment and doe)) and (medical or nurs* or patient* or clinic* or healthcare or health care))

We limited the search to articles in English only which reduced the number of hits from 167 to 159. We saved these 159 titles with abstracts in an EndNote library. Using a similar strategy, we searched the following databases through Ovid:

- Ovid MEDLINE(R) (1966 to week 1, June 2004)
- EMBASE (1988 to week 24, 2004)
- CINAHL (1982 to week 1, June 2004)
- PsycINFO (1985 to week 5, May 2004)

This yielded 287 hits, including many duplicates, which we saved in the same EndNote library as above.

Centre for Reviews and Dissemination (CRD)

We searched all CRD databases and found two articles which we also added to our EndNote library.