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Systematic review of the application of the plan–do–study–act method to improve quality in healthcare

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ABSTRACT

Background Plan–do–study–act (PDSA) cycles provide a structure for iterative testing of changes to improve quality of systems. The method is widely accepted in healthcare improvement; however there is little overarching evaluation of how the method is applied. This paper proposes a theoretical framework for assessing the quality of application of PDSA cycles and explores the consistency with which the method has been applied in peer-reviewed literature against this framework.

Methods NHS Evidence and Cochrane databases were searched by three independent reviewers. Empirical studies were included that reported application of the PDSA method in healthcare. Application of PDSA cycles was assessed against key features of the method, including documentation characteristics, use of iterative cycles, prediction-based testing of change, initial small-scale testing and use of data over time.

Results 73 of 409 individual articles identified met the inclusion criteria. Of the 73 articles, 47 documented PDSA cycles in sufficient detail for full analysis against the whole framework. Many of these studies reported application of the PDSA method that failed to accord with primary features of the method. Less than 20% (14/73) fully documented the application of a sequence of iterative cycles. Furthermore, a lack of adherence to the notion of small-scale change is apparent and only 15% (7/47) reported the use of quantitative data at monthly or more frequent data intervals to inform progression of cycles.

Discussion To progress the development of the science of improvement, a greater understanding of the use of improvement methods, including PDSA, is essential to draw reliable conclusions about their effectiveness. This would be supported by the development of systematic and rigorous standards for the application and reporting of PDSAs.

INTRODUCTION

Delivering improvements in the quality and safety of healthcare remains an international challenge. In recent years, quality improvement (QI) methods such as plan–do–study–act (PDSA) cycles have been used in an attempt to drive such improvements. The method is widely used in healthcare improvement; however there is little overarching evaluation of how the method is applied. This paper proposes a theoretical framework for assessing the quality of application of PDSA cycles and explores the quality and consistency of PDSA cycle application against this framework as documented in peer-reviewed literature.

Use of PDSA cycles in healthcare

Despite increased investment in research into the improvement of healthcare, evidence of effective QI interventions remains mixed, with many systematic reviews concluding that such interventions are only effective in specific settings.^{1–4} To make sense of these findings, it is necessary to understand that delivering improvements in healthcare requires the alteration of processes within complex social systems that change over time in predictable and unpredictable ways.⁵ Research findings highlight the influential effect that local context can have on the success of an intervention^{6–7} and, as such, ‘single-bullet’ interventions are not anticipated to deliver consistent improvements. Instead, effective interventions need to be complex and multi-faceted^{8–11} and developed iteratively to adapt to the local context and respond to unforeseen obstacles and unintended effects.^{12–13} Finding effective QI methods to support iterative development to test and evaluate

interventions to care is essential for delivery of high-quality and high-value care in a financially constrained environment.

PDSA cycles provide one such method for structuring iterative development of change, either as a standalone method or as part of wider QI approaches, such as the Model for Improvement (MFI), Total Quality Management, Continuous QI, Lean, Six Sigma or 'Quality Improvement Collaboratives'.^{3 4 14} Despite increased use of QI methods, the evidence base for their effectiveness is poor and under-theorised.^{15–17} PDSA cycles are often a central component of QI initiatives, however few formal objective evaluations of their effectiveness or application have been carried out.¹⁸ Some PDSA approaches have been demonstrated to result in significant improvements in care and patient outcomes,¹⁹ while others have demonstrated no improvement at all.^{20–22}

Although at the surface level these results appear disheartening for those involved in QI, there is a need to explore the extent to which the PDSA method has been successfully deployed to draw conclusions from these studies. Rather than see the PDSA method as a 'black box' of QI,²³ it is important to understand that the use of PDSA cycles is, itself, a complex intervention made up of a series of interdependent steps and key principles that inform its application^{5 24 25} and that this application is also affected by local context.²⁶ To interpret the results regarding the outcome(s) from the application of PDSA cycles (eg, whether processes or outcomes of care improved) and gauge the effectiveness of the method, it is necessary to understand how the method has been applied.

No formal criteria for evaluating the application or reporting of PDSA cycles currently exist. It is only in recent years, through SQUIRE guidelines, that frameworks for publication have been developed that explicitly consider description of PDSA application.^{27 28} We consider that such criteria are necessary to support and assess the effective application of PDSA cycles and to increase their legitimacy as a scientific method for improvement. We revisited the origins and theory of the method to develop a theoretical framework to evaluate the application of the method.

The origins and theory of PDSA cycles

The PDSA method originates from industry and Walter Shewhart and Edward Deming's articulation of iterative processes which eventually became known as the four stages of PDSA.²⁵ PDCA (plan–do–check–act) terminology was developed following Deming's early teaching in Japan.²⁹ The terms PDSA and PDCA are often used interchangeably in reference to the method. This distinction is rarely referred to in the literature and for the purpose of this article we consider PDSA and PDCA but refer to the methodologies generally as 'PDSA' cycles unless otherwise stated.

Users of the PDSA method follow a prescribed four-stage cyclic learning approach to adapt changes aimed at improvement. In the 'plan' stage a change aimed at improvement is identified, the 'do' stage sees this change tested, the 'study' stage examines the success of the change and the 'act' stage identifies adaptations and next steps to inform a new cycle. The MFI³⁰ and FOCUS³¹ (see figure 1) frameworks have been developed to precede the use of PDSA and PDCA cycles^{30 31} respectively (table 1).

In comparison to more traditional healthcare research methods (such as randomised controlled trials in which the intervention is determined in advance and variation is attempted to be eliminated or controlled for), the PDSA cycle presents a pragmatic scientific method for testing changes in complex systems.³² The four stages mirror the scientific experimental method³³ of formulating a hypothesis, collecting data to test this hypothesis, analysing and interpreting the results and making inferences to iterate the hypothesis.

The pragmatic principles of PDSA cycles promote the use of a small-scale, iterative approach to test interventions, as this enables rapid assessment and provides flexibility to adapt the change according to feedback to ensure fit-for-purpose solutions are developed.^{10 12 13} Starting with small-scale tests provides users with freedom to act and learn; minimising risk to patients, the organisation and resources required and providing the opportunity to build evidence for change and engage stakeholders as confidence in the intervention increases.

In line with the scientific experimental method, the PDSA cycle promotes prediction of the outcome of a test of change and subsequent measurement over time (quantitative or qualitative) to assess the impact of an intervention on the process or outcomes of interest. Thus, learning is primarily achieved through interventional experiments designed to test a change. In recognition of working in complex settings with inherent variability, measurement of data over time helps understand natural variation in a system, increase awareness of other factors influencing processes or outcomes, and understand the impact of an intervention.

As with all scientific methods, documentation of each stage of the PDSA cycle is important to support scientific quality, local learning and reflection and to ensure knowledge is captured to support organisational memory and transferability of learning to other settings.

This review examines the application of PDSA cycles as determined by these principle features of the PDSA method described above. We recognise that a number of health and research related contextual factors may affect application of the method but these factors are beyond the scope of this review. The review intends to improve the understanding of

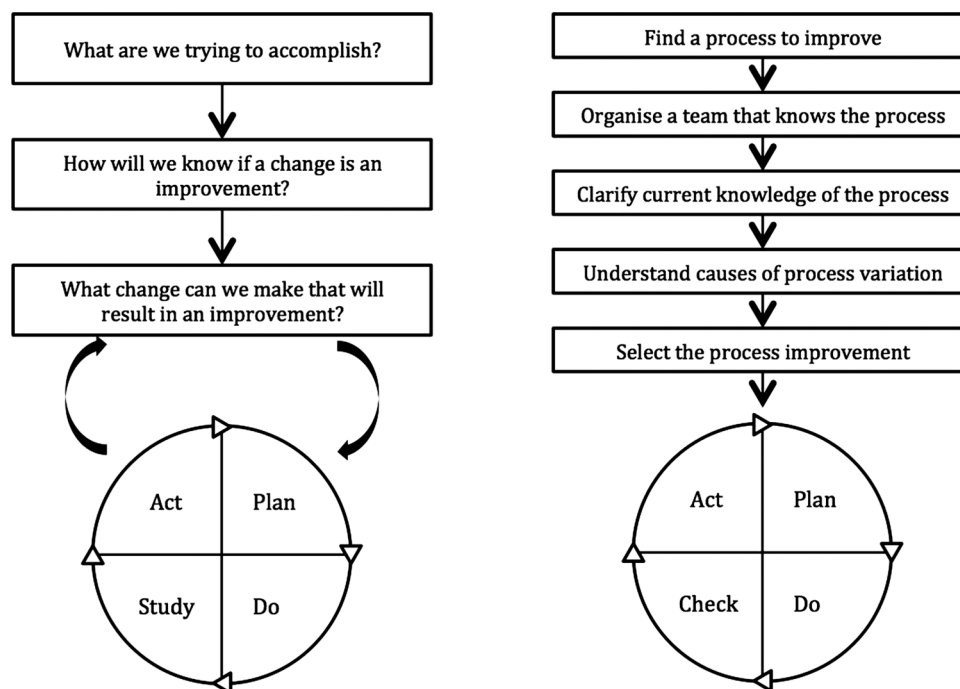


Figure 1 The Model for Improvement; FOCUS.

whether the PDSA method is being used and reported in line with the literature informed criteria and therefore inform the interpretation of studies that have used PDSA cycles to facilitate iterative development of an intervention.

METHODS

A systematic narrative review was conducted in adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.³⁴

Search

The search was designed to identify peer-reviewed publications describing empirical studies that applied the PDSA method. Taking into account the development of the method and terminology, the search terms used were 'PDSA', 'PDCA', 'Deming Cycle', 'Deming Circle', 'Deming Wheel' and 'Shewhart Cycle'. No year of publication restrictions were imposed.

Information sources

The following databases were searched for articles: Allied and Complementary Medicine Database (AMED; 1985 to present), British Nursing Index (BNI; 1985 to present), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1981 to present), Embase (1980 to present), Health Business Elite (EMBESCO Publishing, Ipswich, Massachusetts, USA), the Health Management Information Consortium (HMIC), MEDLINE from PubMed (1950 to present) and PsychINFO (1806 to present) using the NHS Evidence online library (REF), and the Cochrane

Database of Systematic Reviews. The last search date was 25 September 2012.

Data collection process and study selection

Data were collected and tabulated independently by MJT, CM and CN in a manner guided by the Cochrane Handbook. Eligibility was decided independently, in a standardised manner and disagreements were resolved by consensus. If an abstract was not available from the database, the full-text reference was accessed.

Inclusion criteria for articles were as follows: published in peer-reviewed journal; describes PDSA method being applied to improve quality in a health-care setting; published in English. Editorial letters, conference abstracts, opinion and audit articles were excluded from the study selection.

Data items

A theoretical framework was constructed by compartmentalising the key features of the PDSA method into observable variables for evaluation (table 2). This framework was developed in accordance with recommendations for PDSA use cited in the literature, describing the origins and theory of the method. Face validity of the framework was achieved through discussion among authors, with QI facilitators and at local research meetings.

Data were collected regarding application of the PDSA method in line with the theoretical framework. Other data collected included first author, year of publication, country, area of healthcare, use of PDSA or PDCA terminology, and use of MFI or FOCUS as

Table 1 Description of the plan–do–study–act (PDSA) cycle method according to developers and commentators

	Deming (1986) ²⁵ Original description of the method relating to manufacturing	Langley (1996) ³⁰ How the PDSA method may be adapted for use in healthcare contexts	Speroff and O'Connor (2004) ³³ How the PDSA method is analogous to scientific methodology
Plan	Plan a change or test aimed at improvement	<ul style="list-style-type: none"> ▶ Identify objective ▶ Identify questions and predictions ▶ Plan to carry out the cycle (who, when, where, when) 	Formation of a hypothesis for improvement
Do	Carry out the change or test (preferably on a small scale)	<ul style="list-style-type: none"> ▶ Execute the plan ▶ Document problems and unexpected observations ▶ Begin data analysis 	Conduct study protocol with collection of data
Study	Examine the results. What did we learn? What went wrong?	<ul style="list-style-type: none"> ▶ Complete the data analysis ▶ Compare data to predictions ▶ Summarise what was learnt 	Analysis and interpretation of the results
Act	Adopt the change, abandon it or run through cycle again	<ul style="list-style-type: none"> ▶ What changes are to be made? ▶ What will the next cycle entail? 	Iteration for what to do next

supporting frameworks. Ratios were used to analyse the results regarding the majority of variables, and mean scores regarding data associated with length of study, length of PDSA cycle and sample size were also used for analysis. Data were analysed independently by MJT and CM. Discrepancies (which occurred in less than 3% of data items) were resolved by consensus.

Risk of bias in individual studies

The present review aimed to assess the reported application of the PDSA method and the results of individual studies were not analysed in this review.

Risk of bias across studies

Despite our review being focused on reported application, rather than success of interventions, it may still be possible that publication bias affected the results of this study. Research that used PDSA methodology, but did not yield successful results, may be less likely to get published than reports of successful PDSA interventions.

RESULTS

Study selection

A search of the databases yielded 942 articles. After removal of duplicates, 409 remained; 216 and 120

Table 2 Theoretical framework based on key features of the plan–do–study–act (PDSA) cycle method

Feature of PDSA	Description of feature	How this was measured
Iterative cycles	To achieve an iterative approach, multiple PDSA cycles must occur. Lessons learned from one cycle link and inform cycles that follow. Depending on the knowledge gained from a PDSA cycle, the following cycle may seek to modify, expand, adopt or abandon a change that was tested	<ul style="list-style-type: none"> ▶ Were multiple cycles used? ▶ Were multiple cycles linked to one another (ie, does the 'act' stage of one cycle inform the 'plan' stage of the cycle that follows)? ▶ When isolated cycles were used were future actions postulated in the 'act' stage?
Prediction-based test of change	A prediction of the outcome of a change is developed in the 'plan' stage of a cycle. This change is then tested and examined by comparison of results with the prediction	<ul style="list-style-type: none"> ▶ Was a change tested? ▶ Was an explicit prediction articulated?
Small-scale testing	As certainty of success of a test of change is not guaranteed, PDSAs start small in scale and build in scale as confidence grows. This allows the change to be adapted according to feedback, minimises risk and facilitates rapid change and learning	<ul style="list-style-type: none"> ▶ Sample size per cycle? ▶ Temporal duration of cycles? ▶ Number of changes tested per cycle? ▶ Did sequential cycles increase scale of testing?
Use of data over time	Data over time increases understanding regarding the variation inherent in a complex healthcare system. Use of data over time is necessary to understand the impact of a change on the process or outcome of interest	<ul style="list-style-type: none"> ▶ Was data collected over time? ▶ Were statistics used to test the effect of changes and/or understand variation?
Documentation	Documentation is crucial to support local learning and transferability of learning to other settings	<ul style="list-style-type: none"> ▶ How thoroughly was the application of the PDSA method detailed in the reports? ▶ Was each stage of the PDSA cycles documented?

were further discarded following review of abstracts and full texts, respectively. Excluded articles did not apply the PDSA method as part of an empirical study or coincidentally used the acronyms PDSA or PDCA for different terms, or were abstracts for conferences or poster presentations. A total of 73 articles met the inclusion criteria and were included in the review (see figure 2).

General study characteristics

Country of study

The retrieved articles describe studies conducted in the USA (n=46), the UK (n=13), Canada (n=3), Australia (n=3), the Netherlands (n=2) and one each from six other countries (see online supplementary appendix A for complete synthesis of results).

Healthcare discipline to which method was applied

This varied across acute and community care and clinical and organisational settings. The most common settings were those of pain management and surgery (six articles each).

Method terminology

Of the 73 articles identified, 42 articles used 'PDSA' as terminology and 31 referred to the method as 'PDCA'. Eight of these reported using the MFI. Thirty-one articles used 'PDCA' terminology, with 20 using the preceding FOCUS framework. One article described use of FOCUS and MFI. Over time there was an increase in the prevalence of PDSA use with

PDCA use diminishing (see online supplementary figure S1). The earliest reported use of PDCA and PDSA in healthcare was 1993 and 2000, respectively.

Documentation

The following four categories were used to describe the extent to which cycles were documented in articles (n=73): no detail of cycles (n=16); themes of cycles (but no additional details) (n=8); details of individual cycles, but not of stages within cycles (n=8); details of cycles including separated information on stages of cycles (n=41).

Analysis of articles against the developed framework was dependent on the extent to which the application of PDSA cycles was reported. Articles that provided no details of cycles or only themes of cycles were insufficient for full review and excluded for analysis against all features. Articles that provided further details of cycles completed (n=49) were included for analysis against the remaining four features of the framework. A full breakdown of findings can be viewed in online supplementary appendix B.

Application of method

Iterative cycles (n=49)

Fourteen articles described a sequence of iterative cycles (two or more cycles with lessons learned from one cycle linking and informing a subsequent cycle), 33 described isolated cycles that are not linked, and 2 articles described cycles that used PDSA stages in the incorrect order (in one article, one plan, one do, two checks and three acts were described, PDACACA³⁵; a further study did not report use of a 'check' stage; PDA³⁶) and are excluded from further review. Of the 33 articles that described non-iterative cycles, 29 reported a single cycle being used, and 4 described multiple, isolated (non-sequential) cycles. Although future actions are often suggested in articles that reported a single cycle, only three explicitly mentioned the possibility of further cycles taking place. A total of 13.6% (3/22) of PDCA studies described the application of iterative cycles compared with 44% (11/25) of PDSA studies describing the application of iterative cycles (see figure 3).

Prediction-based testing of change (n=47)

The aims of the cycles adhered to one of two themes: tests of a change; and collection or review of data without a change made. Of the 33 articles with single cycles, 30 aimed to test a change while 3 used the PDSA method to collect or review data. Of the 14 articles demonstrating sequential cycle use, 8 solely used their cycles to test change while 5 began with a cycle collecting or reviewing data followed by cycles testing change. One article described a mixture of cycles testing changes and cycles that involved collection/review of data. Four of the 47 studies contained an explicit prediction regarding the outcome of a

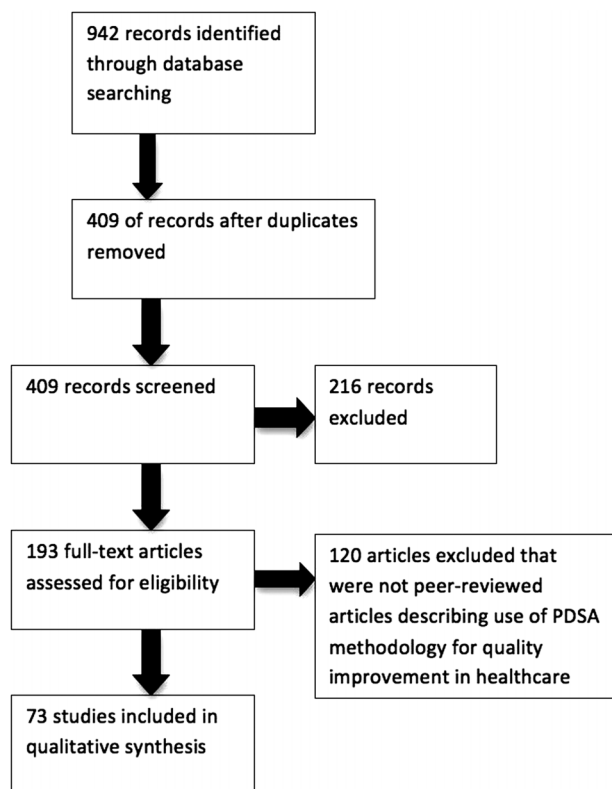


Figure 2 PRISMA diagram.

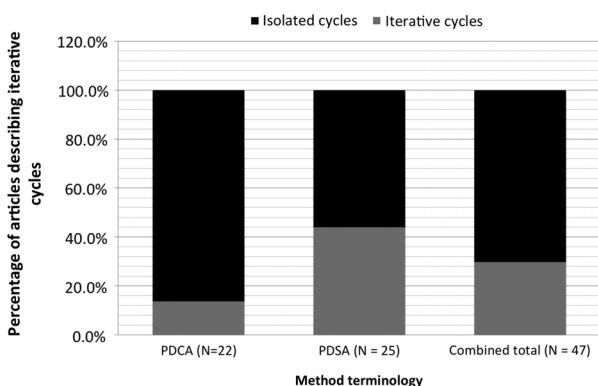


Figure 3 Iterative nature of cycles for all articles and split by plan-do-check-act and plan-do-study-act terminology.

change; all 4 aimed to test a change (see online supplementary table S1).

Small-scale testing (n=47)

Scale was assessed in three ways: sample size, duration and complexity. Sample size refers to quantity of observations used to measure the change; duration refers to the length of PDSA cycle application; and complexity refers to the quantity of changes administered per cycle.

Sample size

Patient data, staff data and case data were used as samples within PDSA cycles. Twenty-seven articles reported a sample size from at least one of their cycles. Twenty-one of these were isolated cycle studies with sample size ranging from 7 to 2079 (mean=323.33, SD=533.60). The remaining six studies reporting individual cycle sample sizes used iterative cycles; the sample size of the first cycles of these ranged from 1 to 34 (mean=16.75, SD=11.47). Two of these studies described the use of incremental sample sizes across cycles, three used non-incremental sample sizes across cycles, and one changed the type of sample. Of the eight iterative cycle articles that did not report individual cycle sample sizes, two did not differentiate sample sizes between cycles and instead gave an overall sample for the chain of cycles and six did not report sample size.

Duration

Reported study duration of isolated cycles ranged from 2 weeks to 5 years (mean=11.91 months, SD=12.81). Only five articles describing iterative cycles explicitly reported individual cycle duration. Individual cycle duration could be estimated from the total duration of the PDSA cycle chain and the number of cycles conducted, resulting in approximate cycle lengths ranging from three cycles in 1 day to one cycle in 16 months (mean=5.41 months, SD=4.80, see online supplementary figure S2). The total PDSA cycle duration for series of iterative cycles

(first to last cycle of one chain) ranged from 1 day to 4 years (mean=20.38, SD=20.39 months).

Complexity

Twenty-two articles reported more than one change being tested within a single cycle. Of the articles describing iterative cycles, 42% administered more than one change per cycle compared with 48% of the articles describing non-iterative PDSA cycles.

Data over time (n=47)

All studies used a form of qualitative and quantitative data to assess cycles. Studies were categorised according to four types of reporting quantitative data: regular (n=15), three or more data points with consistent time intervals; non-regular (n=16), before and after or per PDSA cycle; single data point (n=8), a single data point after PDSA cycle(s); and no quantitative data reported (n=8). Of the 15 articles that used regular data, only 7 used monthly or more frequent data intervals (see online supplementary figure S3 for full frequency of regular quantitative data reporting). No studies reported using statistical process control to analyse data collected from PDSA cycles. Eleven included analysis of data using inferential statistical tests (five of these studies collected isolated data, six involved continuous data collection).

Of the eight articles that did not report any quantitative data, two reported that quantitative analyses had taken place but did not present the findings and six described the use of qualitative feedback only (one non-regular, five single data point). Qualitative data were gathered through a range of mechanisms from informal staff or patient feedback to structured focus groups.

DISCUSSION

PDSA cycles offer a supporting mechanism for iterative development and scientific testing of improvements in complex healthcare systems. A review of the historic development and rationale behind PDSA cycles has informed the development of a theoretical framework to guide the evaluation of PDSA cycles against use of iterative cycles, initial small-scale testing, prediction-based testing of change, use of data over time and documentation.

Using these criteria to assess peer-reviewed publications of PDSA cycles demonstrates an inconsistent approach to the application and reporting of PDSA cycles and a lack of adherence to key principals of the method. Only 2/73^{37 38} articles demonstrated compliance with criteria in all five principles. Assessment of compliance was problematic due to the marked variation in reporting of this method, which reflects a lack of standardised reporting requirements for the PDSA method.

From the articles that reported details of PDSA cycles it was possible to ascertain that variation is

inherent not just in reporting standards, but in the conduct of the method, implying that the key principles of the PDSA method are frequently not followed. Less than 20% (14/73) of reviewed articles reported the conduct of iterative cycles of change, and of these, only 15% (2/14) used initial small-scale tests with increasing scale as confidence in the intervention developed. These results suggest that the full benefits of the PDSA method would probably not have been realised in these studies. Without an iterative approach, learning from one cycle is not used to inform the next cycle, and therefore it is unlikely that interventions will be adapted and optimised for use in a particular setting. Furthermore, large-scale cycles risk significant resource investment in an intervention that has not been tested and optimised within that environment and risk producing 'false' negatives.

Only 14% (7/47) of articles reported use of regular data over time at monthly or more frequent intervals, indicating a lack of understanding around the use of the PDSA method to track change within a 'live' system, and limiting the ability to interpret the results from the study. Cycles that included an explicit prediction of outcomes were reported in only 9% (4/47) of articles, suggesting that PDSA cycles were not used as learning cycles to test and revise theory-based predictions.

Overall these results demonstrate poor compliance with key principles of the PDSA method, suggesting that it is not being used optimally. The increasing trend in using PDSA (as opposed to 'PDCA') cycles in recent years, however, does seem to have been accompanied by an increase in compliance with some key principles, such as use of iterative cycles. Deming was cautious over the use of the 'PDCA' terminology and warned it referred to an explicitly different process, referring to a quality control circle for dealing with faults within a system, rather than the PDSA process, which was intended for iterative learning and improvement of a product or a process.³⁹ This subtle difference in terminologies may help to explain the better compliance with key methodological principles in studies that refer to the method as 'PDSA'.

One of the articles identified in the search included comments by the authors that the PDSA method should be 'more realistically represented',⁴⁰ as ineffective cycles can be 'abandoned' early on, making it needless to go through all four stages in each iteration. These comments may provide insight into an important potential misunderstanding of the PDSA methodology. Ineffective changes will result in learning, which is a fundamental principle behind a PDSA cycle. However minor this abandoned trial may have been, it can still be usefully described as a PDSA cycle. A minor intervention may be planned (P) and put into practice (D). A barrier may be encountered (S), resulting in a decision being made to retract the intervention, and to do something differently (A).

The theoretical framework presented in this paper highlights the complexity of PDSA cycles and the underpinning knowledge required for correct application. The considerable variation in application observed in the reported literature suggests that caution should be taken in interpreting results from evaluations in which PDSAs are used in a controlled setting and as a 'black box' of QI. This review did not compare the effectiveness of use to reported outcomes and therefore this study does not conclude whether better application of the PDSA method results in better outcomes, but instead draws on theoretical principles of PDSAs to rationalise why this would be expected. Prospective mechanistic studies exploring the effective application of the method as well as study outcomes would be of greater use in drawing conclusions regarding the effectiveness of the method. The framework presented in this paper could act as a good starting point for such studies.

The fact that only peer-reviewed publications were assessed in this study means that results may be affected by publication bias. This is anticipated both in terms of what is accepted for publication but also the level and type of detail that is requested and allowed in typical publications (eg, before and after studies are more common than presenting data over time and this may make these types of studies easier to publish). Though QI work may be easier to publish now through recent changes in publication guidelines,²⁷ possible publication outlets continue to be relatively limited.

To support systematic reporting and encourage appropriate usage, we suggest that reporting guidelines be produced for users of the PDSA method to increase transparency as to the issues that were encountered and how they were resolved. While PDSA is analogous to a scientific method, it appears to be rarely used or reported with scientific rigour, which in turn, inhibits perceptions of PDSA as a scientific method. Such guidelines are essential to increase the scientific legitimacy of the PDSA method as well as to improve scientific rigour or application and reporting. Although the SQUIRE guidelines make reference to the potential use of PDSA cycles, further support to users and teachers, and publication of this improvement method seems necessary. Consistent reporting of PDSA structure would allow meta-evaluation and systematic reviews to further build the knowledge of how to use such methods effectively and the principles to apply to increase chances of success.

It is clear from these findings that there is much room for improvement in the application and use of the PDSA method. Previous studies have discussed the influence of different context factors on the use of QI methods, such as motivation, data support infrastructure and leadership.^{20 22 41–43} Understanding how high-quality usage can be promoted and supported needs to become the focus of further research if such

QI methods are going to be used effectively in mainstream healthcare.

CONCLUSIONS

There is varied application and reporting of PDSAs and lack of compliance with the principles that underpin its design as a pragmatic scientific method. The varied practice compromises its effectiveness as a method for improvement and cautions against studies that view QI or PDSA as a 'black box' intervention.

There is an urgent need for greater scientific rigour in the application and reporting of these methods to advance the understanding of the science of improvement and efficacy of the PDSA method. The PDSA method should be applied with greater consistency and with greater accordance to guidelines provided by founders and commentators^{25 30 44 45}

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Appendix A: Studies identified in search that used PDSA method

All 73 studies identified in review.

First author	Year of publication	Country	Title	Length of study (months)	Cycle(s) referred to as PDSAs or PDCA's?	Model for Improvement or FOCUS supporting model?	How thoroughly were PDSA methods described?*
Bader(1)	2002	USA	Using a FOCUS-PDCA quality improvement model for applying the severe traumatic brain injury guidelines to practice: process and outcomes	36	PDCA	FOCUS	4
Baker(2)	2002	USA	Successful performance improvement	unclear	PDCA	none	2
Barry(3)	2006	UK	Small is beautiful	15	PDSA	none	1
Beger(4)	1999	USA	Self-Administered Medication Packet for Patients Experiencing a Vaginal Birth	1	PDCA	FOCUS	4
Bittle(5)	2007	USA	Registration-associated patient misidentification in an academic medical center: causes and corrections	48	PDSA	none	3
Boesch(6)	2012	USA	Prevention of Tracheostomy-related Pressure Ulcers in Children	30	PDSA	none	1
Boyd(7)	2011	UK	Peripheral intravenous catheters: the road to quality improvement and safer patient care	6	PDSA	Mfl	4
Brown(8)	2006	UK	Redesigning patient services	2	PDSA	Mfl	4
Buckley(9)	2010	USA	Linking residency training effectiveness to clinical outcomes: a quality improvement approach	48	PDSA	none	4
Buhr(10)	2006	USA	Quality improvement initiative for chronic pain assessment and management in the nursing home: a pilot study	16	PDSA	none	4

Campbell(11)	2008	Canada	Bridging the gap between primary and secondary care: use of a clinical pathway for the investigation and management of deep vein thrombosis	unclear	PDSA	none	1
Caswell(12)	1996	USA		12	PDCA	FOCUS	4
Chen(13)	2006	China	Improving the management of anemia in hemodialysis patients by implementing the continuous quality improvement program	20	PDCA	none	4
Christie(14)	2009	UK	Using a communication framework at handover to boost patient outcomes	36	PDSA	Mfl	4
Curran(15)	2012	UK	Using a PDSA cycle of improvement to increase preparedness for, and management of, norovirus in NHS Scotland	12	PDSA	none	4
Dobrzanska(16)	2007	UK	Piloting stroke rehabilitation in a community hospital	unclear	PDSA	none	1
Dover(17)	2012	UK	Caring for patients in the right place at the right time	12	PDSA	Mfl	3
Dunn(18)	2011	USA	Developing a nursing model of care? Try focus groups	2	PDSA	none	4
Eckhart(19)	1996	USA	Improved Coumadin therapy using a continuous quality improvement process	24	PDCA	FOCUS	4
Eisenberg(20)	2002	USA	Intravascular therapy process improvement in a multihospital system: don't get stuck with substandard care	18	PDCA	none	4
Esmail(21)	2004	Canada	Quality improvement in the ICU. A Canadian perspective	unclear	PDCA	FOCUS and Mfl	1
Feehery(22)	2003	USA	Flushing 101: using a FOCUS-PDCA quality improvement model to reduce catheter occlusions with standardized protocols	unclear	PDCA	FOCUS	1
Fernandes(23)	2009	Dubai	Using evidence to reduce the rate of episiotomy in a Dubai hospital	13	PDCA	FOCUS	4

Flynt(24)	2002	USA	Using OASIS Data to Improve Skin Care	unclear	PDCA	FOCUS	4
Gillaspie(25)	2010	USA	Better pain management after total joint replacement surgery: a quality improvement	0.033	PDSA	none	3
Gordon(26)	2000	USA	A quality improvement approach to reducing use of meperidine	60	PDCA	none	4
Gordon(27)	2008	USA	Improving reassessment and documentation of pain management	24	PDCA	none	4
Gray(28)	2007	UK	Developing the public health role of a front line clinical service: integrating stop smoking advice into routine podiatry services	6	PDSA	none	2
Hallett(29)	2012	UK	How to address the physical needs of clients in a mental health setting	3	PDSA	Mfl	4
Hoskins(30)	2002	USA	Quality improvement in patient distribution at a major university student health center	6	PDCA	FOCUS	4
Isouard(31)	1999	Australia	Improved turnaround time of laboratory test results using a FOCUS PDCA approach	12	PDCA	FOCUS	4
Johnson(32)	2009	USA	Implementation of a diabetes clinic-in-a-clinic project in a family practice setting: using the plan, do, study, act model	3	PDSA	none	3
Koll(33)	2008	USA	The CLABs Collaborative: A Regionwide Effort to Improve the Quality of Care in Hospitals	unclear	PDSA	none	1
Leone(34)	2009	USA	Implementing a pain management program in a long-term care facility using a quality improvement approach	2	PDSA	none	4
Lynch-Jordan(35)	2010	USA	Applying quality improvement methods to implement a measurement system for chronic pain-related disability	6	PDSA	none	3
Manfredi(36)	2003	Brazil	A model for improving quality in	6	PDCA	none	4

Marang-van de Mheen(37)	2006	Netherlands	nephrology settings Adverse outcomes in surgical patients: implementation of a nationwide reporting system	unclear	PDSA	none	1
Marcellus(38)	2012	USA	Quality Improvement for Neonatal Nurses, Part II: Using a PDSA Quality Improvement Cycle Approach to Implement an Oral Feeding Progression Guideline for Premature Infants	32	PDSA	none	3
McPharlin(39)	1993	USA	FOCUS-PDCA(TM): A quality improvement tool to improve efficiency in the vascular laboratory	14	PDCA	FOCUS	4
Meehan(40)	1993	USA	Improving blood glucose monitoring in a hospital setting using the PDCA approach	unclear	PDCA	none	4
Miano(41)	1998	USA	Implementation of the IV push method of antibiotic administration using the FOCUS/PDCA approach	6	PDCA	FOCUS	4
Miller(42)	1994	USA	Quality management series: Quality improvement in the cutaneous micrographic surgery laboratory	12	PDCA	FOCUS	4
Moran(43)	2009	Ireland	Improving palliative care	unclear	PDSA	none	4
Nakayama(44)	2010	USA	Using a Plan-Do-Study-Act cycle to introduce a new OR service line	1 year	PDSA	Mfl	2
Nayeri(45)	2011	Iran	An investigation into the effects of quality improvement method on patients' satisfaction: A semi experimental research in Iran	unclear	PDCA	FOCUS	4
New(46)	1997	USA	Quality improvement in the ambulatory surgical setting	2	PDCA	FOCUS	4
Nicotra(47)	1996	USA	Process improvement plan for the reduction of nosocomial pneumonia in patients on ventilators	unclear	PDCA	FOCUS	1
Olenginski(48)	2006	USA	Development and Evaluation of a	unclear	PDSA	none	2

Oyler(49)	2011	USA	Vertebral Fracture Assessment Program Using IVA and Its Integration With Mobile DXA Teaching internal medicine residents to sustain their improvement through the quality assessment and improvement curriculum	36	PDSA	none	2
Pace(50)	1997	USA	Clinical research. Performance model anchors successful nutrition support protocol	48	PDCA	FOCUS	4
Porter(51)	2009	Australia	Improving GP diabetes management. A PDSA audit cycle in Western Australia	unclear	PDSA	none	1
Pronovost(52)	2000	USA	Using online and offline change models to improve ICU access and revenues	24	PDSA	none	4
Provance(53)	1994	USA	Quality Improvement and Public Health - Tetanus Immunization in the Emergency Department	12	PDCA	FOCUS	2
Reid(54)	2005	UK	Does client self-booking reduce 'did not attends' (DNAs) in a counselling service?	1	PDSA	none	4
Reid(55)	2005	UK	Improving referral information in community mental health	unclear	PDSA	none	4
Robarts(56)	2008	Canada	A framework for the development and implementation of an advanced practice role for physiotherapists that improves access and quality of care for patients	unclear	PDSA	none	3
Sanchez(57)	2009	USA	Implementation of a diabetic visual foot assessment in a primary care setting	0.5	PDCA	none	4
Saxena(58)	2004	USA	A comprehensive assessment program to improve blood-administering practices using the FOCUS-PDCA model	51	PDCA	FOCUS	1

Simon(59)	1997	USA	Improving the processes of care and outcomes in obstetrics/gynecology	30	PDCA	none	4
Sorokin(60)	2006	USA	Enhancing patient safety during feeding-tube insertion: a review of more than 2,000 insertions	20	PDSA	none	4
Stadt(61)	2005	USA	Best practices that Improved Patient Outcomes and Agency Operational Performance	48	PDSA	none	4
Stevens(62)	2010	USA	A Multi-Institutional Quality Improvement Initiative to Transform Education for Chronic Illness Care in Resident Continuity Practices	36	PDSA	none	1
Sumrall(63)	2011	USA	Achieving appropriate prophylactic antibiotic administration while simultaneously implementing an automated anesthesia record	18	PDSA	none	4
Tea(64)	2008	USA	Proactive patient rounding to increase customer service and satisfaction on an orthopaedic unit		PDCA	none	1
Thakkar(65)	2011	UK	A quality improvement programme to increase compliance with an anti-infective prescribing policy	12	PDSA	none	1
Tomolo(66)	2009	USA	A case study of translating ACGME practice-based learning and improvement requirements into reality: systems quality improvement projects as the key component to a comprehensive curriculum	22	PDSA	Mfl	2
Torkki(67)	2006	Finland	Managing urgent surgery as a process: Case study of a trauma center	12	PDCA	none	4
Van Tiel(68)	2006	The Netherlands	Plan-do-study-act cycles as an instrument for improvement of compliance with infection control measures in care of patients after	15	PDSA	none	2

Varkey(69)	2009	USA	cardiothoracic surgery Using quality-improvement techniques to enhance patient education and counselling of diagnosis and management	0.75	PDSA	none	3
Wheatland(70)	2006	Australia	Initiating a PDSA cycle: improving management of diabetes in rural WA	unclear	PDSA	none	4
Wojciechowski(71)	2007	USA	A case review: designing a new patient education system	48	PDSA	none	4
Wolfenden(72)	2010	UK	Track and trigger system for use in community hospitals	unclear	PDSA	none	1
Zack(73)	2008	USA	Zeroing in on zero tolerance for central line-associated bacteremia	unclear	PDCA	FOCUS	1

*1= No detail of cycles reported, 2 = Themes of cycles provided (but no additional details), 3 = Details of individual cycles, but not of stages

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Appendix B: Studies identified in search that described PDSA method in sufficient detail to be included for full analysis

First Author	Cycle(s) referred to as PDSAs or PDCAs?	Iterative Cycles			Prediction-based test of change	Small-scale testing							Data over time			
		Iterative nature of cycles	Number of cycles / chains of cycles	Content of final "act" stage		Sample		Complexity	Duration				Regular (R) / isolated (I)	Use of statistics	Data Time Interval (months)	Type of Data used to inform cycles
Beger (1)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change - with explicit prediction articulated in plan	33	N/A	No	30	Not Stated	30	30	I	None	Before and after	Quantitative and Qualitative
Bittle(2)	PDSA	Iterative chain	3	1 Not referred to	Testing change	Not Stated	No sample size data	Yes	45	Cycles 1: 4, Cycle 2: 3, Cycle 3: 12	N/A	4; 3; 12	R	<i>p</i> value	12	Quantitative
Boyd(3)	PDSA	Iterative chain	7	5 New PDSA scheduled	Testing change	100	Not incremental	No	7	1	N/A	1	R	<i>p</i> value	Weekly	Quantitative
Brown(4)	PDSA	Single isolated cycle	1	5 New PDSA scheduled	Testing change	Not Stated	N/A	Yes	1	1	N/A	1	N	None	N/A	Qualitative
Buckley(5)	PDSA	Multiple Iterative chains	Chain 1: 6, Chain 2: unclear	2 Further changes implemented	Testing change - with explicit prediction articulated in plan	Not Stated	No sample size data	No	Chain 1: 45, Chain 2: 36	Not Stated	7.5	7.5	R	<i>p</i> value	3	Quantitative
Buhr(6)	PDSA	Multiple isolated cycles	4	3 Changes made permanent	Testing change	Cycle 1: 66, Cycle2, 3, 4: Not stated	N/A	No	16	Cycle 1: 3, Cycle 2: Not stated, Cycle 3: 11, Cycle 4:Not stated	N/A	3; 11	I	none	Before and after	Quantitative

Caswell(7)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	46	N/A	Yes	9	9	N/A	9	I	None	Before and after	Quantitative
Chen(8)	PDCA	Single isolated cycle	1	3 Changes made permanent	Testing change	90	N/A	Yes	20	Not Stated	20	20	I	p value	Before and after	Quantitative
Christie(9)	PDSA	Single isolated cycle	1	2 Further changes implemented	Testing change	Not Stated	N/A	No	Not Stated	Not Stated	Not Stated	Not Stated	I	None	Before and after	Quantitative
Curran(10)	PDSA	Single isolated cycle	1	5 New PDSA scheduled	Testing change	307	N/A	Yes	12	12	N/A	12	R	None	Weekly	Quantitative and Qualitative
Dover(11)	PDSA	Iterative chain	4	3 Changes made permanent	Collecting data in first followed by testing change	Not Stated	No sample size data	No	12	Not Stated	3	3	I	None	Before and after	Quantitative and Qualitative
Dunn(12)	PDSA	Single isolated cycle	1	2 Further changes implemented	Collecting data	332	N/A	No	2	2	N/A	2	N	None	N/A	Qualitative
Eckhart(13)	PDCA	Single isolated cycle	1	4 Further changes suggested	Testing change	43	N/A	No	18	18	N/A	18	I	None	Irregular 4 data points	Quantitative
Eisenberg(14)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	1100	N/A	Yes	18	Not Stated	18	18	N	None	N/A	Quantitative but not presented
Fernandes(15)	PDCA	Single isolated cycle	1	3 Changes made permanent	Testing change	70	N/A	No	13	Not Stated	13	13	R	None	1	Quantitative
Flynt(16)	PDCA	Single isolated cycle	1	4 Further changes suggested	Testing change	Not Stated	N/A	Yes	Not Stated	Not Stated	Not Stated	Not Stated	N	None	N/A	Quantitative but not presented

Gillaspie(17)	PDSA	Iterative chain	3	0 - Unclear	Testing change	Not Stated	No sample size data	No	0.033333333	Not Stated	0.011111111	0.011111111	N	None	N/A	Qualitative
Gordon(18)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	Not Stated	N/A	Yes	60	60	N/A	60	I	None	Irregualr - 5 points	Quantitative
Gordon(19)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	Not Stated	N/A	Yes	24	Not Stated	24	24	R	None	Daily	Quantitative
Hallett(20)	PDSA	Single isolated cycle	1	2 Further changes implemented	Testing change	7	N/A	No	3	3	N/A	3	A	None	N/A	Quantitative
Hoskins(21)	PDCA	Multiple isolated cycles	2	3 Changes made permanent	Testing change	Not Stated	N/A	Yes	Cycle 1:6, Cycle 2: Not Stated	Not Stated	6	6	R	<i>p</i> value	1	Quantitative
Isouard(22)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	Not Stated	N/A	Yes	12	Not Stated	12	12	R	<i>p</i> value	2	Quantitative
Johnson(23)	PDSA	Multiple isolated cycles	5	4 Further changes suggested	Testing change	Not Stated	N/A	Yes	Not Stated	Not Stated	N/A	Not Stated	A	None	N/A	Quantitative
Leone(24)	PDSA	Single isolated cycle	1	5 New PDSA scheduled	Testing change	40	N/A	Yes	2	2	N/A	2	A	None	N/A	Quantitative
Lynch-Jordan(25)	PDSA	Multiple Iterative chains	4 chains of mulitple cycles(not stated)	5 New PDSA scheduled	Testing change	Chain 1:5, Chain 2:34, Chain 3:5, Chain 4:unclear	Incremental of same sample	Yes	6	Not Stated	Not Stated	Not Stated	R	None	Weekly	Quantitative
Manfredi(26)	PDCA	Iterative chain	3	5 New PDSA scheduled	Collecting data in first followed by testing change	29	Not incremental	Yes	6	Not Stated	2	2	I	None	Per PDSA cycle	Quantitative

Marcellus(27)	PDSA	Iterative chain	3	0 - Unclear	Collecting data in first followed by testing change	178	Not incremental	Yes	32	Cycle 1: 8, Cycle 2: 7, Cycle 3: 16	N/A	8; 7; 16	I	None	Per PDSA cycle	Quantitative
McPharlin(28)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	68	N/A	No	14	5	N/A	5	I	None	Before and after	Quantitative
Meehan(29)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change - with explicit prediction articulated in plan	62	N/A	No	0.5	0.5	N/A	0.5	N	None	N/A	Qualitative
Miano(30)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	31	N/A	No	6	6	N/A	6	A	None	N/A	Quantitative
Miller(31)	PDCA	Iterative chain	3	1 Not referred to	Collecting data in first followed by testing change	75	Not incremental	No	Not Stated	Cycle 1: 6, Cycle 2: 6, Cycle 3: Not Stated	N/A	6; 6	R	None	Per data item	Quantitative
Moran(32)	PDSA	Single isolated cycle	1	4 Further changes suggested	Testing change	Not Stated	N/A	Yes	Not Stated	Not Stated	Not Stated	Not Stated	N	None	N/A	Qualitative
Nayeri(33)	PDCA	Single isolated cycle	1	3 Changes made permanent	Testing change	44	N/A	No	Not Stated	Not Stated	Not Stated	Not Stated	I	<i>p</i> value	Before and after	Quantitative
New(34)	PDCA	Single isolated cycle	1	3 Changes made permanent	Testing change	Not Stated	N/A	No	1	1	N/A	1	N	None	N/A	Qualitative
Pace(35)	PDCA	Iterative chain	3	3 Changes made permanent	Collecting data in first followed by testing change	Sample changed during iterative chain	Change sample	Yes	48	Not Stated	16	16	R	None	3	Quantitative
Pronovost(36)	PDSA	Multiple isolated cycles	3	3 Changes made permanent	Testing change	Not Stated	N/A	No	Not Stated	Cycle 1: 3, Cycle 2, 3: Not Stated	N/A	3;3	R	None	1	Quantitative and Qualitative

Reid(37)	PDSA	Single isolated cycle	1	4 Further changes suggested	Collecting data	50	N/A	No	1	Not Stated	1	1	A	None	N/A	Quantitative
Robarts(38)	PDSA	Multiple Iterative chains	2 chains of multiple cycles(not stated)	3 Changes made permanent	Testing change	Not Stated	No sample size data	No	Not Stated	Not Stated	N/A	Not Stated	A	<i>p</i> value	N/A	Quantitative and Qualitative
Sanchez(39)	PDCA	Single isolated cycle	1	4 Further changes suggested	Testing change	52	N/A	No	0.5	0.5	N/A	0.5	A	None	N/A	Quantitative
Simon(40)	PDCA	Single isolated cycle	1	3 Changes made permanent	Testing change	1094	N/A	No	24	Not Stated	24	24	I	<i>p</i> value	Before and after	Quantitative
Sorokin(41)	PDSA	Single isolated cycle	1	2 Further changes implemented	Testing change	2079	N/A	Yes	20	Not Stated	20	20	R	None	3	Quantitative
Stadt(42)	PDSA	Iterative chain	Multiple (not stated)	0 - Unclear	Testing change	Not Stated	Individual cycle sample size not reported	Yes	48	Not Stated	Not Stated	Not Stated	R	None	3	Quantitative and Qualitative
Sumrall(43)	PDSA	Single isolated cycle	1	4 Further changes suggested	Testing change	Not Stated	N/A	Yes	18	Not Stated	18	18	R	None	3	Quantitative
Torkki(44)	PDCA	Single isolated cycle	1	2 Further changes implemented	Testing change	923	N/A	Yes	12	Not Stated	12	12	R	<i>p</i> value	12	Quantitative
Varkey(45)	PDSA	Iterative chain	5	0 - Unclear	Testing change	68	Incremental of same sample	No	0.75	Not Stated	0.15	0.15	I	<i>p</i> value	Before and after	Quantitative
Wheatland(46)	PDSA	Single isolated cycle	1	2 Further changes implemented	Collecting data	253	N/A	No	Not Stated	Not Stated	N/A	Not Stated	A	None	N/A	Quantitative

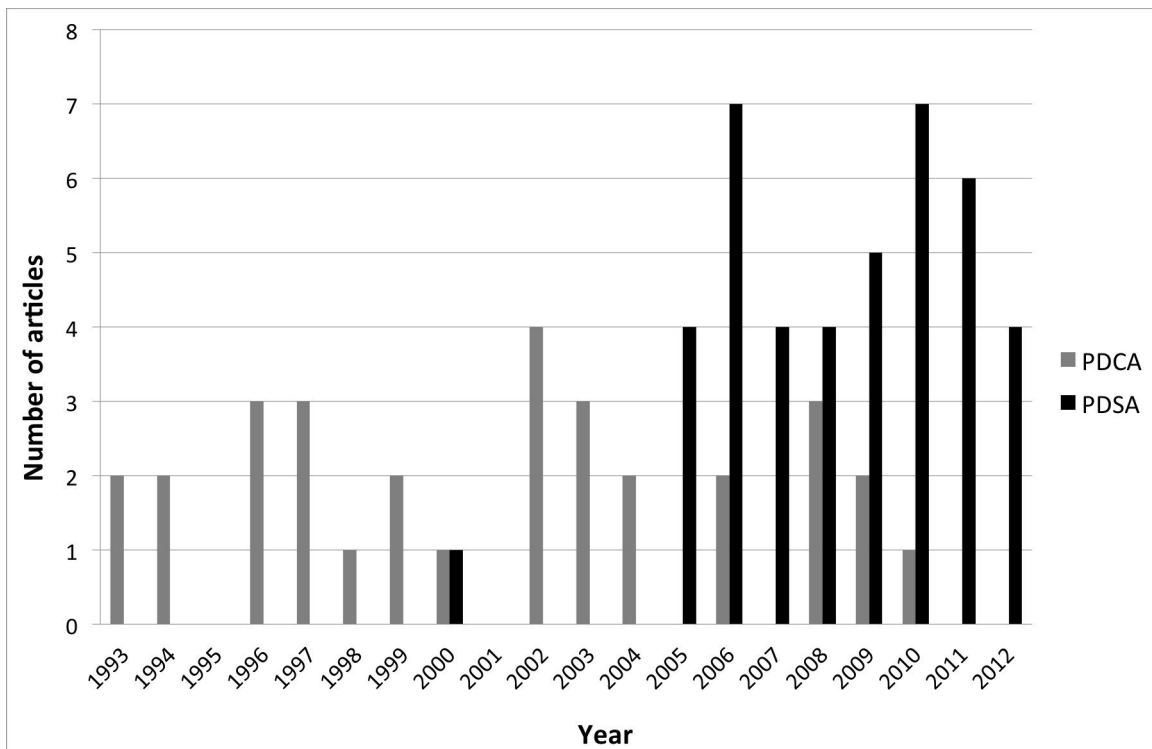
Wojciechowski(47)	PDSA	Multiple Iterative chains	4 chains of multiple cycles(not stated)	5 New PDSA scheduled	Mixed	Not Stated	Not incremental	No	48	Not Stated	Not Stated	Not Stated	I	None	Before and after	Quantitative and Qualitative
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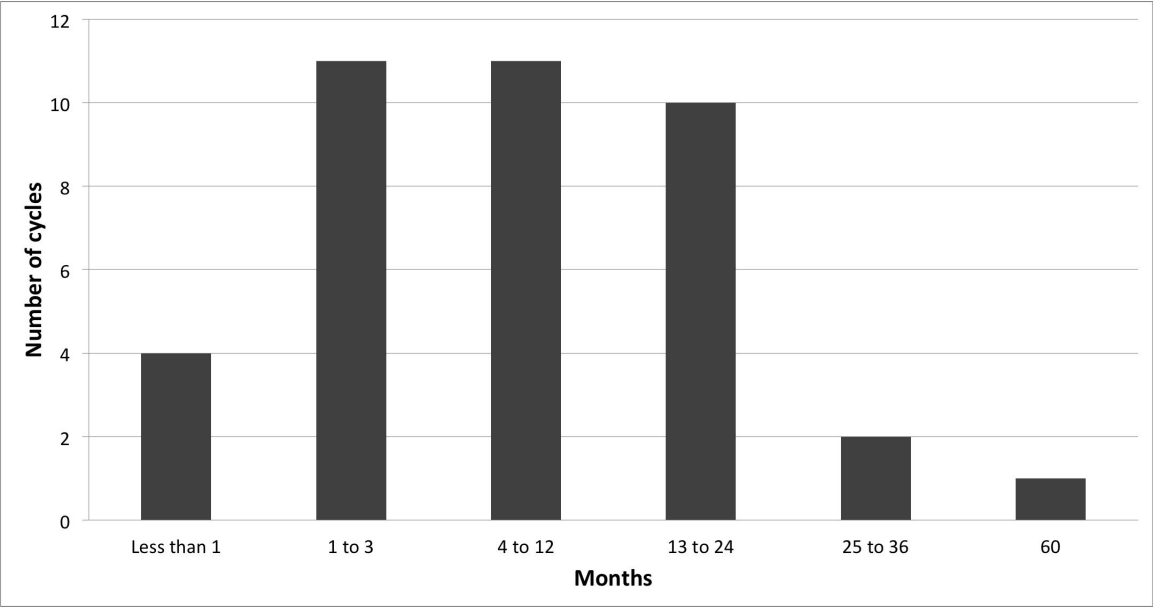
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Supplementary figure 1: Prevalence of PDSA and PDCA terminology in initially included articles over time (n = 73 articles)



Supplementary figure 2: Reported durations of individual cycles of both iterative and isolated nature (n = 45 cycles).



Supplementary figure 3: Regular quantitative data collection intervals (n = 15 articles)

