

1 **A mixed-methods study of challenges experienced by clinical** 2 **teams in measuring improvement**

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32 The study was granted ethical approval by the East Midlands Research Ethics Committee
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1 **Contributorship statement**

2 MDW is the study Chief Investigator. TW conducted the quantitative analysis of the data produced
3 by participating sites, and EL contributed to the analysis of the qualitative data. All authors
4 contributed to data interpretation, manuscript writing and reviewing, and approved its final version.

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A mixed-methods study of challenges experienced by clinical teams in measuring improvement

ABSTRACT

Objective: Measurement is an indispensable element of most quality improvement (QI) projects, but it is undertaken to variable standards. We aimed to characterise challenges faced by clinical teams in undertaking measurement in the context of a safety QI programme that encouraged local selection of measures.

Methods: Drawing on an independent evaluation of a multi-site improvement programme (Safer Clinical Systems), we combined a qualitative study of participating teams' experiences and perceptions of measurement with expert review of measurement plans and analysis of data collected for the programme. Multidisciplinary teams of frontline clinicians at nine UK NHS sites took part across the two phases of the programme between 2011 and 2016.

Results: Developing and implementing a measurement plan against which to assess their improvement goals was an arduous task for participating sites. The operational definitions of the measures that they selected were often imprecise or missed important details. Some measures used by the teams were not logically linked to the improvement actions they implemented. Regardless of the specific type of data used (routinely collected or selected ex-novo), the burdensome nature of data collection was underestimated. Problems also emerged in identifying and using suitable analytical approaches.

Conclusion: Measurement is a highly technical task requiring a degree of expertise. Simply leveraging individual clinicians' motivation is unlikely to defeat the persistent difficulties experienced by clinical teams when attempting to measure their improvement efforts. We suggest that more structural initiatives and broader capability-building programmes should be pursued by the professional community. Improving access to, and ability to use repositories of validated measures, and increasing transparency in reporting measurement attempts, is likely to be helpful.

1 INTRODUCTION

2 Measurement is essential to improving quality and safety in healthcare processes and outcomes.^{1,2}
3 Yet the available evidence suggests that many quality improvement projects may fail to generate
4 reliable or useful data because of challenges in measurement, data collection, and interpretation.³⁻⁶
5 Characteristic problems include missing data or insufficient data points; insufficient baseline periods;
6 poorly chosen, unclear, or changing sampling strategies; poorly annotated data; failure to verify data
7 entry; and poorly chosen or executed analytic strategies.^{7,8} Benn and colleagues found many of
8 these problems when teams sought to implement data collection and analysis systems in local
9 settings as part of a large-scale quality improvement programme.⁹ Similarly, a study of a national
10 system for surveillance of healthcare-associated infections¹⁰ found variability in how well intensive
11 care units designed their data collection systems and in how they interpreted data.

12 Failure to produce reliable data about improvement and to interpret it correctly is an important
13 challenge for quality improvement, limiting the inferences that can be made about the success or
14 otherwise of improvement interventions, as well as eroding confidence in the evidence-base for
15 improvement.¹¹ This problem manifests in summative evaluations but also affects programmes while
16 they are running, when data has potential to be used formatively to optimise the improvement
17 effort.

18 Some of the problems in measuring improvement are likely to be linked to ongoing controversies
19 about the relevant dimensions of quality and safety and the prioritisation of different types of
20 measures, including, for example, the process versus outcome debate.^{8,9,12} Other problems are likely
21 to be more mundane, relating, for example, to issues in establishing data collection systems.¹⁰
22 Importantly, the literature suggests that some problems may also be linked to ownership: studies of
23 measurement have tended to focus on quality measures generated externally to clinical teams (e.g.
24 by regulators or payers), which clinicians may not perceive as directly relevant to their everyday
25 concerns. One suggestion is that clinicians may lack engagement because they perceive externally
26 imposed measures as having little or no relevance to their clinical work and as little more than an
27 administrative burden.⁸ Yet little evidence exists on what happens when clinical teams themselves
28 choose their own measures (rather than having to use those selected externally) and design and
29 implement data collection systems that they see as fitted to their own local circumstances. A well-
30 characterised account of responses to such an opportunity would be very useful.

31 In this article, we use data from a mixed-methods independent evaluation of a nine-site UK patient
32 safety improvement programme to report on clinical teams' experiences of using locally selected
33 measures. We aimed specifically to describe their experiences of planning and conducting
34 measurement activities, collecting data, and analysing and interpreting data for their improvement
35 projects.

36 METHODS

37 The Safer Clinical Systems improvement programme

38 The study we report is based on data from an independent evaluation of a patient safety
39 improvement programme run in the UK, which used an approach known as Safer Clinical Systems.⁷

1 Based on methods of risk management and improvement used in other hazardous industries, the
2 Safer Clinical Systems approach seeks to enable organisations to make improvements to local clinical
3 systems and pathways using a structured methodology for identifying risks and for modifying or re-
4 engineering systems to control risk and enhance reliability.^{7,13} It involves a series of steps in which
5 teams define a clinical pathway and its context; do a detailed diagnostic assessment of the pathway
6 to identify risks and hazards; assess and select options for change and develop an action plan to
7 implement them; and undertake system improvement cycles involving implementation, evaluation
8 of progress against a measurement plan, and revision of interventions.

9 Measurement is a key element of Safer Clinical Systems. During the course of the programme,
10 participating teams were expected to: 1) develop a detailed measurement plan to set out outcome
11 and/or process measures that were appropriate for collecting useful data; 2) establish data
12 collection systems; and 3) analyse and interpret their data using Statistical Process Control (SPC)
13 (Box 1).

14 Box 1

15 A distinctive feature of Safer Clinical Systems is that it does not try to impose predefined solutions,
16 but instead seeks to help organisations develop their own capacity to detect and address
17 weaknesses in their systems, and to measure and report their improvement outcomes. It does so by
18 offering training on a range of improvement tools and techniques (including how to measure for
19 improvement), and emphasising the need to engage local staff (clinical and managerial) in
20 improvement attempts.

21 Funded by an independent charity (The Health Foundation), the programme was run in a total of
22 nine UK hospitals in two phases: the main phase, which ran 2011–14 and included eight sites, and
23 the extension phase, which ran 2014–16 and included six sites (five of the original sites plus an
24 additional one that had not taken part in the main phase). Each of the nine hospitals taking part in
25 the programme used the Safer Clinical Systems approach to proactively assess risks and hazards in
26 their clinical pathways and to develop effective risk-control interventions (Table 1).

27 In the main programme phase, participating sites received training and guidance, and were
28 monitored in their progress, by a dedicated programme support team. Support on measurement
29 included approximately one day of training on principles of measuring improvement, statistical
30 process control (SPC), and use of software for capturing their data and generating charts. In the
31 extension phase, teams were expected to use the Safer Clinical Systems approach on their own,
32 without the support and control that characterised the main phase.

33 Table 1

34 Programme evaluation

35 We undertook an independent evaluation of the Safer Clinical Systems programme using a mixed-
36 method design. We combined a qualitative study, which aimed to describe how participating teams
37 experienced taking part in the Safer Clinical Systems programme, with expert review of
38 measurement plans and analysis of data collected for the programme. The study was granted ethical
39 approval by the [*name omitted*] Research Ethics Committee [*number reference omitted*].

1 *Qualitative study*

2 We conducted semi-structured interviews with members of the participating teams and
3 unstructured ethnographic observations of teams' activities related to programme participation.
4 Particular effort went into capturing how teams undertook tasks relating to measurement (e.g.
5 identified and selected their quality measures, and developed and implemented a measurement
6 plan to assess the impact of their improvements). We were also interested in characterising the
7 challenges and hurdles faced by the teams in doing so.

8 Observations and interviews were conducted by non-clinical researchers who were members of the
9 evaluation team. Interviews were conducted in person or on the phone, were recorded digitally, and
10 transcribed verbatim. All interviewees signed an informed consent form. Observations were
11 unstructured and included routine clinical activities, team meetings, and informal chats with
12 relevant staff. Extensive field notes were taken during visits, and researchers were then debriefed by
13 other members of the evaluation team on return from visits.

14 *Expert review of measurement plans*

15 All the measurement plans prepared by the participating teams were reviewed by one author (XX),
16 who is a specialist in measurement for improvement and an expert in SPC. Published checklists
17 aimed at improving the quality of measurement were used as review criteria.^{3 14} The level of
18 information on each step of the measurement process provided by teams was deemed unclear if it
19 was not sufficient for author XX to know how to repeat the measurement process. The reviews of
20 these plans were used for evaluation purposes (e.g. to assess the quality of the plans) and to provide
21 formative feedback to the participating teams. This feedback was provided to each team through ad
22 hoc coaching sessions, led by author XX and the programme support team in the main phase, and
23 author XX alone in the extension phase. Up to two such sessions, conducted by telephone, were
24 offered to each team.

25 Towards the end of each phase of the programme, XX reviewed and independently analysed the raw
26 data from a selection of the participating sites (four sites in the main phase and four sites in the
27 extension phase). We initially sought to select sites that would ensure the greatest diversity of
28 projects. However, some sites did not produce data, or did not produce data in a form suitable for
29 analysis, and could not be included. Table 1 illustrated the four sites in each phase that had their raw
30 data subject to independent SPC analysis.

31 *Data analysis and synthesis*

32 Analysis of the qualitative data was based on the constant comparative method, inductively
33 generating thematic categories, and using the literature on measurement and quality improvement
34 as sensitising concepts.¹⁵ We first analysed data site-by-site to ensure that it was understood in
35 terms of relevant context. Then, for each site, we integrated qualitative data and findings from the
36 expert review to produce a comprehensive and in-depth picture of sites' experiences of
37 measurement. Finally, we conducted cross-site analysis in order to develop higher-level concepts
38 and broader learning on measurement.

1 RESULTS

2 Across the two phases of the study (main and extension), the qualitative evaluation study involved
3 862 hours of observation and 143 interviews (Table 2) covering all aspects of the programme (not
4 just measurement). The participating site teams specified, between them, a total of 67 measures
5 that they planned to use to monitor their processes before and after introduction of their risk-
6 control interventions. The data for 49 of these measures – which were sourced from four of the
7 eight sites participating in the main phase, and from four of the six sites participating in the
8 extension phase – were independently analysed by the evaluation team (Table 2).

9 Table 2

10 The clinical teams participating in the programme typically comprised a clinical lead (often a senior
11 physician), a project manager, others from a clinical or managerial background, and an executive
12 sponsor (a senior individual who reported to the board but was not involved in day-to-day running
13 of the project). The participating sites varied in the extent to which they enjoyed active support from
14 executive or non-executive board members, and from other clinicians; the interaction of the work
15 with infrastructure such as large IT system projects; a pre-existing audit culture and organisational
16 capability for managing complex data; and the resources available to the teams, including release of
17 staff to undertake project work. In the account below, we offer an analysis of measurement-specific
18 issues, and specifically on teams' ability to: 1) manage the tasks associated with developing
19 measurement plans; 2) establish and use reliable data collection systems; and 3) analyse and report
20 data in appropriate ways. Our analysis is focused on drawing out generalisable learning across the
21 programme, and does not seek to compare/contrast sites.

22 **Developing a detailed measurement plan**

23 The measurement plans that the teams were asked to develop were intended to identify and define
24 suitable measures in advance of any improvement interventions being implemented, and to specify
25 a sampling and analytical strategy. In the main phase (in which participating teams received
26 dedicated measurement support and guidance) all teams produced a measurement plan document;
27 in the extension phase, two out of the six teams did so. When no measurement plan was available,
28 the evaluation team assessed any written material provided by the teams that included elements of
29 measurement planning. Our review of the measurement plans (or related documents) indicated that
30 most demonstrated great enthusiasm but also multiple problems – here, we describe six.

31 The first problem was the over-ambitious nature of the plans. Several teams initially identified very
32 many measures (up to 15 in some cases) that were highly diverse in character. Given the formative
33 nature of the evaluation, these sites were asked to reduce the number of measures in their final
34 measurement plans to five or six, and to concentrate their efforts on those (Table 1 reports the final
35 number of measures used by each team after feedback).

36 Second, many plans did not demonstrate the level of specification or understanding of the
37 underlying methodological principles necessary to gather good quality data, consistent with varying
38 confidence about measurement expressed in interviews.

1 *I am very confident actually, very confident our data is accurate, given the sort of work we*
2 *did around some of the reliability and the training. (Interview, main phase of the programme)*

3 *The measures are the bit that we're struggling with the most at the moment, using the*
4 *BaseLine software I'm not finding easy at all, I'm struggling with it.... I don't feel that I've had*
5 *enough training in it. (Interview, main phase of the programme)*

6 Every measurement plan contained examples of operation definitions of measures that were
7 imprecise, lacked important details, or were difficult to understand by those outside the project
8 team. For example, some sites used compliance with a care bundle (e.g. medication reconciliation or
9 review) as a measure, but did not always specify the operational definition of the individual
10 components of the bundle. One team used a measure labelled as “Number of patients [...] who have
11 their medicines 100% correct at 24 hours” without specifying how staff should ascertain that
12 medicines were correct. Similarly, terms such as “delay”, “error”, “time zero”, and “baseline” were
13 not fully defined, leaving room for different interpretations between observers and over time. When
14 sites reported that some data were “not applicable” to certain measures, they did not always give a
15 reason for this.

16 *Different names are used to refer to the same measures in this document when compared*
17 *with the others, and also in different parts of the same document. For example, the following*
18 *two measure names seem to be used interchangeably: “% of patients on EAU [emergency*
19 *assessment unit] who have all their medicines correct at 24 hours” and “Accuracy of*
20 *prescription at 24h on EAU”. (Evaluation team’s review of the measurement plan, extension*
21 *phase)*

22 The third problem was that some measures selected by the teams were insufficiently sensitive to
23 capture the spectrum of improvements sought by the sites. For example, one site’s definition of
24 compliance with its medication reconciliation bundle stated that all ten elements of care in the
25 bundle should be in place. Even if nine elements of the bundle were in place and one was not, the
26 patient’s care was deemed non-compliant. Bundles should usually include fewer elements (three to
27 five),^{16 17} suggesting perhaps suboptimal design of the bundle, but also indicating that full
28 compliance was unrealistic and that use of this measure might fail to detect potential
29 improvements.

30 Fourth, specification of sampling procedures was typically weak, and it was often unclear what
31 procedure was to be used for random selection. Inclusion and exclusion criteria necessary for
32 determining who or what should be counted were often unclear. For instance, one site in the
33 extension phase reported in their measurement plan that “each week a random sample of 5 patient
34 case notes should be selected for admission, transfer and discharge”, without specifying how such
35 random sampling should be done. If, for example, staff selected patients randomly from physical
36 stacks of notes, bias might be introduced if some patients’ notes were unavailable.

37 The fifth problem was that some selected measures were not logically linked to the improvement
38 actions they implemented. For example, one site opted to measure the average proportion of
39 patients going to the operating theatre with a completed perioperative care plan, but then struggled
40 to implement an intervention that would increase completion of the plans. In this site, due to
41 uncertainty about the renewal of the hospital IT contract, it was difficult to make available

1 documents relevant to surgery on the trust's IT system at the operation stage, and this improvement
2 action was therefore abandoned. Thus, although the site recorded an improvement between the
3 two measurement periods (from 65% to 78% of patients with a complete plan), it was difficult to
4 attribute the site's improvement to its Safer Clinical Systems project.

5 Sixth, in general the measurement plans produced by the teams did not look sufficiently far ahead.
6 For example, the plans did not contain the specifics of how the data would be analysed, thus
7 impacting on important considerations such as the appropriate length of the baseline and how much
8 data over what period would be needed to establish whether an improvement had been made.
9 Most plans did not touch on who was responsible for taking action for improvement based on the
10 findings of the analysis, or on embedding measurement in routine care.

11 **Collecting data**

12 Interviews and observations showed that teams generally struggled to set up and run data collection
13 systems, and that running the systems consumed a huge amount of time and resource at several
14 sites. Some challenges were related to teams' decisions to use entirely new measures for the first
15 time (including "home-grown" measures). Some teams started by using lengthy, unwieldy manual
16 data collection forms that were sometimes amended or abandoned after a short time. In other
17 cases, teams used routinely collected data, but these data were often not as clean or well set up as
18 originally anticipated, and often required extensive effort to bring them up to a standard suitable for
19 use.

20 *It's been a nightmare actually... We've been looking...at readmissions, and in retrospect I*
21 *don't think the organisation had a consistent metric for readmissions, in terms of what it*
22 *meant and how they were collecting it. A lot of people that were being classified as*
23 *readmissions weren't being readmitted, a lot of people were double-counted or triple-*
24 *counted or worse, and of course then we had really untidy data... (Interview, main phase)*

25 *I had to write a database with the coders, had to pay...the data people to give us the feed of*
26 *the patients going to [operating rooms]. [This] took a huge amount of time and it meant that*
27 *until February I was manually having to get that data from systems which was an absolute*
28 *nightmare. But it's better now. (Interview, main phase)*

29 Data collection often depended on voluntary, unpaid or extra activity that was unsustainable.

30 *It certainly has been extra work for all of us, for example observing the handover is not*
31 *something that would normally be part of my day-to-day job. But obviously it has been a time*
32 *investment. We have used the Health Foundation money to pay for part of it, but there*
33 *certainly has been extra goodwill from people who collected the data. (Interview, main*
34 *phase)*

35 Data collection systems were not always run exactly as designed, sometimes resulting in missing
36 data. One team struggled to get reliable data collection at weekends. In one site, a special form that
37 was supposed to be used for data collection was not consistently used, with data instead collected in
38 a notebook or on odd pieces of paper in non-standard formats. In another example, attempts to
39 collect data from doctors at the end of night shifts was met with difficulty, as the physicians were
40 tired and wanted to finish their clinical tasks before going off duty.

1 A further challenge was that teams did not reliably collect baseline data before they introduced
2 interventions aimed at improvement. In part, this was because once the participating sites became
3 aware of the many (and, in some cases, severe) hazards threatening patient safety in their clinical
4 systems through use of the Safer Clinical Systems diagnostic tools, they were understandably eager
5 to address these hazards quickly. Accordingly, some sites proceeded to implement improvement
6 actions before measurement had started. The consequent absence of a baseline period, while well-
7 justified in terms of addressing risk, meant that it was difficult to demonstrate that any
8 improvement was attributable to the programme or indeed that the risk was now well-controlled.

9 **Analysing and interpreting data**

10 The teams' ability to conduct SPC analysis to present and interpret their data was highly variable.
11 Some sites succeeded in analysing data on their key process measures regularly and producing high
12 quality reports. For example, one site recorded changes in clerked weekday in-hours and out-of-
13 hours admissions or senior reviews within four hours of admission; another site analysed the
14 percentage of patients who had the correct medications at 24 hours after admission. These analyses
15 were undertaken to a high level of competence and accuracy. Other sites, however, struggled with
16 undertaking appropriate analysis of their data.

17 One reason for these differences lay in the variable mix of skills and experience in participating
18 teams. One team included an academic advisor who had expertise in measurement and experience
19 working with the hospital's Quality Improvement Directorate. Other sites lacked such a skillset:

20 *It would have been great to have someone with data analysis skills, or someone from our*
21 *informatics team who was dedicated to [our project]. We've used up a lot of our teams' time*
22 *learning where different bits are kept. (Interview, main phase)*

23 In some cases, appropriate analysis was not possible because of basic weaknesses in the measures
24 or data recording, for example, when the definitions used were so poorly specified that it was not
25 clear exactly what was being measured. For instance, in measuring the time from admission to the
26 diagnostic test being done, one team recorded the time but not the date of the test. It was therefore
27 impossible to distinguish whether the test had taken, for example, four or 28 hours.

28 Analysis was also severely hindered by missing data. For example, in one site, missing data for one
29 week meant that it was not possible to complete SPC analysis of one of their key measures. This
30 site's measurement planning did not include any strategies for minimising or mitigating missing data,
31 a common theme across the sites. In another site, data collection was frustrated by the small
32 number of patients meeting the eligibility criteria, complicating any attempts to make valid
33 inferences or draw conclusions about the impact of the intervention. Since very few measurement
34 plans included an advance plan for the type of analysis, many sites failed to exploit some available
35 support tools that would have proved highly beneficial. For example, when using a p-chart,¹⁸ tables
36 could be used to identify an appropriate frequency of data collection and a subgrouping strategy (i.e.
37 weekly percentages versus monthly or other period) to make sure that the chart is sensitive enough
38 to be useful.¹⁹

39 Analysis and interpretation were sometimes flawed: we saw evidence of sites assuming that their
40 data provided evidence of improvement, but such interpretations were not always backed up by

1 sound statistical analysis. One site reported improvement on a measure from around 75% to just
2 under 90%, but no statistical analysis was presented to back up this claim. Visual inspection of a time
3 series chart seemed to show a potentially unstable process; it was therefore impossible to draw
4 accurate conclusions from such statements. Another site presented data for two measures that
5 showed possible evidence of improvement, but without statistical process control analysis it was not
6 possible to conclude whether this was true improvement in the process.

7 **DISCUSSION**

8 Our study suggests that improvement programmes that emphasise local ownership and local
9 selection of measures, such as Safer Clinical Systems, may not escape the pervasive challenges of
10 high quality measurement. Teams may struggle to produce a high quality measurement plan, to
11 provide clear definitions of their measures and data, or to complete data collection and analysis
12 reliably. Participating teams often selected unreliable or inappropriate measures, some of them
13 “home-grown”, indicating that an emphasis on local ownership of measures is not always
14 compatible with the need to use the kind of validated measures that are most suited to producing
15 sound, credible evidence. The range of skills required to collect and analyse data was not generally
16 sufficient in most teams, despite some training being provided by the programme. These challenges
17 were pervasive across sites irrespective of the specific data, measures, and analytical approach
18 adopted – to the point that they may indicate a systemic problem.⁷

19 We did not aim to explain differences across sites, nor to identify the contextual factors promoting
20 or inhibiting effective measurement in each setting, but our analysis does allow insight into
21 widespread challenges that may hamper teams’ measurement efforts. The effective execution of
22 measurement across the lifespan of a quality improvement initiative requires expertise in a range of
23 technical activities: selecting measures, high fidelity data collection, statistical analysis, and
24 interpretation of results. The consequences of decisions made in the early stages of designing
25 measures may not become apparent until the middle or end of an improvement initiative, by which
26 time it may be too late to secure high quality data. Experience of working on several improvement
27 initiatives provides valuable insights into the constraints of data access and collection in healthcare
28 systems, and enables more realistic planning for future initiatives. This study highlights the tendency
29 for teams without such knowledge and experience to underestimate the challenges they may face in
30 enacting their measurement plans, and the resulting mismatch in skills and time dedicated to
31 measurement activities. All of this indicates the need for clinical teams to access dedicated capability
32 and capacity for measurement. The optimal approach to building or sourcing this capability and
33 capacity across local and national health systems is not clear, and it seems likely this will take
34 considerable time to achieve.²⁰ Our study does suggest that it is not realistic to assume that brief
35 training interventions and manuals will be enough to bring most clinical teams fully up to speed.

36 As well as measurement-specific issues, broader characteristics of the organisational setting, well
37 established in the literature as influencers of success in improvement, played a role in enabling or
38 hindering the teams’ ability to measure effectively.²¹⁻²³ This complexity means that narrow
39 interventions are unlikely to be sufficient to improve the quality of measurement in quality
40 improvement. Some relatively simple forms of support might, however, be helpful. Existing
41 repositories of validated measures, such as the US-based AHRQ Measures Clearing House, are
42 important resources that may not be having their desired impact; teams in this study did not

1 reference such repositories in their plans. This may be due to a lack of awareness that such
2 repositories exist, limitations in the coverage and relevance of repositories for specific improvement
3 initiatives, and deficits in technical skills and knowledge needed to use centrally constructed
4 measure definitions. Further research is needed to understand these issues, and to support
5 healthcare professionals to capitalise on existing resources.

6 Improving access, and ability to use, repositories of validated measures could go some way to
7 addressing some of the challenges we identify. Increasing transparency in reporting (e.g. publishing
8 failed measurement attempts and inappropriate endpoints) might serve the same purpose while
9 enhancing the evidence base for measurement. Yet, such actions are likely to have limited impact
10 without a broader programme of measurement capability-building at a system level. The definitions
11 of measures will always need to be interpreted and implemented in local systems to account for
12 variation in processes across settings.¹⁰ Increased capability in measurement is necessary for staff at
13 all levels to understand and act in response to measures.

14 Our study of measurement does have limitations. Although we used established techniques (e.g.
15 integrating multiple sources of data and collecting data at multiple points in time) to improve the
16 rigour and generalisability of our analysis, our study is limited the fact that we have examined a
17 specific improvement programme, which took place in hospitals only and was focused on the
18 identification of risks in clinical systems.

19 The potential benefits of robust measurement in improvement initiatives are clear. Yet it is not clear
20 how best to realise those benefits in practice. Countering the problems of measurement that hinder
21 quality improvement projects is vital, not least because they undermine the credibility of the
22 enterprise and diminish the prospect that clinicians will take the results seriously in future
23 improvement efforts. Unfortunately, using a local ownership approach does not seem to provide an
24 escape from these problems. We conclude that, in driving improvement, the data (and the data
25 source) need to be seen as credible by potential participants, while at the same time not too irksome
26 or burdensome to collect,⁸ but how to achieve an optimal balance between expert input and local
27 ownership requires further examination. Future research should focus on understanding how
28 measurement can be planned, executed, and drawn on to best support improvement in quality of
29 care for patients. Different models for measurement, aiming to address the challenges highlighted in
30 this study, should be evaluated. Such models could include those that involve more extensive
31 training of NHS personnel, loaning of information analysts to improvement teams, resources to
32 support better planning and execution of measurement, and provision of consultancy expertise.

33

1 **Box 1: Measurement in the Safer Clinical Systems approach**

Measurement is a key element of the Safer Clinical Systems approach, which emphasises local ownership and local selection of measures for the monitoring of improvement. The approach does not recommend or impose any external measures, though it does recommend that Statistical Process Control (SPC) be used as a means of monitoring and analysis of data.

SPC is an approach to understanding and acting on variation observed in measured properties of a system. In this approach, data is used to gain insight into how a healthcare system or process is performing, and how this performance is changing over time. These insights inform actions on the system, targeted at causes of poor performance. Continuing analysis is used to understand whether these actions have led to improvement.

Control charts are the main analytical tool used in SPC. A control chart shows a time series of how the measure varies over time. The centre line represents typical performance of the process or outcome that the team is seeking to improve. Control limits (dotted lines parallel to the centre line) show the degree of variation that is to be expected assuming that the process or outcome being measured has not changed. SPC provides sets of rules that are used to assess a time series for the presence of special cause variation – evidence that performance has changed.

1 Table 1: Sites involved in each phase of the programme and in independent SPC analysis by the evaluation teams

	Aim of the project		Data subject to independent SPC analysis by XX		Key challenges and achievements in measurement	
	Main phase	Extension phase	Main phase	Extension phase	Main phase	Extension phase
Loganberry	Improve the medication management pathway for patients with Parkinson's disease between primary and secondary care.	Improve the recognition and treatment of venous thromboembolism in patients admitted for surgery.	No (data was not suitable for SPC analysis)	Yes, data from 6 measures	<ul style="list-style-type: none"> Six measures reported in safety set (no data was available on one of these) SPC analysis does not appear to have been used; simple before and after comparisons are reported. The small numbers of patients meeting inclusion criteria made it difficult to analyse for change over time for all measures. 	<ul style="list-style-type: none"> Six measures reported in safety set. The team were able to collect data against measures, but no explicit baseline period was stated. Operational definitions were ambiguous (e.g. no meaning ascribed to "Not Applicable" for some variables). Sampling procedure was described as random but it was not clear from what population this was taken nor how this was done.
Elderberry	Improve prescribing accuracy for patients with an acute medical illness by developing a prescribing pathway between the emergency department and the emergency admissions unit.	Improve the accuracy of prescriptions in the emergency admission unit (follow up).	No (not included in sample for independent analysis)	Yes, data from 7 measures	<ul style="list-style-type: none"> Of the five measures in the original safety set, only two were reported on at the end of the project. Although this site was not included in the sample for independent SPC analysis, the measurement report produced by the team indicates that SPC analysis, presentation, and interpretation for two measures was conducted appropriately. 	<ul style="list-style-type: none"> Seven measures reported in safety set. No formal measurement plan was developed, but elements of measurement planning appeared in other project documents. Unclear how denominator was established for three of these measures. Sampling procedures were unclear. Despite this, overall data quality was high with little missing or invalid data. The team's measurement ability seemed to improve over the course of the project.
Beechtree	Improve the handover across primary, secondary, and tertiary care for children with complex illnesses.	Improve the recognition of, and timely response to, sepsis or potential sepsis in patients admitted to the emergency department.	No (not included in sample for independent analysis)	Yes, data from 4 measures	<ul style="list-style-type: none"> Seven measures reported in safety set. No data was available on two of these measures. Many missing data on two measures, and data on two further measures was difficult to interpret due to poor quality presentation. 	<ul style="list-style-type: none"> Four measures reported in safety set. No formal measurement plan was developed. Operational definitions were initially unclear but were clarified later in the project. Data quality was poor in places leading to difficulties in interpretation.
Cedartree	Improve safety and effectiveness of the transfer of care between daytime and out-of-hours clinical teams.	Refine the Safety Case approach, explore its scalability and its potential application to a complex pathway (i.e. surgery).	Yes, data from 5 measures	No (no data were collected)	<ul style="list-style-type: none"> Five measures reported in safety set. The large amount of data collected by this team placed considerable strain on resources. The team lacked experience to access and use the relevant data and IT systems, and initially struggled balancing desired data collection against available staff time, leading to some missing data. Operational definitions of some measures were unclear. Only one month of baseline data was available, making it hard to evaluate improvement. 	The project stalled after the diagnostic phase. No risk controls were implemented and no measurement plan was in place.

Rowanberry	Reduce the number of medication prescribing errors that reached the patient in the acute medical unit.	Improve the reliability and accuracy of medicines reviews and reconciliation on admission and discharge.	Yes, data for 4 measures	Yes, data from 3 measures and 10 sub-measures	<ul style="list-style-type: none"> Four measures reported in safety set. The measurement plan evolved over time, as the team realised that they were trying to measure too much and not were not measuring the right things. Team were able to collect data successfully for their revised measures. 	<ul style="list-style-type: none"> Three main measures and ten sub-measures reported in the safety set. Initially the team planned to record only pre-aggregated total figures, rather than patient-level data. Following formative feedback, this approach was modified to enable patient-level data to be recorded. The team then successfully established a measurement system providing data on their safety set measures on a regular basis.
Ashtree	Improve the quality and safety of shared care of renal patients receiving surgical intervention.	<i>Did not take part in this phase</i>	Yes, data from 6 measures	/	<ul style="list-style-type: none"> Six measures reported in safety set. Some operational definitions were ambiguous. Due to missing data resulting in small denominators, some measures suffered from low sensitivity. Baseline periods not clearly stated. The team were able to conduct control chart analysis appropriately for some measures. 	/
Hollyberry	Reduce medications prescription errors and increase the safety of the prescribing pathway for patients admitted to the acute medicine admissions unit from primary care or the emergency department.	<i>Did not take part in this phase</i>	Yes, data from 4 measures	/	<ul style="list-style-type: none"> Four measures reported in safety set. Some ambiguity in the operational definitions used by the team (e.g. it was not clear what was meant by a "complete" or "satisfactory" drug chart). Missing data led to a lack of sensitivity in some measures. However, the team were able to collect a large amount of data to ascertain the outcomes of their improvement projects. 	/
Oaktree	Reduce the number of unplanned readmissions to hospital among patients aged 75 years or older.	<i>Did not take part in this phase</i>	No (data not suitable for SPC analysis)	/	<ul style="list-style-type: none"> Three measures reported in safety set. During the early part of the project, the team discovered that the way readmission rates were being calculated at their organisation had a flaw, and had to undertake a data cleaning exercise to resolve this. The methodology used to detect change was never clearly described. 	
Blueberry	<i>Did not take part in this phase</i>	Improve the medication management process (with particular focus on sepsis six care-bundle) and explore the possibility to use the Safety Case approach for assurance purposes.	/	No data were collected.	/	The project stalled after the diagnostic phase. No risk controls were implemented and no measurement plan was in place.

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Table 2: Data collected in the evaluation of each phase of the programme

	Qualitative data	Quantitative data
Main phase	668 hours of observations 94 recorded interviews	Measurement plans for 8 sites Data from 37 measures were available for independent SPC analysis, 19 of which were included (data from 18 measures were not amenable to independent analysis)
Extension phase	194 hours of observations 49 recorded interviews	Measurement plans for 6 sites Data from 30 measures were included in independent SPC analysis
Total	862 hours of observations 143 recorded interviews	Data from 67 measures , 49 of which were included in independent SPC analysis

REFERENCES

1. May C. A rational model for assessing and evaluating complex interventions in health care. *BMC Health Services Research* 2006;6
2. Chassin MR, Loeb JM, Schmaltz SP, et al. Accountability measures--using measurement to promote quality improvement. *N Engl J Med* 2010;363(7):683-8. doi: 10.1056/NEJMSb1002320 [published Online First: 2010/06/25]
3. Needham DM, Sinopoli DJ, Dinglas VD, et al. Improving data quality control in quality improvement projects. *International journal for quality in health care : journal of the International Society for Quality in Health Care* 2009;21(2):145-50. doi: 10.1093/intqhc/mzp005 [doi]
4. Lindenauer PK. Effects of quality improvement collaboratives. *BMJ: British Medical Journal* 2008;336(7659):1448.
5. Pronovost PJ, Berenholtz SM, Goeschel CA. Improving the quality of measurement and evaluation in quality improvement efforts. *American Journal of Medical Quality : The Official Journal of the American College of Medical Quality* 2008;23(2):143-46. doi: 10.1177/1062860607313146 [doi]
6. Terris DD, Litaker DG. Data Quality Bias: An Underrecognized Source of Misclassification in Pay-for-Performance Reporting? *Quality Management in Healthcare* 2008;17(1):19-26.
7. Dixon-Woods M, Martin G, Tarrant C, et al. Safer Clinical Systems: evaluation findings. Learning from the independent evaluation of the second phase of the Safer Clinical Systems programme. London: The Health Foundation, 2014.
8. Mountford J, Shojania KG. Refocusing quality measurement to best support quality improvement: local ownership of quality measurement by clinicians. *BMJ quality & safety* 2012;21(6):519-23.
9. Benn J, Burnett S, Parand A, et al. Studying large-scale programmes to improve patient safety in whole care systems: challenges for research. *Social science & medicine* 2009;69(12):1767-76.
10. Dixon-Woods M, Leslie M, Bion J, et al. What Counts? An ethnographic study of infection data reported to a patient safety program. *Milbank Quarterly* 2012
11. Dixon-Woods M, Martin GP. Does quality improvement improve quality? *Future Hospital Journal* 2016;3(3):191-94.
12. Meyer GS, Nelson EC, Pryor DB, et al. More quality measures versus measuring what matters: a call for balance and parsimony. *BMJ quality & safety* 2012;21(11):964-68. doi: 10.1136/bmjqs-2012-001081; 10.1136/bmjqs-2012-001081
13. Warwick Medical S, The Health F. Safer Clinical Systems site team reference manual. Warwick/London: unpublished, 2013.

- 1 14. Berenholtz SM, Needham DM, Lubomski LH, et al. Improving the Quality of Quality Improvement
2 Projects. *The Joint Commission Journal on Quality and Patient Safety* 2010;36(10):468-73.
3 doi: [https://doi.org/10.1016/S1553-7250\(10\)36069-7](https://doi.org/10.1016/S1553-7250(10)36069-7)
- 4 15. Charmaz K. Constructing grounded theory: A practical guide through qualitative analysis. London:
5 Sage 2006.
- 6 16. Goderis G, Borgermans L, Mathieu C, et al. Barriers and facilitators to evidence based care of
7 type 2 diabetes patients: Experiences of general practitioners participating to a quality
8 improvement program. *Implementation Science* 2009;4(1)
- 9 17. Resar R, Griffin F, Haraden C, et al. Using care bundles to improve health care quality. *IHI*
10 *Innovation Series white paper Cambridge, Massachusetts: Institute for Healthcare*
11 *Improvement* 2012
- 12 18. Mohammed MA, Worthington P, Woodall WH. Plotting basic control charts: tutorial notes for
13 healthcare practitioners. *Quality & Safety in Health Care* 2008;17:137-45. doi:
14 10.1136/qshc.2004.012047
- 15 19. Perla RJ, Provost LP, Murray SK. Sampling considerations for health care improvement. *Quality*
16 *Management in Healthcare* 2014;23(4):268-79.
- 17 20. Bardsley M. Understanding analytical capability in health care. *Do we have more data than*
18 *insight London: The Health Foundation* 2016
- 19 21. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research
20 findings into practice: a consolidated framework for advancing implementation science.
21 *Implementation science : IS* 2009;4:50. doi: 10.1186/1748-5908-4-50
- 22 22. Dixon-Woods M, Leslie M, Tarrant C, et al. Explaining Matching Michigan: an ethnographic study
23 of a patient safety program. *Implementation science* 2013;8(1):70.
- 24 23. Reed JE, Howe C, Doyle C, et al. Simple rules for evidence translation in complex systems: A
25 qualitative study. *BMC Medicine* 2018;16(1):92. doi: 10.1186/s12916-018-1076-9

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