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How, in what contexts, and why do quality dashboards lead to improvements in care quality? Protocol for a realist feasibility evaluation

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3 1 **Title: How, in what contexts, and why do quality dashboards lead to improvements in care**
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5 2 **quality? Protocol for a realist feasibility evaluation**
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ARTICLE SUMMARY

Strengths and limitations of this study

- This study combines a controlled interrupted time series study with a qualitative multi-site case study in order to provide an understanding of not only whether use of a quality dashboard leads to quality improvement but also how, in what contexts, and why.
- In addition to assessing the feasibility of a trial, the study will determine the components of QualDash to be preserved in a definitive trial, appropriate outcome measures, and the contexts in which a definitive trial should be undertaken.
- The study will contribute to understanding of how realist methods can contribute to feasibility studies and the design of trials.

INTRODUCTION

National clinical audits (NCAs), which provide comparative data on the performance of healthcare providers, are one means by which health systems around the world monitor care quality and safety. In England, a programme of over 60 NCAs is managed by the Healthcare Quality Improvement Partnership (HQIP) and all healthcare providers that contribute to delivery of the National Health Service (NHS) are required to participate. Such audits are anticipated to reduce unexplained variations in healthcare quality by stimulating quality improvement (QI) [1 2]. While there is evidence of positive impacts of NCAs [3-5], variation within and between providers in the extent to which they engage with NCAs mean that the potential for NCA data to inform QI is not being realised [6 7].

Quality dashboards are a form of audit and feedback (A&F) that provide visualisations of audit data with the aim of informing QI efforts [8]. Healthcare providers are increasingly using quality dashboards. For example, use of quality dashboards has been reported in Canada [9], the UK [10], and the Netherlands [11]. While quality dashboards have been shown to have positive effects on some performance indicators [9], empirical evidence regarding their impact remains limited [12].

1 QualDash

2 QualDash is an interactive web-based quality dashboard designed to support clinical teams and
3 managers to explore data from two national audits, the Myocardial Ischaemia National Audit Project
4 (MINAP) and the Paediatric Intensive Care Audit Network (PICANet), for the purpose of QI (Fig. 1).
5 Information used to inform the design of QualDash was collected using a combination of methods,
6 including: interviews, with 50 clinicians and managers across five NHS Trusts (providers) and four
7 healthcare commissioners, that explored what supports and constrains their use of NCA data for QI;
8 observations of meetings at different levels of the Trusts where audit data are discussed; a workshop
9 with suppliers of NCAs; and two co-design workshops with clinicians and managers from one Trust.

11 Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using
12 simulated data).

13 [Figure 1 should go approximately here]

15 The interviews revealed that use of NCA data is largely at the clinical team level, with more limited use
16 of NCA data at divisional and corporate (Board and sub-committees that report to the Board, such as
17 Quality and Safety Committees) levels. At all levels, a key constraint in use of NCA data for QI is lack
18 of access to timely data. QualDash seeks to overcome this constraint, providing users with a means to
19 visualise their own data which they upload to the NCAs, rather than having to wait for data to be returned
20 from the NCAs. There is also variation between Trusts in the extent to which NCA data are currently
21 used, often related to resources; Trusts that make greater use of NCA data tend to have local databases
22 from which they can generate visualisations of the data (e.g. bar charts) and audit support staff who
23 have the time and skills to be able to generate such visualisations. Therefore, QualDash provides
24 visualisations of key metrics, each metric being represented within a 'QualCard' (Fig. 2), enabling Trusts
25 to use NCA data for QI, regardless of existing resources. Sites are also able to create additional
26 QualCards, to reflect local priorities. However, the benefits perceived from using QualDash may vary
27 between sites, with under-resourced sites that previously made little use of NCA data for QI perceiving
28 greater impact than those sites that already have the means to use NCA data for this purpose. There
29 are also constraints on use of NCA data for QI that it may be difficult for QualDash to address. For
30 example, in some Trusts, clinical team members perceive that the relevant managers will not agree to

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2
3 1 provide the resources necessary for QI initiatives, which reduces motivation to engage with NCA data
4
5 2 and may affect the extent to which QualDash is used. However, QualDash provides means for
6
7 3 visualisations to be downloaded and incorporated into presentations and reports, which may support
8
9 4 clinical teams in making a stronger case for QI initiatives.

10
11 5
12
13 6 Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the
14
15 7 Mortality QualCard expanded (using simulated data).

16
17 8 [Figure 2 should go approximately here]
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20
21 10 In this paper, we describe the methods for a realist feasibility evaluation of QualDash, informed by our
22
23 11 understanding of how, in what contexts, and why NCA data are used and our expectations of how, in
24
25 12 what contexts, and why QualDash will be used. The objectives of the study are:

- 26
27 13 1. To understand how, in what contexts, and why use of QualDash leads to QI; and
28
29 14 2. To assess the feasibility of conducting a randomised controlled trial (RCT) of QualDash.

30
31 15 As no checklists exist for the reporting of realist evaluation protocols, in presenting this protocol we
32
33 16 draw on the RAMESES II reporting standards for realist evaluations [13] (Additional file 1).
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38 19 **METHODS AND ANALYSIS**

39 20 **Study design**

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41 21 Use of theory is needed for design and evaluation of A&F interventions [14-16], and QI initiatives more
42
43 22 generally [17-19]. This project draws on Realist Evaluation (RE), which involves building, testing, and
44
45 23 refining the underlying assumptions or theories of how an intervention is supposed to work [20]. These
46
47 24 theories are expressed in the form of Context Mechanism Outcome (CMO) configurations, where
48
49 25 $C+M=O$, reflecting the realist understanding that it is recipients' reasoning about and responses to the
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51 26 resources that the intervention provides (the intervention mechanisms) that determine the impact of the
52
53 27 intervention, and such responses are highly influenced by context [21]. Consequently, RE seeks to
54
55 28 answer not only the question of 'what works?' but 'what works for whom, in what circumstances, and
56
57 29 why?' [22]. It is concerned with both intended and unintended outcomes. RE is recommended for
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3 1 studying QI [23] and has been used successfully for studying the implementation and impact of large-
4
5 2 scale QI programmes [24].
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9 4 There is increasing interest in use of realist methods in feasibility evaluations [25-27]. By understanding
10
11 5 the relationship between contexts, mechanisms, and outcomes, we aim to identify those components
12
13 6 of QualDash associated with mechanisms that produce the desired outcomes in order for them to be
14
15 7 preserved in a definitive trial, whereas other components may be adapted to suit the local context. By
16
17 8 understanding both intended and unintended consequences, appropriate outcome measures can also
18
19 9 be determined. Additionally, findings regarding contexts can be used to inform the decision about
20
21 10 contexts in which the definitive trial should be undertaken, in terms of level of the organisation (clinical
22
23 11 team, division, and/or corporate) and clinical area. This understanding will consequently inform which
24
25 12 NCAs will be included in the trial.
26
27 13

28 14 We have drawn on a range of sources to develop CMO configurations which describe how, in what
29
30 15 contexts, and why use of QualDash is anticipated to lead to QI (see Additional file 2). Data generated
31
32 16 from the interviews, observations, and workshops described above have been essential to this, as have
33
34 17 discussions with the designers of QualDash (ME and RAR) who, drawing on their expertise in
35
36 18 information visualisation, have their own literature-informed theories regarding why certain features of
37
38 19 QualDash will provide benefit to users [28 29]. We have also drawn on substantive theories regarding
39
40 20 how A&F lead to QI at the individual micro level (Contextual Feedback Intervention Theory [30] and the
41
42 21 model of actionable feedback [31]), the organisational meso level (Van Helden and Tilemma's model of
43
44 22 benchmarking [32]), and the macro level (institutional theory [33 34]). The CMO configurations focus
45
46 23 on use of QualDash by clinical teams, as this is where NCA data are most actively used, but also
47
48 24 suggest how outputs produced via QualDash may become integrated in division and corporate quality
49
50 25 monitoring processes.
51
52 26

53 27 Data collection is designed to enable testing of the CMO configurations. Outcome data, in the form of
54
55 28 key MINAP and PICANet measures, will be collected and analysed in a controlled interrupted time series
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57 29 (CITS) study, while a multi-site case study [35] will provide insight into the contexts and mechanisms that
58
59 30 lead to those outcomes, as well as providing data on intermediate outcomes such as increased use of
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3 1 NCA data. A&F interventions, and QI interventions more generally, require longitudinal evaluation to
4
5 2 allow sufficient time for staff to implement changes and incorporate them into their practice [36-38].
6
7 3 Similarly, evaluation of health IT (HIT) should allow time for staff to integrate the technology into their
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9 4 practices and evolve those practices to take advantage of the functionality offered by the technology [39].
10
11 5 Therefore, data will be collected over a 12 month period, from August 2019.
12
13 6

7 **Public and patient involvement**

16
17 8 A Lay Advisory Group has been established, who have contributed to the design of QualDash by
18
19 9 reviewing the topic guide for the interviews that were conducted, providing their perspective on the
20
21 10 findings of the interview study, and participating in the usability evaluation of QualDash. For the realist
22
23 11 feasibility evaluation, they have provided advice on aspects to pay attention to when undertaking
24
25 12 observations. They will contribute to analysis of a sample of the qualitative data, to provide a patient
26
27 13 perspective. They will advise on dissemination of findings to relevant interest groups and will contribute
28
29 14 to the creation of outputs by reviewing them for comprehensibility.
30
31 15

16 **Setting/context**

33
34 17 QualDash will be evaluated in the five NHS acute Trusts in which the interview study that informed the
35
36 18 design of QualDash was undertaken. Three Trusts are teaching hospitals that participate in both MINAP
37
38 19 and PICANet and have been selected to ensure variation in key outcome measures (MINAP: 30-day
39
40 20 mortality for patients hospitalised with ST-elevation myocardial infarction; PICANet: risk adjusted
41
42 21 standardised mortality ratio). Two Trusts are District General Hospitals (DGHs) that participate in
43
44 22 MINAP but do not have a PICU and so do not participate in PICANet. These have been selected to
45
46 23 ensure variation in the same key MINAP measure.
47
48 24

25 **Multi-site case study**

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52 26 In the multi-site case study, data will be collected through ethnographic observation and interviews.
53
54 27 Ethnographic methods, such as non-participant observation, have been argued as essential for
55
56 28 studying the implementation of QI interventions [19] and the introduction of HIT [40]. Ethnography is
57
58 29 well suited to RE because it involves observing phenomena in context, supporting understanding of
59
60 30 how context influences the response to an intervention [41]. We will follow the Biography of Artefacts

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2
3 1 approach [42], which is concerned with capturing the way in which particular contexts and
4
5 2 appropriations of a technology lead to different processes and generate different outcomes, a parallel
6
7 3 to RE's concern with contexts, mechanisms, and outcomes [43]. It involves longitudinal 'strategic
8
9 4 ethnography' [42], where data collection is guided by a provisional understanding of the moments and
10
11 5 locales in which a technology and associated practices evolve [43].
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13 6

7 ***Data collection***

16 8 In the three teaching hospitals, we will undertake a minimum of 24 periods of observation per Trust, to
17
18 9 be split across activities related to cardiology and the PICU, and in the two DGHs we will undertake a
19
20 10 minimum of 12 periods of observation per Trust, to be spent observing activities related to cardiology.
21
22 11 Each period of observation will be a minimum of four hours (total n=384 hours). While the researchers
23
24 12 will return to each Trust monthly, to understand how use of QualDash changes over time, more time
25
26 13 will be spent in the first few months following the introduction of QualDash, because this is when users
27
28 14 are most likely to engage with and explore the affordances of QualDash and establish new practices
29
30 15 around it, generating information with implications for system enhancement [43]. Observations will be
31
32 16 scheduled to take place at different times of day and on different days of the week, to ensure that the
33
34 17 account of what is observed is as complete and representative as possible [44].
35
36 18

37 19 At each case site, an initial phase of general observation will provide an opportunity for researchers to
38
39 20 become familiar with the setting and for those in the setting to become familiar with the presence of the
40
41 21 researchers. Following a previous study of dashboards [10], observations will be undertaken in clinical
42
43 22 areas to understand clinical teams' working practices and capture 'corridor committees' where issues
44
45 23 of quality and safety are discussed more informally [45]. In the PICUs, initial observations will take place
46
47 24 on the PICU, for example with the researchers positioning themselves by the nurses' station, as well as
48
49 25 observing handovers, safety huddles, and ward rounds. Because activities related to cardiology tend to
50
51 26 be more dispersed across hospitals, researchers will first shadow clinical team members (consultant
52
53 27 cardiologists and acute chest pain nurses) to determine where it is most appropriate to conduct
54
55 28 subsequent observations. These initial observations will also provide the opportunity to record general
56
57 29 details of the setting that may influence use of QualDash, such as staffing levels and availability of
58
59 30 computers.
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5 2 After this initial phase, observation will be guided by the CMO configurations under investigation. In
6
7 3 addition to observing formal meetings where quality and safety are discussed, predominantly at ward
8
9 4 level but also at divisional and corporate level, observation will involve shadowing staff members as
10
11 5 they undertake particular activities: collection and entry of NCA data, to see if and how this changes
12
13 6 over time; accessing and interrogating NCA data, whether using QualDash or some other means;
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15 7 preparation of reports and/or presentations using NCA data, again whether using QualDash or some
16
17 8 other means. Where visualisations from QualDash are incorporated into presentations and written
18
19 9 reports, we will follow the path of those documents, to identify staff members who may not use
20
21 10 QualDash directly but are receiving QualDash outputs. Attention will be paid to how, in what contexts,
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23 11 and why QualDash and QualDash outputs are used or not, understood in the context of broader
24
25 12 practices and use of other sources of information for monitoring care quality, and how this changes over
26
27 13 time. We will also follow local QI initiatives, recording data on, for example, when and how the need for
28
29 14 the QI initiative was identified, contextual factors that appear to support and constrain its introduction,
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31 15 how the impact of the QI initiative is monitored, and other contextual factors that appear to influence
32
33 16 the metric that the QI initiative is targeting.

34 17
35 18 Researchers will record observations in fieldnotes. The scope of the notes will be kept wide on the basis
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37 19 that what previously seemed insignificant may come to take on new meaning in light of subsequent
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39 20 events [44]. In addition, the researchers will record incidents of observer effects (e.g. participants asking
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41 21 'What are you writing?') to allow analysis of whether participants' awareness of the researchers'
42
43 22 presence changed over time [46]. Fieldnotes will be written up in detail as soon after data collection as
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45 23 possible.

46 24
47 25 Brief interviews will be undertaken opportunistically during the course of conducting observations to
48
49 26 clarify aspects of practice that are not immediately intelligible to an observer, with participant responses
50
51 27 recorded in fieldnotes [47]. As data collection progresses, longer semi-structured interviews will be used
52
53 28 to discuss revisions to our CMO configurations. These interviews will be undertaken using a particular
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55 29 approach from RE, referred to as the teacher-learner cycle, whereby the theories under investigation
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57 30 are made explicit to the interviewee so that the interviewee can use their experiences to refine the
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3 1 researcher's understanding [48]. Additionally, being concerned with the reasoning of intervention
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5 2 recipients, mechanisms are often not observable [21] and so these longer interviews will also provide
6
7 3 the opportunity to explore staff reasoning about QualDash. These longer interviews will be audio
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9 4 recorded and transcribed verbatim.

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11 5
12 6 Logfiles are widely used to evaluate visualisation tools [49] and with QualDash will record information
13
14 7 about a user (job title, etc.), data used (audit, year, variables displayed, etc.), overall time spent using
15
16 8 QualDash, functionality used, and whether the user downloaded the QualDash visualisations. In
17
18 9 addition to providing important data regarding extent of QualDash use, how QualDash is used and by
19
20 10 whom (e.g. whether the most frequent users are nurses, consultants, or audit support staff), and how
21
22 11 this changes over time, information from logfiles will be used to inform qualitative data collection (e.g.
23
24 12 asking in interviews why participants use particular QualCards and not others).

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26 13
27
28 14 At the end of the data collection period, we will ask participants to complete a questionnaire based on
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30 15 the Technology Acceptance Model, using well validated items that have been used in numerous
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32 16 evaluations of HIT [50], including dashboards [51]. This will provide participants' perceptions of the
33
34 17 usefulness of QualDash and data on whether they intend to continue using QualDash after the study
35
36 18 period.

37 38 39 20 **Analysis**

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41 21 An iterative approach to data collection and analysis will be taken, to enable: ongoing testing and
42
43 22 refinement of the CMO configurations; gathering of further data in light of such revisions; and refinement
44
45 23 of QualDash in response to participants' feedback. Fieldnotes and interview transcripts will be entered
46
47 24 into NVivo 11. Narrative analysis will be undertaken to develop a 'biography' of QualDash, which will
48
49 25 describe use of QualDash and its outputs by a range of stakeholders at different levels (clinical team,
50
51 26 divisional, and corporate) and the interconnections between them [10]. Narrative analysis is consistent
52
53 27 with a realist approach due to its emphasis on preserving connections within the data, thereby helping
54
55 28 to understand causality [52]. This analysis will be supplemented with analysis of the logfiles and
56
57 29 questionnaire data. Findings will be compared with the CMO configurations, to determine whether they
58
59 30 support, refute, or suggest a revision or addition to the CMO configurations.

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3 1
45 2 **Controlled interrupted time series study**

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7 3 CITS studies provide a robust method of assessing the effect of an intervention and have been used to
8
9 4 assess the effectiveness of a variety of complex interventions [53]. Data will be collected across the five
10
11 5 Trusts, with two control Trusts per intervention Trust. Control Trusts will be matched according to their
12
13 6 size and outcomes pre-intervention.
14

15 7

16 8 Given the study intention to determine the feasibility of and inform the design of a trial, a range of
17
18 9 measures will be considered. Initially, we selected two process measures, one for MINAP and one for
19
20 10 PICANet. For MINAP, we selected the composite process measure Cumulative Missed Opportunities
21
22 11 for Care (CMOC). This has nine components (pre-hospital ECG, acute use of aspirin, timely perfusion,
23
24 12 referral for cardiac rehabilitation, and prescription at hospital discharge of what are considered to be
25
26 13 the gold standard drugs – aspirin, thienopyridine inhibitor, ACE-inhibitor, HMG-CoA reductase inhibitor,
27
28 14 and beta blockers) and is inversely associated with mortality [54]. As some of these components, such
29
30 15 as pre-hospital ECG, are outside the direct control of the Trust, we will also explore the impact of
31
32 16 QualDash on the individual measures that make up CMOC. On the basis of the measures that
33
34 17 cardiology clinicians described in the interview study as being important for measuring care quality, we
35
36 18 will also look at the percentage of patients who receive an angiogram within 72 hours from first
37
38 19 admission to hospital, which is part of the Best Practice Tariff financial incentive scheme, and, for those
39
40 20 hospitals that provide percutaneous coronary intervention (PCI), the proportion of patients who have a
41
42 21 door-to-balloon time (the time from arrival at the hospital to PCI) of less than 60 minutes. Our CMO
43
44 22 configurations (Additional file 2) suggest that improvement will be seen in measures if: clinical teams
45
46 23 perceive them as being important indicators of care and/or they relate to financial incentives;
47
48 24 performance is not in line with expectations; they perceive the measure as being within their control;
49
50 25 and the team is resourced to introduce QI initiatives in relation to these measures.
51

52 26

53 27 For PICANet, we initially selected use of non-invasive ventilation first for patients requiring ventilation,
54
55 28 which has been shown to be associated with reduced mortality [55]. However, this was not raised as
56
57 29 an area of concern in our interviews with PICU clinicians. On the basis of this and two additional
58
59 30 considerations – it would require loading additional data into QualDash which would reduce the
60

1 performance of QualDash in terms of speed and it requires computation of the data, while the focus of
2 QualDash is on visualising the data – a QualCard has not been created for this metric. Therefore, we
3 do not hypothesise that this measure will change, unless other sources of information, such as the
4 PICANet annual report, draw a PICU team's attention to it. However, accidental extubation was
5 identified in our interviews with PICU clinicians as being an important indicator of care quality; QualDash
6 includes a QualCard for accidental extubation, which displays the number of patients receiving invasive
7 ventilation, and we will include this as a measure. Unplanned readmission within 48 hours was also
8 identified in our interviews as being an important indicator of care quality, so a QualCard for this has
9 been created and we will include this as a measure. On the basis of our CMO configurations (Additional
10 file 2), we would expect to see an improvement in these measures in sites where performance is not in
11 line with expectations, if the team is resourced to introduce QI initiatives in relation to these measures.

12 13 **Sample size considerations**

14 A CITS study requires data for a minimum of three time points pre-intervention and three time points
15 post-intervention and must also allow for any seasonal effect on the outcomes [56]. Monthly data will
16 be obtained for 24 months pre-intervention and 12 months post-intervention. Consequently, for each
17 intervention Trust, there will be 72 data points prior to introduction (24 for the intervention Trust and 48
18 for the control Trusts) and 36 data points post intervention (12 for the intervention Trust and 24 for the
19 control Trusts).

20 21 **Analysis**

22 Monthly MINAP and PICANet data will be extracted to spreadsheets for analysis with R software [57].
23 For both NCAs, each outcome will be regressed upon time and the intervention. The time component
24 will include a seasonal effect (quarterly effect) and will allow for a (linear) time trend. To account for
25 clustering of monthly observations within hospitals a random intercept will be fitted, although a fixed
26 effect for hospital as a sensitivity analysis will be explored. Although the intervention is abrupt, its impact
27 may well be 'phased in' over a few months, perhaps three. The timing of the bedding in of the
28 intervention will be reported from the multi-site case study. Then a partial effect can be considered for
29 this period with the interaction effect stepping up in a linear fashion.

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3 1 The results of the CITS analysis will be incorporated into the biography of QualDash, the analysis of
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5 2 the data from the multi-site case study describing how contextual factors shape the evolution of
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7 3 practices around QualDash and how this leads to the resulting outcome pattern.
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10 5 **Assessment of trial feasibility**

11 6 Criteria for progression to an RCT are: (i) the number of people who engage with either MINAP or
12 7 PICANet data (via QualDash or some other means) is the same or higher than the number of people
13 8 who engaged with either MINAP or PICANet data prior to QualDash's introduction; (ii) data completeness
14 9 in the national audit improves or remains the same; (iii) 50% or more of participants in the questionnaire
15 10 survey perceive QualDash to be useful and express the intention to continue using it after the study
16 11 period. Criteria (i) and (ii) are concerned with ensuring that the intervention does not have unintended
17 12 negative consequences which would affect the success of the intervention. Criterion (ii) is also concerned
18 13 with the feasibility of outcome assessment. Criterion (iii) is concerned with acceptability and uptake of
19 14 the intervention, and therefore has implications for recruitment to a trial, as well as being concerned with
20 15 participants' perceptions of the impact of QualDash on care. While not formally assessed as part of the
21 16 progression criteria, the impact of QualDash on processes of care as identified in the CITS will also be
22 17 considered in determining whether a future cluster randomised controlled trial is justified. A traffic light
23 18 system will be used to determine if a trial is feasible (green), feasible with modifications to QualDash
24 19 (amber), or not feasible (red) [58 59].
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41 21 **ETHICS AND DISSEMINATION**

42 22 Ethics approval has been received from the University of Leeds School of Healthcare Research Ethics
43 23 Committee (Approval no.HREC16-044). Written consent will be obtained from participants for interviews
44 24 and for meeting observations.
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51 26 Study results will provide an initial understanding of how, in what contexts, and why quality dashboards
52 27 may lead to improvements in care quality. We will disseminate these results to academic audiences,
53 28 study participants, hospital IT departments, and National Clinical Audits. If the results show a trial of
54 29 QualDash is feasible, we will design a stepped wedge cluster randomised trial, which will, in addition to
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3 1 providing further understanding of the impact of quality dashboards on care quality, result in wider
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5 2 dissemination of the QualDash software.
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9 4 **Acknowledgements**

10 5 This research is funded by the National Institute for Health Research (NIHR) Health Services and
11 6 Delivery Research (HS&DR) Programme (project number 16/04/06). The views and opinions expressed
12 7 are those of the presenter and do not necessarily reflect those of the HS&DR programme, NIHR, NHS
13 8 or the Department of Health.
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20 10 **Data statement**

21 11 The qualitative data gathered during the course of this evaluation will be kept until June 2030 and can
22 12 be accessed by other researchers during this time, subject to the necessary ethical approvals being
23 13 obtained. Requests for access to this data should be addressed to the corresponding author.
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30 15 **Authors' contributions**

31 16 RR is Principal Investigator for the study. She conceived, designed, and secured funding for the study
32 17 in collaboration with JG, RW, AF, CPG, RP, JK, RAR, JL, MM, and DD. NA and LM led the qualitative
33 18 data collection and analysis that informed the design of QualDash and the design of evaluation. ME
34 19 developed the QualDash software and contributed to the design of the evaluation. RP and RF provided
35 20 data for the testing of QualDash and provided significant feedback on its design. All authors provided
36 21 input into various aspects of the evaluation design and revised drafts of the protocol. RR led the writing
37 22 of this protocol manuscript. All authors read and approved the final manuscript.
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48 24 **Funding statement**

49 25 This research is funded by the National Institute for Health Research (NIHR) Health Services and
50 26 Delivery Research (HS&DR) Programme (project number 16/04/06).
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1 Competing interests statement

2 Chris Gale is a member of the MINAP Academic and Steering Groups. Richard Feltbower is Principal
3 Investigator for PICANet and Roger Parslow was previously Principal Investigator for PICANet. The
4 authors have no other competing interests to declare.

6 Additional files

7 Additional file 1: Checklist of RAMESES II reporting standards for realist evaluations (PDF)

8 Additional file 2: Context Mechanism Outcome configurations to be tested in the realist feasibility
9 evaluation (PDF)

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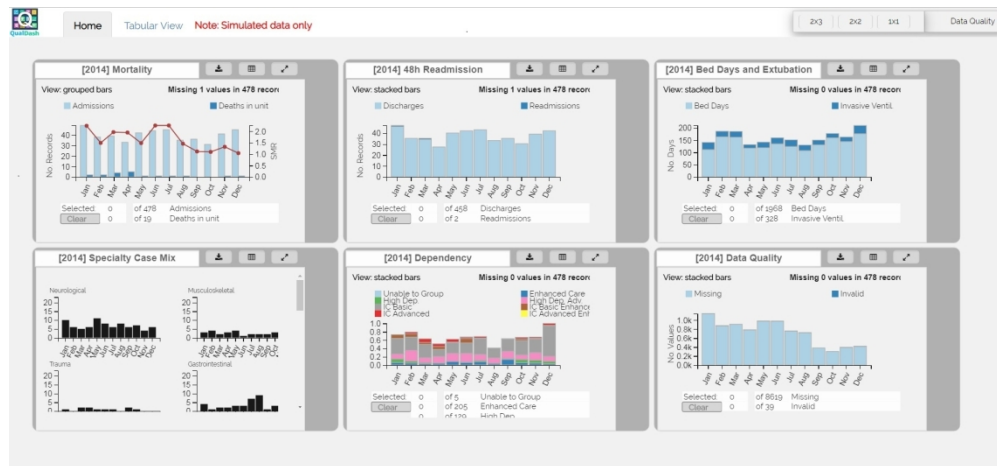


Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using simulated data).

161x74mm (300 x 300 DPI)



Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the Mortality QualCard expanded (using simulated data).

161x85mm (300 x 300 DPI)

How, in what contexts, and why do quality dashboards lead to improvements in care quality? Protocol for a realist feasibility evaluation (Randell et al.)

Additional file 2

#	Context	+	Resource	Mechanism	Response	=	Outcome
1.	Teams previously constrained in their ability to use NCA data for monitoring service performance because data not considered to be timely, accurate, and/or complete	+	QualDash offers easy access to key metrics	Teams are able to see whether the data displayed are timely, accurate, and/or complete and, where they are not, adjust their data collection processes in order to benefit from QualDash	Teams use QualDash to embed NCA data within their monitoring processes e.g. in clinical governance meetings where data is presented visually via screens.	=	Improvement in data quality in terms of timeliness, accuracy, and completeness – as data quality improves, use of QualDash increases
2.	Teams previously using NCA data to monitor service performance routinely by extracting raw data and producing reports for review in meetings and by individuals	+	QualDash visualises key metrics in ways that clearly show whether service performance is within an expected range and provides functions to interrogate that data	Teams use QualDash to facilitate their existing processes for monitoring service performance using NCA data		=	Reduced time spent in accessing, and preparing visualisations of, NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
3.	Teams who want to use NCA data but were previously constrained by data quality and existing systems did not provide functions to easily access and interact with the data	+	QualDash provides functions that enable users to interact with NCA data and explore relationships between variables	Teams will use these functions to interrogate anomalies in the data, which will help them to understand what has impacted performance, thereby enabling them to identify appropriate strategies for improving performance		=	Introduction of QI initiatives in relation to metrics that teams consider important and where performance is not in line with expectations Over time, improvement in metrics that QI initiatives target
4.	Performance in key metrics, such as the Best Practice Tariff, is in line with expectations Relevant audit/IT support staff have time and willingness to support use of QualDash	+	QualDash offers teams the ability to quickly and easily add new QualCards (within NCA parameters)	Teams add new QualCards to be able to monitor and interrogate metrics they have chosen as important		=	Introduction of QI initiatives in relation to metrics shown on new QualCards when performance is not in line with expectations Over time, improvement in metrics that QI initiatives target

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#	Context	+	Resource	Mechanism	Response	=	Outcome
5.	Teams who previously did not, or were not able to, monitor key metrics routinely	+	QualDash provides quick and easy access to key metrics	Teams will become aware of discrepancies between performance and targets in key metrics, which they will take action to address		=	Introduction of QI initiatives in relation to key metrics Over time, improvement in those metrics
	Performance is not in line with expectations in key metrics						
	Teams are resourced to make practice changes						
6.	Teams are asked to produce reports and recommendations for managers and other groups about service performance, e.g. at the time of publication of NCA annual report	+	QualDash offers easy access to NCA data and visualisations that can be exported into reports	Teams will use QualDash to produce performance reports requested by other groups		=	Reduced time spent in report preparation Increased use of NCA data at divisional and corporate levels via outputs produced by QualDash Over time, use of QualDash at divisional and/or corporate levels, due to increased awareness of NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
7.	Teams receive data requests from service managers	+	QualDash can be easily accessed via the web by multiple users	Service managers will use QualDash to access the information they need quickly and easily		=	Streamlines the use of NCA data for clinical managers Reduced time spent by audit support staff/clinical team in producing data reports for managers
8.	Teams need to evidence their performance to managers and other groups in order to support a case for practice change e.g. in business meetings with managers or in the NCA annual report summary	+	QualDash visualises performance metrics, which can also be exported into reports and presentations	Teams will use these functions to evidence service performance, in order to convince other Trust groups that change is needed		=	Other Trust groups, who are able to offer additional resource to teams, are convinced of the need for change based on the evidence provided. However, this is likely to be where those outputs are clearly associated with Trust priorities, e.g. relating to Trust reputation or avoiding penalties/gaining incentives.

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RAMESES II reporting standards for realist evaluations

How, in what contexts, and why do quality dashboards lead to improvements in care quality? Protocol for a realist feasibility evaluation			Reported in document Y/N/NA	Page(s) in document	Comment
1		In the title, identify the document as a realist evaluation	Y	1	
SUMMARY OR ABSTRACT					
2		<p>Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions</p> <p>Where journals require it and the nature of the study is appropriate, brief details of respondents to the</p>	Y	2	

		evaluation and recruitment and sampling processes may also be included Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined			
INTRODUCTION					
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	6	
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	7-8 and Additional file 1	Placed in body of article, rather than Introduction, as more appropriate for protocol
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	6	
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant	Y	15	Stated under declarations as required by journal

		authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why			
METHODS					
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	7	
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	8	
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	4-5	Description of intervention placed in Background as this seemed more appropriate in providing the context for the protocol
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation	Y	7-14	

		design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist			
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	9-12	
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	8	Sampling of sites, rather than individuals, is described; Recruitment will be described when reporting the results of the study
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of	Y	12, 14	

		analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded			
RESULTS					
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	NA		Protocol so no results to report
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	NA		Protocol so no results to report
DISCUSSION					
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	NA		Protocol so no results to report
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be	NA		Discussion of the strengths and limitations will be covered when

		<p>limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged</p> <p>In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions</p>			reporting the results of the study
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NA		Protocol so no results to compare with existing literature
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NA		Protocol so no results on which to base recommendations
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the	Y	16	

		funder (if any) and any conflicts of interests of the evaluators			
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BMJ Open

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033208.R1
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3 1 **Title: How, in what contexts, and why do quality dashboards lead to improvements in care**
4
5 2 **quality in acute hospitals? Protocol for a realist feasibility evaluation**
6
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8

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1
2
3 **1 ABSTRACT**

4 **2 Introduction:** National audits are used to monitor care quality and safety and are anticipated to reduce
5
6 unexplained variations in quality by stimulating quality improvement. However, variation within and
7
8 between providers in the extent to which they engage with national audits mean that the potential for
9
10 national audit data to inform quality improvement is not being realised. This study aims to undertake a
11
12 feasibility evaluation of QualDash, a quality dashboard designed to support clinical teams and
13
14 managers to explore data from two national audits, the Myocardial Ischaemia National Audit Project
15
16 (MINAP) and the Paediatric Intensive Care Audit Network (PICANet).
17

18 **9 Methods and analysis:** Realist evaluation, which involves building, testing, and refining theories of
19
20 how an intervention is supposed to work, provides an overall framework. Realist hypotheses that
21
22 describe how, in what contexts, and why QualDash is expected to provide benefit will be tested across
23
24 five hospitals. A controlled interrupted time series analysis will investigate impacts of QualDash using
25
26 key MINAP and PICANet measures. Ethnographic observations and interviews over 12 months will
27
28 provide insight into contexts and mechanisms that lead to those impacts. Feasibility outcomes include
29
30 the extent to which MINAP and PICANet data are used, data completeness in the audits, and the extent
31
32 to which participants perceive QualDash to be useful and express the intention to continue using it after
33
34 the study period.
35

36 **18 Ethics and dissemination:** The study has been approved by University of Leeds School of Healthcare
37
38 Research Ethics Committee. Study results will provide an initial understanding of how, in what contexts,
39
40 and why quality dashboards may lead to improvements in care quality. These will be disseminated to
41
42 academic audiences, study participants, hospital IT departments, and national audits. If results show a
43
44 trial of QualDash is feasible, we will disseminate the QualDash software through a stepped wedge
45
46 cluster randomised trial.
47

48 **24 Trial registration:** ISRCTN18289782
49
50

51 **26 Keywords:** Dashboard, audit and feedback, quality improvement, realist evaluation
52
53

54 **28 Word count:** 4,078
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ARTICLE SUMMARY

Strengths and limitations of this study

- This study combines a controlled interrupted time series study with a qualitative multi-site case study in order to provide an understanding of not only whether use of a quality dashboard leads to quality improvement but also how, in what contexts, and why.
- In addition to assessing the feasibility of a trial, the study will determine the components of QualDash to be preserved in a definitive trial, appropriate outcome measures, and the contexts in which a definitive trial should be undertaken.
- The study will contribute to understanding of how realist methods can contribute to feasibility studies and the design of trials.
- Issues of data quality may be a limitation of the CITS; data completeness, and whether this changes over the course of the study, will be assessed,

INTRODUCTION

National clinical audits (NCAs), which provide comparative data on the performance of healthcare providers, are one means by which health systems around the world monitor care quality and safety. In England, a programme of over 30 NCAs is managed by the Healthcare Quality Improvement Partnership (HQIP) and all healthcare providers that contribute to delivery of the National Health Service (NHS) are required to participate. Such audits are anticipated to reduce unexplained variations in healthcare quality by stimulating quality improvement (QI) [1 2]. While there is evidence of positive impacts of NCAs [3-5], variation within and between providers in the extent to which they engage with NCAs mean the potential for NCA data to inform QI is not being realised [6 7].

Quality dashboards are a form of audit and feedback (A&F) that provide visualisations of audit data with the aim of informing QI efforts [8]. Healthcare providers are increasingly using quality dashboards. For example, quality dashboard use has been reported in Canada [9], the UK [10], and the Netherlands [11]. While quality dashboards have been shown to have positive effects on some performance indicators [9], empirical evidence regarding their impact remains limited [12].

1

2 **QualDash**

3 QualDash is an interactive web-based quality dashboard designed to support clinical teams and
4 managers to explore data from two national audits, the Myocardial Ischaemia National Audit Project
5 (MINAP) and the Paediatric Intensive Care Audit Network (PICANet), for the purpose of QI (Fig. 1).
6 Information used to inform design of QualDash was collected through interviews with 50 clinicians and
7 managers across five NHS Trusts (providers) and four healthcare commissioners, observations of
8 meetings where audit data are discussed, a workshop with NCA suppliers, and two co-design
9 workshops with clinicians and managers from one Trust.

10

11 Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using
12 simulated data).

13 [Figure 1 should go approximately here]

14

15 The interviews revealed that use of NCA data is largely at the clinical team level, with more limited use
16 at divisional and corporate (Board and sub-committees that report to the Board, such as Quality and
17 Safety Committees) levels. At all levels, a key constraint in use of NCA data for QI is lack of access to
18 timely data; there was consensus among interviewees that data should not be more than three months
19 old. QualDash seeks to improve access to timely data, providing users with a means to visualise the
20 data they collect for the NCAs, without having to wait for data to be returned to them from the NCAs.
21 There is variation between Trusts in the extent to which NCA data are used, often related to resources,
22 which in turn impacts on timeliness of data; Trusts that make greater use of NCA data tend to have
23 local databases from which they can generate visualisations of the data (e.g. bar charts) and audit
24 support staff who have the time and skills to be able to generate such visualisations. In contrast, where
25 such resources are not available, Trusts rely on the NCA annual reports, where data may be 15 months
26 old (e.g. one annual report published in June 2017 reported data from April 2015 to March 2016).
27 QualDash provides visualisations of key metrics, each metric being represented within a 'QualCard'
28 (Fig. 2), enabling Trusts to use NCA data for QI, regardless of existing resources. QualCards for MINAP
29 and PICANet are listed in Table 1; while there is only one set of QualCards for PICANet, for MINAP an

1 additional QualCard is provided for teaching hospitals, as discussions with sites revealed that the
 2 metrics of interest are different between teaching hospitals and District General Hospitals (DGHs). Sites
 3 are also able to create additional QualCards, to reflect local priorities.

4
 5 Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the
 6 Mortality QualCard expanded (using simulated data).

7 [Figure 2 should go approximately here]

8
 9 Table 1: QualCards

	Metric
MINAP – all sites	Mortality Door (arrival in Accident and Emergency) to angiogram time Gold standard drugs on discharge Referral for cardiac rehabilitation Acute use of aspirin
MINAP teaching hospital specific	Call (by patient/relative to emergency services) to balloon (percutaneous coronary intervention) time
PICANet – all sites	Mortality 48 hour unplanned readmission Bed days and accidental extubation Specialty case mix Data quality (number of records with a missing value) Patient dependency

10

11

12 To load new data into QualDash, NCA data are either extracted from the site's database or downloaded
 13 from the NCA website and then fed to a small script (written in R), which in turn updates the dashboard.
 14 Users can add new data as often as they want, but at a minimum they will load data into QualDash at
 15 the same time as uploading to the NCAs (typically every three months).

16

17 The benefits perceived from using QualDash may vary between sites, with under-resourced sites that
 18 previously made little use of NCA data for QI perceiving greater impact than those that already have
 19 the means to use NCA data for QI. There are also constraints on use of NCA data for QI that it may be
 20 difficult for QualDash to address. For example, in some Trusts, clinical team members perceive that
 21 relevant managers will not agree to provide the resources necessary for QI initiatives, which reduces
 22 motivation to engage with NCA data and may affect the extent to which QualDash is used. However,
 23 QualDash provides means for visualisations to be downloaded and incorporated into presentations and

1 reports, which may support clinical teams in making a stronger case for QI initiatives. Another constraint
2 on use of NCA data for QI relates to clinicians' trust in the quality of the data. Interviews revealed
3 variations across sites in processes for ensuring data quality. However, some interviewees also
4 suggested that having the means to make more use of NCA data via QualDash would motivate them
5 to improve their processes for ensuring data quality, although this will be dependent on local resources.

6
7 In this paper, we describe the methods for a realist feasibility evaluation of QualDash. The study
8 objectives are:

- 9 1. To understand how, in what contexts, and why use of QualDash leads to QI; and
- 10 2. To assess the feasibility of conducting a trial of QualDash.

11 As no checklists exist for reporting of realist evaluation protocols, in presenting this protocol we draw
12 on the RAMESES II reporting standards for realist evaluations [13] (Additional file 1).

14 **METHODS AND ANALYSIS**

15 **Study design**

16 Use of theory is needed for design and evaluation of A&F interventions [14-16], and QI initiatives more
17 generally [17-19]. This project draws on Realist Evaluation (RE), which involves building, testing, and
18 refining theories about how an intervention is supposed to work [20]. These theories are expressed in
19 the form of Context Mechanism Outcome (CMO) configurations, where C+M=O, reflecting the realist
20 understanding that it is recipients' responses to the resources that an intervention provides (the
21 intervention mechanisms) that determine the impact of the intervention, and such responses are highly
22 influenced by context [21]. Consequently, RE seeks to answer not only the question of 'what works?'
23 but 'what works for whom, in what circumstances, and why?' [22]. It is concerned with both intended
24 and unintended outcomes. RE is recommended for studying QI [23] and has been used for studying
25 the implementation and impact of large-scale QI programmes [24]. There is increasing interest in use
26 of realist methods in feasibility evaluations [25-27].

27
28 We have drawn on a range of sources to develop CMO configurations which describe how, in what
29 contexts, and why use of QualDash is anticipated to lead to QI (see Additional file 2). Data generated
30 from the interviews, observations, and workshops described above have been essential to this, as have

1
2
3 1 discussions with the designers of QualDash (ME and RAR) who, drawing on their expertise in
4
5 2 information visualisation, have their own literature-informed theories regarding why certain features of
6
7 3 QualDash will provide benefit to users [28 29]. We have also drawn on substantive theories regarding
8
9 4 how A&F lead to QI at the micro [30 31], meso [32], and macro level [33 34].
10

11 5
12 6 Data collection is designed to enable testing of the CMO configurations. Outcome data, in the form of
13
14 7 key MINAP and PICANet measures, will be collected and analysed in a controlled interrupted time series
15
16 8 (CITS) study, while a multi-site case study [35] will provide insight into the contexts and mechanisms that
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18 9 lead to those outcomes, as well as providing data on intermediate outcomes such as increased use of
19
20 10 NCA data. A&F interventions, and QI interventions more generally, require longitudinal evaluation to
21
22 11 allow sufficient time for staff to implement changes and incorporate them into their practice [36-38].
23
24 12 Similarly, evaluation of health IT (HIT) should allow time for staff to integrate the technology into their
25
26 13 practices and evolve those practices to take advantage of the functionality offered by the technology [39].
27
28 14 Therefore, data will be collected over a 12 month period, from August 2019.
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30 15

31 32 16 **Public and patient involvement**

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34 17 A Lay Advisory Group has been established, which has contributed to the design of QualDash by
35
36 18 reviewing the topic guide for the interviews that were conducted, providing their perspective on the
37
38 19 findings of the interview study, and participating in the usability evaluation of QualDash. For the realist
39
40 20 feasibility evaluation, they have provided advice on aspects to pay attention to when undertaking
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42 21 observations. They will contribute to analysis of a sample of the qualitative data, to provide a patient
43
44 22 perspective. They will advise on dissemination of findings to relevant interest groups and will review
45
46 23 outputs for comprehensibility.
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49 25 **Setting/context**

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51 26 QualDash will be evaluated in the five NHS acute Trusts in which the interview study that informed the
52
53 27 design of QualDash was undertaken. Three Trusts are teaching hospitals that participate in both MINAP
54
55 28 and PICANet and have been selected to ensure variation in key outcome measures (MINAP: 30-day
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57 29 mortality for patients hospitalised with ST-elevation myocardial infarction; PICANet: risk adjusted
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59 30 standardised mortality ratio). Two Trusts are DGHs that participate in MINAP but do not have a PICU
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1
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3 1 and so do not participate in PICANet. These have been selected to ensure variation in the same key
4
5 2 MINAP measure.
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7 3

4 **Multi-site case study**

5 In the multi-site case study, data will be collected through ethnographic observation and interviews.
6 Ethnographic methods have been argued as essential for studying implementation of QI interventions
7 [19] and introduction of HIT [40]. Ethnography is well suited to RE because it involves observing
8 phenomena in context, supporting understanding of how context influences the response to an
9 intervention [41]. We will follow the Biography of Artefacts approach [42], which is concerned with
10 capturing how particular contexts and appropriations of a technology lead to different processes and
11 generate different outcomes, a parallel to RE's concern with contexts, mechanisms, and outcomes [43].
12 It involves longitudinal 'strategic ethnography' [42], where data collection is guided by a provisional
13 understanding of the moments and locales in which a technology and associated practices evolve [43].
14

15 **Data collection**

16 In the three teaching hospitals, we will undertake a minimum of 24 periods of observation per Trust, to
17 be split across activities related to cardiology and the PICU, and in the two DGHs we will undertake a
18 minimum of 12 periods of observation per Trust, to be spent observing activities related to cardiology.
19 Each period of observation will be a minimum of four hours (total n=384 hours). While researchers will
20 return to each Trust monthly, to understand how use of QualDash changes over time, more time will be
21 spent in the first few months following the introduction of QualDash, because this is when users are
22 most likely to engage with and explore the affordances of QualDash and establish new practices around
23 it, generating information with implications for system enhancement [43]. Observations will be
24 scheduled to take place at different times of day and on different days of the week, to ensure the account
25 of what is observed is as complete and representative as possible [44].
26

27 At each case site, an initial phase of general observation will provide an opportunity for researchers to
28 become familiar with the setting and for those in the setting to become familiar with the presence of the
29 researchers. Following a previous study of dashboards [10], observations will be undertaken in clinical
30 areas to understand clinical teams' working practices and capture 'corridor committees' where issues

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3 1 of quality and safety are discussed more informally [45]. In the PICUs, initial observations will take place
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5 2 on the PICU, e.g. with the researchers positioning themselves by the nurses' station, as well as
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7 3 observing handovers, safety huddles, and ward rounds. Because activities related to cardiology tend to
8
9 4 be more dispersed across hospitals, researchers will first shadow clinical team members (consultant
10
11 5 cardiologists and acute chest pain nurses) to determine where it is most appropriate to conduct
12
13 6 subsequent observations. These initial observations will also be used to record general details of the
14
15 7 setting that may influence QualDash use, such as staffing levels and availability of computers.
16
17 8

18 9 After this initial phase, observation will be guided by the CMO configurations under investigation. In
19
20 10 addition to observing formal meetings where quality and safety are discussed, predominantly at ward
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22 11 level but also at divisional and corporate level, observation will involve shadowing staff members as
23
24 12 they undertake particular activities: collection and entry of NCA data, to see if and how this changes
25
26 13 over time; accessing and interrogating NCA data, whether using QualDash or some other means;
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28 14 preparation of reports and/or presentations using NCA data, again whether using QualDash or some
29
30 15 other means. Where visualisations from QualDash are incorporated into presentations and written
31
32 16 reports, we will follow the path of those documents, to identify staff members who may not use
33
34 17 QualDash directly but are receiving QualDash outputs. Attention will be paid to how, in what contexts,
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36 18 and why QualDash and QualDash outputs are used or not, understood in the context of broader
37
38 19 practices and use of other sources of information for monitoring care quality, and how this changes over
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40 20 time. We will also follow local QI initiatives, recording data on, for example, when and how the need for
41
42 21 the QI initiative was identified, contextual factors that appear to support and constrain its introduction,
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44 22 how the impact of the QI initiative is monitored, and other contextual factors that appear to influence
45
46 23 the metric that the QI initiative is targeting. Researchers will record observations in fieldnotes, which
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48 24 will be written up in detail as soon after data collection as possible.
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51 26 Brief interviews will be undertaken opportunistically during the course of conducting observations to
52
53 27 clarify aspects of practice that are not immediately intelligible to an observer, with participant responses
54
55 28 recorded in fieldnotes [46]. As data collection progresses, longer semi-structured interviews will be used
56
57 29 to discuss revisions to our CMO configurations. These will be undertaken using a particular approach
58
59 30 from RE, referred to as the teacher-learner cycle, whereby the theories under investigation are made
60

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3 1 explicit to the interviewee so that the interviewee can use their experiences to refine the researcher's
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5 2 understanding [47]. Being concerned with the reasoning of intervention recipients, mechanisms are
6
7 3 often not observable [21], so these longer interviews will also provide the opportunity to explore staff
8
9 4 reasoning about QualDash. These longer interviews will be audio recorded and transcribed verbatim.

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11 5
12
13 6 Logfiles are widely used to evaluate visualisation tools [48]. QualDash logfiles will record information
14
15 7 about the user (job title, etc.), data used (audit, year), overall time spent using QualDash, time spent
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17 8 interacting with different QualCards (including new QualCards that have been created), functionality
18
19 9 used, and whether QualDash visualisations were downloaded. In addition to providing data regarding
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21 10 extent of QualDash use, how QualDash is used and by whom, and how this changes over time,
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23 11 information from logfiles will be used to inform qualitative data collection (e.g. asking in interviews why
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25 12 participants use particular QualCards and not others and the motivation behind the creation of new
26
27 13 QualCards).

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30 15 At the end of the data collection period, we will ask participants to complete a questionnaire based on
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32 16 the Technology Acceptance Model, using well validated items that have been used in numerous
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34 17 evaluations of HIT [49], including dashboards [50]. This will provide participants' perceptions of the
35
36 18 usefulness of QualDash and data on whether they intend to continue using QualDash after the study
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38 19 period.

20 21 **Analysis**

22
23 22 An iterative approach to data collection and analysis will be taken, to enable: ongoing testing and
24
25 23 refinement of the CMO configurations; gathering of further data in light of such revisions; and refinement
26
27 24 of QualDash in response to participants' feedback. Fieldnotes and interview transcripts will be entered
28
29 25 into NVivo 11. Narrative analysis will be undertaken to develop a 'biography' of QualDash, which will
30
31 26 describe use of QualDash and its outputs by a range of stakeholders at different levels (clinical team,
32
33 27 divisional, and corporate) and the interconnections between them [10]. Narrative analysis is consistent
34
35 28 with a realist approach due to its emphasis on preserving connections within the data, thereby helping
36
37 29 to understand causality [51]. This analysis will be supplemented with analysis of the logfiles and

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2
3 1 questionnaire data. Findings will be compared with the CMO configurations, to determine whether they
4
5 2 support, refute, or suggest a revision or addition to the CMO configurations.
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7 3

4 **Controlled interrupted time series study**

5 Interrupted time series studies provide a robust method of assessing the effect of an intervention and
6
7 have been used to assess effectiveness of a variety of complex interventions [52]. In a CITS, the
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9 addition of a control group enhances causal inference because the presence of seasonal trends and
10
11 other potential time-varying confounders can be assessed [53]. Data will be collected across the five
12
13 Trusts, with two control Trusts per intervention Trust, providing a total of 10 control Trusts. Control
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15 Trusts will be matched according to their size and outcomes pre-intervention. Having more than one
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17 control site per intervention site increases power but, as the number of control sites per intervention site
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19 increases, quality of matching decreases. Therefore, we have chosen to have two control Trusts per
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21 intervention Trust to increase power while maintaining quality of the matching.
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32 15 Given the study intention to determine the feasibility of and inform the design of a trial, a range of
33
34 16 measures will be considered. Initially, we selected two process measures, one for MINAP and one for
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36 17 PICANet. For MINAP, we selected the composite process measure Cumulative Missed Opportunities
37
38 18 for Care (CMOC). This has nine components (pre-hospital ECG, acute use of aspirin, timely perfusion,
39
40 19 referral for cardiac rehabilitation, and prescription at hospital discharge of what are considered to be
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42 20 the gold standard drugs – aspirin, thienopyridine inhibitor, ACE-inhibitor, HMG-CoA reductase inhibitor,
43
44 21 and beta blockers) and is inversely associated with mortality [54]. As some of these components, such
45
46 22 as pre-hospital ECG, are outside the direct control of the Trust, we will also explore the impact of
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48 23 QualDash on the individual measures that make up CMOC. On the basis of the measures that
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50 24 cardiology clinicians described in the interviews as being important for measuring care quality, we will
51
52 25 also look at the percentage of patients who receive an angiogram within 72 hours from first admission
53
54 26 to hospital, which is part of the Best Practice Tariff financial incentive scheme, and, for those hospitals
55
56 27 that provide percutaneous coronary intervention (PCI), the proportion of patients who have a door-to-
57
58 28 balloon time (the time from arrival at the hospital to PCI) of less than 60 minutes. Our CMO
59
60 29 configurations (Additional file 2) suggest improvement will be seen in measures if: clinical teams
30
perceive them as being important indicators of care and/or they relate to financial incentives;

1 performance is not in line with expectations; they perceive the measure as being within their control;
2 and the team is resourced to introduce QI initiatives in relation to these measures.

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9 For PICANet, we initially selected use of non-invasive ventilation first for patients requiring ventilation,
10 which has been shown to be associated with reduced mortality [55]. However, this was not raised as
11 an area of concern in our interviews with PICU clinicians. On the basis of this and two additional
12 considerations – it would require loading additional data into QualDash which would reduce the
13 performance of QualDash in terms of speed and it requires computation of the data, while the focus of
14 QualDash is on visualising the data – a QualCard has not been created for this metric. Therefore, we
15 do not hypothesise that this measure will change, unless other sources of information, such as the
16 PICANet annual report, draw a PICU team's attention to it. However, accidental extubation and
17 unplanned readmission within 48 hours were identified in our interviews with PICU clinicians as being
18 important indicators of care quality, so we will include these two measures in the CITS. On the basis of
19 our CMO configurations (Additional file 2), we would expect to see an improvement in these measures
20 in sites where performance is not in line with expectations, if the team is resourced to introduce QI
21 initiatives in relation to these measures.

22 **Sample size considerations**

23 A CITS study requires data for a minimum of three time points pre-intervention and three time points
24 post-intervention and must also allow for any seasonal effect on the outcomes [56]. Monthly data will
25 be obtained for 24 months pre-intervention and 12 months post-intervention. Consequently, for each
26 intervention Trust, there will be 72 data points prior to introduction (24 for the intervention Trust and 48
27 for the control Trusts) and 36 data points post intervention (12 for the intervention Trust and 24 for the
28 control Trusts). Sample size calculations were undertaken based on our two initial measures, CMO
29 for MINAP and use of non-invasive ventilation first for patients requiring ventilation for PICANet; full
30 details are provided in Additional file 3.

31 **Analysis**

32 Monthly MINAP and PICANet data will be extracted to spreadsheets for analysis with R software [57].
33 For both NCAs, each outcome will be regressed upon time and the intervention. The time component

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2
3 1 will include a seasonal effect (quarterly effect) and will allow for a (linear) time trend. To account for
4
5 2 clustering of monthly observations within hospitals, a random intercept will be fitted, although a fixed
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7 3 effect for hospital as a sensitivity analysis will be explored. Although the intervention is abrupt, its impact
8
9 4 may well be 'phased in' over a few months, perhaps three. The timing of the bedding in of the
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11 5 intervention will be reported from the multi-site case study. Then a partial effect can be considered for
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13 6 this period with the interaction effect stepping up in a linear fashion.

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15 7
16 8 Results of the CITS analysis will be incorporated into the biography of QualDash, the analysis of the
17
18 9 data from the multi-site case study describing how contextual factors shape the evolution of practices
19
20 10 around QualDash and how this leads to the resulting outcome pattern.

21 22 11 23 24 12 **Trial feasibility assessment and design**

25
26 13 Our trial progression criteria are: (i) the number of people who engage with either MINAP or PICANet
27
28 14 data (via QualDash or some other means) is the same or higher than the number of people who engaged
29
30 15 with either MINAP or PICANet data prior to QualDash's introduction; (ii) data completeness in the national
31
32 16 audit improves or remains the same; (iii) 50% or more of participants in the questionnaire survey perceive
33
34 17 QualDash to be useful and express the intention to continue using it after the study period. Criteria (i)
35
36 18 and (ii) are concerned with ensuring the intervention does not have unintended negative consequences
37
38 19 which would affect success of the intervention. Criterion (ii) is also concerned with feasibility of outcome
39
40 20 assessment. Criterion (iii) is concerned with acceptability and uptake of the intervention, and therefore
41
42 21 has implications for recruitment to a trial, as well as being concerned with participants' perceptions of the
43
44 22 impact of QualDash on care. While not formally assessed as part of the progression criteria, the impact
45
46 23 of QualDash on care as identified in the CITS will be considered in determining whether a future trial is
47
48 24 justified. A traffic light system will be used to determine if a trial is feasible (green), feasible with
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50 25 modifications to QualDash (amber), or not feasible (red) [58 59].

51 26
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53 27 If the results show a trial of QualDash is feasible, we will design a stepped wedge cluster randomised
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55 28 trial. Data from the CITS will be used to inform the selection of NCAs to be included in the trial (MINAP
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57 29 and/or PICANet) and will provide information about variability of outcomes and about how long a trial
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59 30 intervention period would need to be. Findings from the multi-site case study will be used to inform the
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3 1 selection of categories of user to be included in the trial and, associated with this, the level of
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5 2 randomisation (Trust, hospital, or ward). Using the understanding of the relationship between contexts,
6
7 3 mechanisms, and outcomes provided by the study, we will identify QualDash components associated
8
9 4 with mechanisms that produce the desired outcomes in order for them to be preserved in the trial, while
10
11 5 other components can be adapted to suit the local context.
12
13 6

7 **ETHICS AND DISSEMINATION**

16 8 Ethics approval has been received from the University of Leeds School of Healthcare Research Ethics
17
18 9 Committee (Approval no.HREC16-044). Written consent will be obtained from participants for interviews
19
20 10 and for meeting observations.
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22 11

24 12 Study results will provide initial understanding of how and in what contexts quality dashboards may lead
25
26 13 to improvements in care quality. We will disseminate these results to academic audiences, study
27
28 14 participants, hospital IT departments, and NCAs. If we progress to a trial, in addition to providing further
29
30 15 understanding of the impact of quality dashboards on care quality, this will result in wider dissemination
31
32 16 of the QualDash software.
33
34 17

18 **Acknowledgements**

37 19 This research is funded by the National Institute for Health Research (NIHR) Health Services and
38
39 20 Delivery Research (HS&DR) Programme (project number 16/04/06). The views and opinions expressed
40
41 21 are those of the presenter and do not necessarily reflect those of the HS&DR programme, NIHR, NHS
42
43 22 or the Department of Health.
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45 23

24 **Data statement**

49 25 The qualitative data gathered during the course of this evaluation will be kept until June 2030 and can
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51 26 be accessed by other researchers during this time, subject to the necessary ethical approvals being
52
53 27 obtained. Requests for access to this data should be addressed to the corresponding author.
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1 **Authors' contributions**

2 RR is Principal Investigator for the study. She conceived, designed, and secured funding for the study
3 in collaboration with JG, RW, AF, CPG, RP, JK, RAR, JL, MM, and DD. NA and LM led the qualitative
4 data collection and analysis that informed the design of QualDash and the design of evaluation. ME
5 developed the QualDash software and contributed to the design of the evaluation. RP and RF provided
6 data for the testing of QualDash and provided significant feedback on its design. All authors provided
7 input into various aspects of the evaluation design and revised drafts of the protocol. RR led the writing
8 of this protocol manuscript. All authors read and approved the final manuscript.

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11 Delivery Research (HS&DR) Programme (project number 16/04/06).

12 **Competing interests statement**

13 Chris Gale is a member of the MINAP Academic and Steering Groups. Richard Feltbower is Principal
14 Investigator for PICANet and Roger Parslow was previously Principal Investigator for PICANet. The
15 authors have no other competing interests to declare.

16 **Additional files**

- 17 Additional file 1: Checklist of RAMESES II reporting standards for realist evaluations (PDF)
18 Additional file 2: Context Mechanism Outcome configurations to be tested in the realist feasibility
19 evaluation (PDF)
20 Additional file 3: Sample size calculations for controlled interrupted time series (PDF)

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Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the Mortality QualCard expanded (using simulated data).

161x85mm (300 x 300 DPI)

RAMESES II reporting standards for realist evaluations

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation			Reported in document Y/N/NA	Page(s) in document	Comment
1		In the title, identify the document as a realist evaluation	Y	1	
SUMMARY OR ABSTRACT					
2		Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions Where journals require it and the nature of the study is appropriate, brief details of respondents to the	Y	3	

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		<p>evaluation and recruitment and sampling processes may also be included</p> <p>Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined</p>			
INTRODUCTION					
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	7	
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	8 and Additional file 2	Placed in body of article, rather than Introduction, as more appropriate for protocol
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	7	
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant	Y	15	

		authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why			
METHODS					
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	7-8	
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	8-9	
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	5-7	Description of intervention placed in Introduction as this seemed more appropriate in providing the context for the protocol
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation	Y	7-14	

		design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist			
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	9-11	
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	8-9	Sampling of sites, rather than individuals, is described; Recruitment will be described when reporting the results of the study
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of	Y	11-12, 13-14	

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		analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded			
RESULTS					
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	NA		Protocol so no results to report
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	NA		Protocol so no results to report
DISCUSSION					
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	NA		Protocol so no results to report
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be	4		Strengths and limitations of study design

		<p>limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged</p> <p>In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions</p>			
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NA		Protocol so no results to compare with existing literature
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NA		Protocol so no results on which to base recommendations
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the	Y	16	

		funder (if any) and any conflicts of interests of the evaluators			
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For peer review only

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How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation
(Randell et al.)

Additional file 2

#	Context	+	Resource	Mechanism	Response	=	Outcome
1.	Teams previously constrained in their ability to use NCA data for monitoring service performance because data not considered to be timely, accurate, and/or complete	+	QualDash offers easy access to key metrics	Teams are able to see whether the data displayed are timely, accurate, and/or complete and, where they are not, adjust their data collection processes in order to benefit from QualDash	Teams use QualDash to embed NCA data within their monitoring processes e.g. in clinical governance meetings where data is presented visually via screens.	=	Improvement in data quality in terms of timeliness, accuracy, and completeness – as data quality improves, use of QualDash increases
2.	Teams previously using NCA data to monitor service performance routinely by extracting raw data and producing reports for review in meetings and by individuals	+	QualDash visualises key metrics in ways that clearly show whether service performance is within an expected range and provides functions to interrogate that data	Teams use QualDash to facilitate their existing processes for monitoring service performance using NCA data		=	Increased routine use of NCA data in performance monitoring, providing opportunities for its use in quality improvement
						=	Reduced time spent in accessing, and preparing visualisations of, NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
3.	Teams who want to use NCA data but were previously constrained by data quality and existing systems did not provide functions to easily access and interact with the data	+	QualDash provides functions that enable users to interact with NCA data and explore relationships between variables	Teams will use these functions to interrogate anomalies in the data, which will help them to understand what has impacted performance, thereby enabling them to identify appropriate strategies for improving performance		=	Introduction of QI initiatives in relation to metrics that teams consider important and where performance is not in line with expectations Over time, improvement in metrics that QI initiatives target
4.	Performance in key metrics, such as the Best Practice Tariff, is in line with expectations Relevant audit/IT support staff have time and willingness to support use of QualDash	+	QualDash offers teams the ability to quickly and easily add new QualCards (within NCA parameters)	Teams add new QualCards to be able to monitor and interrogate metrics they have chosen as important		=	Introduction of QI initiatives in relation to metrics shown on new QualCards when performance is not in line with expectations Over time, improvement in metrics that QI initiatives target

For peer review only

#	Context	+	Resource	Mechanism	Response	=	Outcome
5.	Teams who previously did not, or were not able to, monitor key metrics routinely	+	QualDash provides quick and easy access to key metrics	Teams will become aware of discrepancies between performance and targets in key metrics, which they will take action to address		=	Introduction of QI initiatives in relation to key metrics Over time, improvement in those metrics
	Performance is not in line with expectations in key metrics						
	Teams are resourced to make practice changes						
6.	Teams are asked to produce reports and recommendations for managers and other groups about service performance, e.g. at the time of publication of NCA annual report	+	QualDash offers easy access to NCA data and visualisations that can be exported into reports	Teams will use QualDash to produce performance reports requested by other groups		=	Reduced time spent in report preparation Increased use of NCA data at divisional and corporate levels via outputs produced by QualDash Over time, use of QualDash at divisional and/or corporate levels, due to increased awareness of NCA data

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#	Context	+	Resource	Mechanism	Response	=	Outcome
7.	Teams receive data requests from service managers	+	QualDash can be easily accessed via the web by multiple users	Service managers will use QualDash to access the information they need quickly and easily		=	Streamlines the use of NCA data for clinical managers Reduced time spent by audit support staff/clinical team in producing data reports for managers
8.	Teams need to evidence their performance to managers and other groups in order to support a case for practice change e.g. in business meetings with managers or in the NCA annual report summary	+	QualDash visualises performance metrics, which can also be exported into reports and presentations	Teams will use these functions to evidence service performance, in order to convince other Trust groups that change is needed		=	Other Trust groups, who are able to offer additional resource to teams, are convinced of the need for change based on the evidence provided. However, this is likely to be where those outputs are clearly associated with Trust priorities, e.g. relating to Trust reputation or avoiding penalties/gaining incentives.

1
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3 **How, in what contexts, and why do quality dashboards lead to improvements in care quality in**
4 **acute hospitals? Protocol for a realist feasibility evaluation (Randell et al.)**

5
6 **Additional file 2**
7
8

9 The average CMOC for patients on a ward will be averaged for each month, so that there are 36
10 observations clustered within each of 15 hospitals. Taking the intra-class correlation to be 0.15, this
11 yields a design effect of 6.25. Hence the effective number of observations is $15 \times 36 / 6.25 = 86.4$. Using
12 Cohen's approach to sample size calculation means an effect size of 0.17 can be estimated with 80%
13 given that there are six parameters in the model (including the coefficient for QualDash). Converting
14 this to the percentage of variation that can be explained by the model, this yields 20.5%. Translating
15 this back to CMOC, currently 49.6% of patients are discharged from hospital without missing any of
16 the nine opportunities for care, and we would be powered at the 80% level to detect an improvement
17 from an average of 8.33 opportunities achieved to 8.46. Thus our study has good power to detect
18 small but meaningful clinical improvements. For PICANet, 10% of the admitted population receive
19 non-invasive ventilation first [1]. On average there are 5.25 ventilation cases per month per hospital.
20 With a further design effect from patients clustered within hospitals, based on the reported intraclass
21 correlation coefficient of 0.065 giving a design effect of 1.276, the actual anticipated number of
22 patients is 1701 giving an effective number of 213: 71 exposed to QualDash and 142 controls. This
23 yields 80% power to detect a change from 32% to 53%.
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BMJ Open

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation

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3 1 **Title: How, in what contexts, and why do quality dashboards lead to improvements in care**
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5 2 **quality in acute hospitals? Protocol for a realist feasibility evaluation**
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ARTICLE SUMMARY

Strengths and limitations of this study

- This study combines a controlled interrupted time series study with a qualitative multi-site case study in order to provide an initial understanding of not only whether use of a quality dashboard leads to quality improvement but also how, in what contexts, and why.
- In addition to assessing the feasibility of a trial, the study will determine the components of QualDash to be preserved in a definitive trial, appropriate outcome measures, and the contexts in which a definitive trial should be undertaken.
- The study will contribute to understanding of how realist methods can contribute to feasibility studies and the design of trials.
- Issues of data quality may be a limitation of the CITS; data completeness, and whether this changes over the course of the study, will be assessed,

INTRODUCTION

National clinical audits (NCAs), which provide comparative data on the performance of healthcare providers, are one means by which health systems around the world monitor care quality and safety. In England, a programme of over 30 NCAs is managed by the Healthcare Quality Improvement Partnership (HQIP) and all healthcare providers that contribute to delivery of the National Health Service (NHS) are required to participate. Such audits are anticipated to reduce unexplained variations in healthcare quality by stimulating quality improvement (QI) [1 2]. While there is evidence of positive impacts of NCAs [3-5], variation within and between providers in the extent to which they engage with NCAs mean the potential for NCA data to inform QI is not being realised [6 7].

Quality dashboards are a form of audit and feedback (A&F) that provide visualisations of audit data with the aim of informing QI efforts [8]. Healthcare providers are increasingly using quality dashboards. For example, quality dashboard use has been reported in Canada [9], the UK [10], and the Netherlands [11]. While quality dashboards have been shown to have positive effects on some performance indicators [9], empirical evidence regarding their impact remains limited [12].

1

2 **QualDash**

3 QualDash is an interactive web-based quality dashboard designed to support clinical teams and
4 managers to explore data from two national audits, the Myocardial Ischaemia National Audit Project
5 (MINAP) and the Paediatric Intensive Care Audit Network (PICANet), for the purpose of QI (Fig. 1).
6 Information used to inform design of QualDash was collected through interviews with 50 clinicians and
7 managers across five NHS Trusts (providers) and four healthcare commissioners, observations of
8 meetings where audit data are discussed, a workshop with NCA suppliers, and two co-design
9 workshops with clinicians and managers from one Trust.

10

11 Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using
12 simulated data).

13 [Figure 1 should go approximately here]

14

15 The interviews revealed that use of NCA data is largely at the clinical team level, with more limited use
16 at divisional and corporate (Board and sub-committees that report to the Board, such as Quality and
17 Safety Committees) levels. At all levels, a key constraint in use of NCA data for QI is lack of access to
18 timely data; there was consensus among interviewees that data should not be more than three months
19 old. QualDash seeks to improve access to timely data, providing users with a means to visualise the
20 data they collect for the NCAs, without having to wait for data to be returned to them from the NCAs.
21 There is variation between Trusts in the extent to which NCA data are used, often related to resources,
22 which in turn impacts on timeliness of data; Trusts that make greater use of NCA data tend to have
23 local databases from which they can generate visualisations of the data (e.g. bar charts) and audit
24 support staff who have the time and skills to be able to generate such visualisations. In contrast, where
25 such resources are not available, Trusts rely on the NCA annual reports, where data may be 15 months
26 old (e.g. one annual report published in June 2017 reported data from April 2015 to March 2016).
27 QualDash provides visualisations of key metrics, each metric being represented within a 'QualCard'
28 (Fig. 2), enabling Trusts to use NCA data for QI, regardless of existing resources. QualCards for MINAP
29 and PICANet are listed in Table 1; while there is only one set of QualCards for PICANet, for MINAP an

1 additional QualCard is provided for teaching hospitals, as discussions with sites revealed that the
 2 metrics of interest are different between teaching hospitals and District General Hospitals (DGHs). Sites
 3 are also able to create additional QualCards, to reflect local priorities.

4
 5 Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the
 6 Mortality QualCard expanded (using simulated data).

7 [Figure 2 should go approximately here]

8
 9 Table 1: QualCards

	Metric
MINAP – all sites	Mortality Door (arrival in Accident and Emergency) to angiogram time Gold standard drugs on discharge Referral for cardiac rehabilitation Acute use of aspirin
MINAP teaching hospital specific	Call (by patient/relative to emergency services) to balloon (percutaneous coronary intervention) time
PICANet – all sites	Mortality 48 hour unplanned readmission Bed days and accidental extubation Specialty case mix Data quality (number of records with a missing value) Patient dependency

10

11

12 To load new data into QualDash, NCA data are either extracted from the site's database or downloaded
 13 from the NCA website and then fed to a small script (written in R), which in turn updates the dashboard.
 14 Users can add new data as often as they want, but at a minimum they will load data into QualDash at
 15 the same time as uploading to the NCAs (typically every three months).

16

17 The benefits perceived from using QualDash may vary between sites, with under-resourced sites that
 18 previously made little use of NCA data for QI perceiving greater impact than those that already have
 19 the means to use NCA data for QI. There are also constraints on use of NCA data for QI that it may be
 20 difficult for QualDash to address. For example, in some Trusts, clinical team members perceive that
 21 relevant managers will not agree to provide the resources necessary for QI initiatives, which reduces
 22 motivation to engage with NCA data and may affect the extent to which QualDash is used. However,
 23 QualDash provides means for visualisations to be downloaded and incorporated into presentations and

1 reports, which may support clinical teams in making a stronger case for QI initiatives. Another constraint
2 on use of NCA data for QI relates to clinicians' trust in the quality of the data. Interviews revealed
3 variations across sites in processes for ensuring data quality. However, some interviewees also
4 suggested that having the means to make more use of NCA data via QualDash would motivate them
5 to improve their processes for ensuring data quality, although this will be dependent on local resources.

6
7 In this paper, we describe the methods for a realist feasibility evaluation of QualDash. The study
8 objectives are:

- 9 1. To develop an initial understanding of how, in what contexts, and why use of QualDash leads to QI;
- 10 and
- 11 2. To assess the feasibility of conducting a trial of QualDash.

12 As no checklists exist for reporting of realist evaluation protocols, in presenting this protocol we draw
13 on the RAMESES II reporting standards for realist evaluations [13] (Additional file 1).

14 15 **METHODS AND ANALYSIS**

16 **Study design**

17 Use of theory is needed for design and evaluation of A&F interventions [14-16], and QI initiatives more
18 generally [17-19]. This project draws on Realist Evaluation (RE), which involves building, testing, and
19 refining theories about how an intervention is supposed to work [20]. These theories are expressed in
20 the form of Context Mechanism Outcome (CMO) configurations, where C+M=O, reflecting the realist
21 understanding that it is recipients' responses to the resources that an intervention provides (the
22 intervention mechanisms) that determine the impact of the intervention, and such responses are highly
23 influenced by context [21]. Consequently, RE seeks to answer not only the question of 'what works?'
24 but 'what works for whom, in what circumstances, and why?' [22]. It is concerned with both intended
25 and unintended outcomes. RE is recommended for studying QI [23] and has been used for studying
26 the implementation and impact of large-scale QI programmes [24]. There is increasing interest in use
27 of realist methods in feasibility evaluations [25-27].

28
29 We have drawn on a range of sources to develop CMO configurations which describe how, in what
30 contexts, and why use of QualDash is anticipated to lead to QI (see Additional file 2). Data generated

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3 1 from the interviews, observations, and workshops described above have been essential to this, as have
4
5 2 discussions with the designers of QualDash (ME and RAR) who, drawing on their expertise in
6
7 3 information visualisation, have their own literature-informed theories regarding why certain features of
8
9 4 QualDash will provide benefit to users [28 29]. We have also drawn on substantive theories regarding
10
11 5 how A&F lead to QI at the micro [30 31], meso [32], and macro level [33 34].
12
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14 7 Data collection is designed to enable testing of the CMO configurations. Outcome data, in the form of
15
16 8 key MINAP and PICANet measures, will be collected and analysed in a controlled interrupted time series
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18 9 (CITS) study, while a multi-site case study [35] will provide an initial understanding of the contexts and
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20 10 mechanisms that lead to those outcomes, as well as providing data on intermediate outcomes such as
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22 11 increased use of NCA data. A&F interventions, and QI interventions more generally, require longitudinal
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24 12 evaluation to allow sufficient time for staff to implement changes and incorporate them into their practice
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26 13 [36-38]. Similarly, evaluation of health IT (HIT) should allow time for staff to integrate the technology into
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28 14 their practices and evolve those practices to take advantage of the functionality offered by the technology
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30 15 [39]. Therefore, data will be collected over a 12 month period, from August 2019.
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33 34 17 **Public and patient involvement**

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36 18 A Lay Advisory Group has been established, which has contributed to the design of QualDash by
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38 19 reviewing the topic guide for the interviews that were conducted, providing their perspective on the
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40 20 findings of the interview study, and participating in the usability evaluation of QualDash. For the realist
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42 21 feasibility evaluation, they have provided advice on aspects to pay attention to when undertaking
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44 22 observations. They will contribute to analysis of a sample of the qualitative data, to provide a patient
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46 23 perspective. They will advise on dissemination of findings to relevant interest groups and will review
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48 24 outputs for comprehensibility.
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51 26 **Setting/context**

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53 27 The feasibility study will be conducted in the five NHS acute Trusts in which the interview study that
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55 28 informed the design of QualDash was undertaken. Three Trusts are teaching hospitals that participate
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57 29 in both MINAP and PICANet and have been selected to ensure variation in key outcome measures
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59 30 (MINAP: 30-day mortality for patients hospitalised with ST-elevation myocardial infarction; PICANet:
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3 1 risk adjusted standardised mortality ratio). Two Trusts are DGHs that participate in MINAP but do not
4 have a PICU and so do not participate in PICANet. These have been selected to ensure variation in the
5 same key MINAP measure.
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10 **Multi-site case study**

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12 In the multi-site case study, data will be collected through ethnographic observation and interviews.
13 Ethnographic methods have been argued as essential for studying implementation of QI interventions
14 [19] and introduction of HIT [40]. Ethnography is well suited to RE because it involves observing
15 phenomena in context, supporting understanding of how context influences the response to an
16 intervention [41]. We will follow the Biography of Artefacts approach [42], which is concerned with
17 capturing how particular contexts and appropriations of a technology lead to different processes and
18 generate different outcomes, a parallel to RE's concern with contexts, mechanisms, and outcomes [43].
19 It involves longitudinal 'strategic ethnography' [42], where data collection is guided by a provisional
20 understanding of the moments and locales in which a technology and associated practices evolve [43].
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31 **Data collection**

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33 In the three teaching hospitals, we will undertake a minimum of 24 periods of observation per Trust, to
34 be split across activities related to cardiology and the PICU, and in the two DGHs we will undertake a
35 minimum of 12 periods of observation per Trust, to be spent observing activities related to cardiology.
36 Each period of observation will be a minimum of four hours (total n=384 hours). While researchers will
37 return to each Trust monthly, to understand how use of QualDash changes over time, more time will be
38 spent in the first few months following the introduction of QualDash, because this is when users are
39 most likely to engage with and explore the affordances of QualDash and establish new practices around
40 it, generating information with implications for system enhancement [43]. Observations will be
41 scheduled to take place at different times of day and on different days of the week, to ensure the account
42 of what is observed is as complete and representative as possible [44].
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55 At each case site, an initial phase of general observation will provide an opportunity for researchers to
56 become familiar with the setting and for those in the setting to become familiar with the presence of the
57 researchers. Following a previous study of dashboards [10], observations will be undertaken in clinical
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3 1 areas to understand clinical teams' working practices and capture 'corridor committees' where issues
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5 2 of quality and safety are discussed more informally [45]. In the PICUs, initial observations will take place
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7 3 on the PICU, e.g. with the researchers positioning themselves by the nurses' station, as well as
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9 4 observing handovers, safety huddles, and ward rounds. Because activities related to cardiology tend to
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11 5 be more dispersed across hospitals, researchers will first shadow clinical team members (consultant
12
13 6 cardiologists and acute chest pain nurses) to determine where it is most appropriate to conduct
14
15 7 subsequent observations. These initial observations will also be used to record general details of the
16
17 8 setting that may influence QualDash use, such as staffing levels and availability of computers.
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19 9

20 10 After this initial phase, observation will be guided by the CMO configurations under investigation. In
21
22 11 addition to observing formal meetings where quality and safety are discussed, predominantly at ward
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24 12 level but also at divisional and corporate level, observation will involve shadowing staff members as
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26 13 they undertake particular activities: collection and entry of NCA data, to see if and how this changes
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28 14 over time; accessing and interrogating NCA data, whether using QualDash or some other means;
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30 15 preparation of reports and/or presentations using NCA data, again whether using QualDash or some
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32 16 other means. Where visualisations from QualDash are incorporated into presentations and written
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34 17 reports, we will follow the path of those documents, to identify staff members who may not use
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36 18 QualDash directly but are receiving QualDash outputs. Attention will be paid to how, in what contexts,
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38 19 and why QualDash and QualDash outputs are used or not, understood in the context of broader
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40 20 practices and use of other sources of information for monitoring care quality, and how this changes over
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42 21 time. We will also follow local QI initiatives, recording data on, for example, when and how the need for
43
44 22 the QI initiative was identified, contextual factors that appear to support and constrain its introduction,
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46 23 how the impact of the QI initiative is monitored, and other contextual factors that appear to influence
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48 24 the metric that the QI initiative is targeting. Researchers will record observations in fieldnotes, which
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50 25 will be written up in detail as soon after data collection as possible.
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53 27 Brief interviews will be undertaken opportunistically during the course of conducting observations to
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55 28 clarify aspects of practice that are not immediately intelligible to an observer, with participant responses
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57 29 recorded in fieldnotes [46]. As data collection progresses, longer semi-structured interviews will be used
58
59 30 to discuss revisions to our CMO configurations. These will be undertaken using a particular approach
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3 1 from RE, referred to as the teacher-learner cycle, whereby the theories under investigation are made
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5 2 explicit to the interviewee so that the interviewee can use their experiences to refine the researcher's
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7 3 understanding [47]. Being concerned with the reasoning of intervention recipients, mechanisms are
8
9 4 often not observable [21], so these longer interviews will also provide the opportunity to explore staff
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11 5 reasoning about QualDash. These longer interviews will be audio recorded and transcribed verbatim.
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13 6

14 7 Logfiles are widely used to evaluate visualisation tools [48]. QualDash logfiles will record information
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16 8 about the user (job title, etc.), data used (audit, year), overall time spent using QualDash, time spent
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18 9 interacting with different QualCards (including new QualCards that have been created), functionality
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20 10 used, and whether QualDash visualisations were downloaded. In addition to providing data regarding
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22 11 extent of QualDash use, how QualDash is used and by whom, and how this changes over time,
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24 12 information from logfiles will be used to inform qualitative data collection (e.g. asking in interviews why
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26 13 participants use particular QualCards and not others and the motivation behind the creation of new
27
28 14 QualCards).
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32 16 At the end of the data collection period, we will ask participants to complete a questionnaire based on
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34 17 the Technology Acceptance Model, using well validated items that have been used in numerous
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36 18 evaluations of HIT [49], including dashboards [50]. This will provide participants' perceptions of the
37
38 19 usefulness of QualDash and data on whether they intend to continue using QualDash after the study
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40 20 period.
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43 22 **Analysis**

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45 23 An iterative approach to data collection and analysis will be taken, to enable: ongoing testing and
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47 24 refinement of the CMO configurations; gathering of further data in light of such revisions; and refinement
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49 25 of QualDash in response to participants' feedback. Fieldnotes and interview transcripts will be entered
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51 26 into NVivo 11. Narrative analysis will be undertaken to develop a 'biography' of QualDash, which will
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53 27 describe use of QualDash and its outputs by a range of stakeholders at different levels (clinical team,
54
55 28 divisional, and corporate) and the interconnections between them [10]. Narrative analysis is consistent
56
57 29 with a realist approach due to its emphasis on preserving connections within the data, thereby helping
58
59 30 to understand causality [51]. This analysis will be supplemented with analysis of the logfiles and
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3 1 questionnaire data. Findings will be compared with the CMO configurations, to determine whether they
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5 2 support, refute, or suggest a revision or addition to the CMO configurations.
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4 **Controlled interrupted time series study**

5 Interrupted time series studies provide a robust method of assessing the effect of an intervention and
6
7 have been used to assess effectiveness of a variety of complex interventions [52]. In a CITS, the
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9 addition of a control group enhances causal inference because the presence of seasonal trends and
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11 other potential time-varying confounders can be assessed [53]. Data will be collected across the five
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13 Trusts, with two control Trusts per intervention Trust, providing a total of 10 control Trusts. Control
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15 Trusts will be matched according to their size and outcomes pre-intervention. Having more than one
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17 control site per intervention site increases power but, as the number of control sites per intervention site
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19 increases, quality of matching decreases. Therefore, we have chosen to have two control Trusts per
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21 intervention Trust to increase power while maintaining quality of the matching.
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15 Given the study intention to determine the feasibility of and inform the design of a trial, a range of
16
17 measures will be considered. Initially, we selected two process measures, one for MINAP and one for
18
19 PICANet. For MINAP, we selected the composite process measure Cumulative Missed Opportunities
20
21 for Care (CMOC). This has nine components (pre-hospital ECG, acute use of aspirin, timely perfusion,
22
23 referral for cardiac rehabilitation, and prescription at hospital discharge of what are considered to be
24
25 the gold standard drugs – aspirin, thienopyridine inhibitor, ACE-inhibitor, HMG-CoA reductase inhibitor,
26
27 and beta blockers) and is inversely associated with mortality [54]. As some of these components, such
28
29 as pre-hospital ECG, are outside the direct control of the Trust, we will also explore the impact of
30
31 QualDash on the individual measures that make up CMOC. On the basis of the measures that
32
33 cardiology clinicians described in the interviews as being important for measuring care quality, we will
34
35 also look at the percentage of patients who receive an angiogram within 72 hours from first admission
36
37 to hospital, which is part of the Best Practice Tariff financial incentive scheme, and, for those hospitals
38
39 that provide percutaneous coronary intervention (PCI), the proportion of patients who have a door-to-
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41 balloon time (the time from arrival at the hospital to PCI) of less than 60 minutes. Our CMO
42
43 configurations (Additional file 2) suggest improvement will be seen in measures if: clinical teams
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45 perceive them as being important indicators of care and/or they relate to financial incentives;

1 performance is not in line with expectations; they perceive the measure as being within their control;
2 and the team is resourced to introduce QI initiatives in relation to these measures.

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9 For PICANet, we selected use of non-invasive ventilation first for patients requiring ventilation, which
10 has been shown to be associated with reduced mortality [55]. However, this was not raised as an area
11 of concern in our interviews with PICU clinicians. On the basis of this and two additional considerations
12 – it would require loading additional data into QualDash which would reduce the performance of
13 QualDash in terms of speed and it requires computation of the data, while the focus of QualDash is on
14 visualising the data – a QualCard has not been created for this metric. Therefore, while we will still
15 include this measure in the CITS, we do not hypothesise that it will change, unless other sources of
16 information, such as the PICANet annual report, draw a PICU team's attention to it. However, accidental
17 extubation and unplanned readmission within 48 hours were identified in our interviews with PICU
18 clinicians as being important indicators of care quality, so we will include these two measures in the
19 CITS. On the basis of our CMO configurations (Additional file 2), we would expect to see an
20 improvement in these measures in sites where performance is not in line with expectations, if the team
21 is resourced to introduce QI initiatives in relation to these measures.

22 **Sample size considerations**

23 A CITS study requires data for a minimum of three time points pre-intervention and three time points
24 post-intervention and must also allow for any seasonal effect on the outcomes [56]. Monthly data will
25 be obtained for 24 months pre-intervention and 12 months post-intervention. Consequently, for each
26 intervention Trust, there will be 72 data points prior to introduction (24 for the intervention Trust and 48
27 for the control Trusts) and 36 data points post intervention (12 for the intervention Trust and 24 for the
28 control Trusts). Sample size calculations were undertaken based on our two initial measures, CMO
29 for MINAP and use of non-invasive ventilation first for patients requiring ventilation for PICANet; full
30 details are provided in Additional file 3.

31 **Analysis**

32 Monthly MINAP and PICANet data will be extracted to spreadsheets for analysis with R software [57].
33 For both NCAs, each outcome will be regressed upon time and the intervention. The time component

1
2
3 1 will include a seasonal effect (quarterly effect) and will allow for a (linear) time trend. To account for
4
5 2 clustering of monthly observations within hospitals, a random intercept will be fitted, although a fixed
6
7 3 effect for hospital as a sensitivity analysis will be explored. Although the intervention is abrupt, its impact
8
9 4 may well be 'phased in' over a few months, perhaps three. The timing of the bedding in of the
10
11 5 intervention will be reported from the multi-site case study. Then a partial effect can be considered for
12
13 6 this period with the interaction effect stepping up in a linear fashion.
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15 7

16 8 Results of the CITS analysis will be incorporated into the biography of QualDash, the analysis of the
17
18 9 data from the multi-site case study describing how contextual factors shape the evolution of practices
19
20 10 around QualDash and how this leads to the resulting outcome pattern.
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22 11

23 12 **Trial feasibility assessment and design**

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26 13 Our trial progression criteria are: (i) the number of people who engage with either MINAP or PICANet
27
28 14 data (via QualDash or some other means) is the same or higher than the number of people who engaged
29
30 15 with either MINAP or PICANet data prior to QualDash's introduction; (ii) data completeness in the national
31
32 16 audit improves or remains the same; (iii) 50% or more of participants in the questionnaire survey perceive
33
34 17 QualDash to be useful and express the intention to continue using it after the study period. Criteria (i)
35
36 18 and (ii) are concerned with ensuring the intervention does not have unintended negative consequences
37
38 19 which would affect success of the intervention. Criterion (ii) is also concerned with feasibility of outcome
39
40 20 assessment. Criterion (iii) is concerned with acceptability and uptake of the intervention, and therefore
41
42 21 has implications for recruitment to a trial, as well as being concerned with participants' perceptions of the
43
44 22 impact of QualDash on care. While not formally assessed as part of the progression criteria, the impact
45
46 23 of QualDash on care as identified in the CITS will be considered in determining whether a future trial is
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48 24 justified. A traffic light system will be used to determine if a trial is feasible (green), feasible with
49
50 25 modifications to QualDash (amber), or not feasible (red) [58 59].
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53 27 If the results show a trial of QualDash is feasible, we will design a stepped wedge cluster randomised
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55 28 trial. Data from the CITS will be used to inform the selection of NCAs to be included in the trial (MINAP
56
57 29 and/or PICANet) and will provide information about variability of outcomes and about how long a trial
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59 30 intervention period would need to be. Findings from the multi-site case study will be used to inform the
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3 1 selection of categories of user to be included in the trial and, associated with this, the level of
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5 2 randomisation (Trust, hospital, or ward). Using the understanding of the relationship between contexts,
6
7 3 mechanisms, and outcomes provided by the study, we will identify QualDash components associated
8
9 4 with mechanisms that produce the desired outcomes in order for them to be preserved in the trial, while
10
11 5 other components can be adapted to suit the local context.
12
13 6

7 **ETHICS AND DISSEMINATION**

16 8 Ethics approval has been received from the University of Leeds School of Healthcare Research Ethics
17
18 9 Committee (Approval no.HREC16-044). Written consent will be obtained from participants for interviews
19
20 10 and for meeting observations.
21
22 11

24 12 Study results will provide initial understanding of how and in what contexts quality dashboards may lead
25
26 13 to improvements in care quality. We will disseminate these results to academic audiences, study
27
28 14 participants, hospital IT departments, and NCAs. If we progress to a trial, in addition to providing further
29
30 15 understanding of the impact of quality dashboards on care quality, this will result in wider dissemination
31
32 16 of the QualDash software.
33
34 17

18 **Acknowledgements**

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38
39 20 Delivery Research (HS&DR) Programme (project number 16/04/06). The views and opinions expressed
40
41 21 are those of the presenter and do not necessarily reflect those of the HS&DR programme, NIHR, NHS
42
43 22 or the Department of Health.
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24 **Data statement**

49 25 The qualitative data gathered during the course of this evaluation will be kept until June 2030 and can
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51 26 be accessed by other researchers during this time, subject to the necessary ethical approvals being
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53 27 obtained. Requests for access to this data should be addressed to the corresponding author.
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1 **Authors' contributions**

2 RR is Principal Investigator for the study. She conceived, designed, and secured funding for the study
3 in collaboration with JG, RW, AF, CPG, RP, JK, RAR, JL, MM, and DD. NA and LM led the qualitative
4 data collection and analysis that informed the design of QualDash and the design of evaluation. ME
5 developed the QualDash software and contributed to the design of the evaluation. RP and RF provided
6 data for the testing of QualDash and provided significant feedback on its design. All authors provided
7 input into various aspects of the evaluation design and revised drafts of the protocol. RR led the writing
8 of this protocol manuscript. All authors read and approved the final manuscript.

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11 Delivery Research (HS&DR) Programme (project number 16/04/06).

12 **Competing interests statement**

13 Chris Gale is a member of the MINAP Academic and Steering Groups. Richard Feltbower is Principal
14 Investigator for PICANet and Roger Parslow was previously Principal Investigator for PICANet. The
15 authors have no other competing interests to declare.

16 **Additional files**

- 17 Additional file 1: Checklist of RAMESES II reporting standards for realist evaluations (PDF)
18 Additional file 2: Context Mechanism Outcome configurations to be tested in the realist feasibility
19 evaluation (PDF)
20 Additional file 3: Sample size calculations for controlled interrupted time series (PDF)

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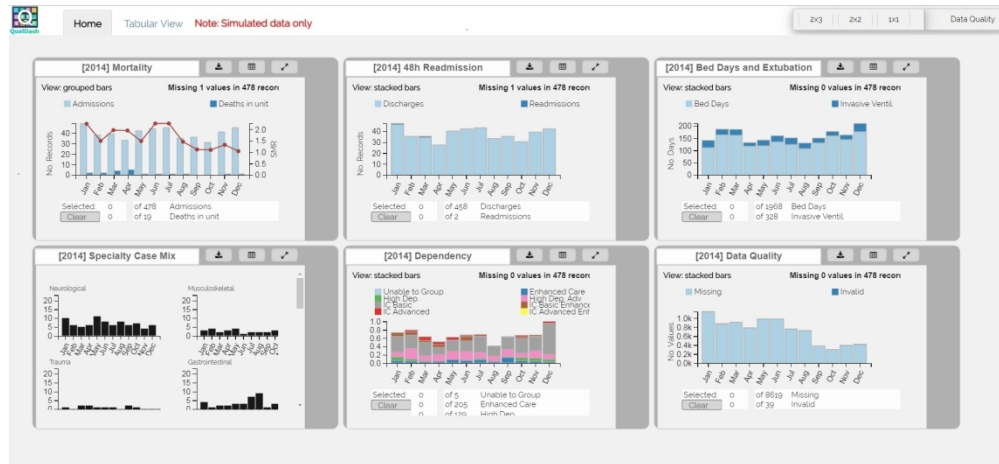


Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using simulated data).

161x74mm (300 x 300 DPI)



Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the Mortality QualCard expanded (using simulated data).

161x85mm (300 x 300 DPI)

RAMESES II reporting standards for realist evaluations

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation			Reported in document Y/N/NA	Page(s) in document	Comment
1		In the title, identify the document as a realist evaluation	Y	1	
SUMMARY OR ABSTRACT					
2		Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions Where journals require it and the nature of the study is appropriate, brief details of respondents to the	Y	3	

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		<p>evaluation and recruitment and sampling processes may also be included</p> <p>Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined</p>			
INTRODUCTION					
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	7	
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	8 and Additional file 2	Placed in body of article, rather than Introduction, as more appropriate for protocol
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	7	
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant	Y	15	

		authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why			
METHODS					
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	7-8	
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	8-9	
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	5-7	Description of intervention placed in Introduction as this seemed more appropriate in providing the context for the protocol
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation	Y	7-14	

		design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist			
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	9-11	
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	8-9	Sampling of sites, rather than individuals, is described; Recruitment will be described when reporting the results of the study
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of	Y	11-12, 13-14	

		analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded			
RESULTS					
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	NA		Protocol so no results to report
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	NA		Protocol so no results to report
DISCUSSION					
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	NA		Protocol so no results to report
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be	4		Strengths and limitations of study design

		<p>limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged</p> <p>In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions</p>			
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NA		Protocol so no results to compare with existing literature
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NA		Protocol so no results on which to base recommendations
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the	Y	16	

		funder (if any) and any conflicts of interests of the evaluators			
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For peer review only

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How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation
(Randell et al.)

Additional file 2

#	Context	+	Resource	Mechanism	Response	=	Outcome
1.	Teams previously constrained in their ability to use NCA data for monitoring service performance because data not considered to be timely, accurate, and/or complete	+	QualDash offers easy access to key metrics	Teams are able to see whether the data displayed are timely, accurate, and/or complete and, where they are not, adjust their data collection processes in order to benefit from QualDash	Teams use QualDash to embed NCA data within their monitoring processes e.g. in clinical governance meetings where data is presented visually via screens.	=	Improvement in data quality in terms of timeliness, accuracy, and completeness – as data quality improves, use of QualDash increases
2.	Teams previously using NCA data to monitor service performance routinely by extracting raw data and producing reports for review in meetings and by individuals	+	QualDash visualises key metrics in ways that clearly show whether service performance is within an expected range and provides functions to interrogate that data	Teams use QualDash to facilitate their existing processes for monitoring service performance using NCA data		=	Increased routine use of NCA data in performance monitoring, providing opportunities for its use in quality improvement
						=	Reduced time spent in accessing, and preparing visualisations of, NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
3.	Teams who want to use NCA data but were previously constrained by data quality and existing systems did not provide functions to easily access and interact with the data	+	QualDash provides functions that enable users to interact with NCA data and explore relationships between variables	Teams will use these functions to interrogate anomalies in the data, which will help them to understand what has impacted performance, thereby enabling them to identify appropriate strategies for improving performance		=	Introduction of QI initiatives in relation to metrics that teams consider important and where performance is not in line with expectations Over time, improvement in metrics that QI initiatives target
4.	Performance in key metrics, such as the Best Practice Tariff, is in line with expectations Relevant audit/IT support staff have time and willingness to support use of QualDash	+	QualDash offers teams the ability to quickly and easily add new QualCards (within NCA parameters)	Teams add new QualCards to be able to monitor and interrogate metrics they have chosen as important		=	Introduction of QI initiatives in relation to metrics shown on new QualCards when performance is not in line with expectations Over time, improvement in metrics that QI initiatives target

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#	Context	+	Resource	Mechanism	Response	=	Outcome
5.	Teams who previously did not, or were not able to, monitor key metrics routinely Performance is not in line with expectations in key metrics Teams are resourced to make practice changes	+	QualDash provides quick and easy access to key metrics	Teams will become aware of discrepancies between performance and targets in key metrics, which they will take action to address		=	Introduction of QI initiatives in relation to key metrics Over time, improvement in those metrics
6.	Teams are asked to produce reports and recommendations for managers and other groups about service performance, e.g. at the time of publication of NCA annual report	+	QualDash offers easy access to NCA data and visualisations that can be exported into reports	Teams will use QualDash to produce performance reports requested by other groups		=	Reduced time spent in report preparation Increased use of NCA data at divisional and corporate levels via outputs produced by QualDash Over time, use of QualDash at divisional and/or corporate levels, due to increased awareness of NCA data

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#	Context	+	Resource	Mechanism	Response	=	Outcome
7.	Teams receive data requests from service managers	+	QualDash can be easily accessed via the web by multiple users	Service managers will use QualDash to access the information they need quickly and easily		=	Streamlines the use of NCA data for clinical managers Reduced time spent by audit support staff/clinical team in producing data reports for managers
8.	Teams need to evidence their performance to managers and other groups in order to support a case for practice change e.g. in business meetings with managers or in the NCA annual report summary	+	QualDash visualises performance metrics, which can also be exported into reports and presentations	Teams will use these functions to evidence service performance, in order to convince other Trust groups that change is needed		=	Other Trust groups, who are able to offer additional resource to teams, are convinced of the need for change based on the evidence provided. However, this is likely to be where those outputs are clearly associated with Trust priorities, e.g. relating to Trust reputation or avoiding penalties/gaining incentives.

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3 **How, in what contexts, and why do quality dashboards lead to improvements in care quality in**
4 **acute hospitals? Protocol for a realist feasibility evaluation (Randell et al.)**

5
6 **Additional file 3**
7
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9 The average CMOC for patients on a ward will be averaged for each month, so that there are 36
10 observations clustered within each of 15 hospitals. Taking the intra-class correlation to be 0.15, this
11 yields a design effect of 6.25. Hence the effective number of observations is $15 \times 36 / 6.25 = 86.4$. Using
12 Cohen's approach to sample size calculation means an effect size of 0.17 can be estimated with 80%
13 given that there are six parameters in the model (including the coefficient for QualDash). Converting
14 this to the percentage of variation that can be explained by the model, this yields 20.5%. Translating
15 this back to CMOC, currently 49.6% of patients are discharged from hospital without missing any of
16 the nine opportunities for care, and we would be powered at the 80% level to detect an improvement
17 from an average of 8.33 opportunities achieved to 8.46. Thus our study has good power to detect
18 small but meaningful clinical improvements. For PICANet, 10% of the admitted population receive
19 non-invasive ventilation first [1]. On average there are 5.25 ventilation cases per month per hospital.
20 With a further design effect from patients clustered within hospitals, based on the reported intraclass
21 correlation coefficient of 0.065 giving a design effect of 1.276, the actual anticipated number of
22 patients is 1701 giving an effective number of 213: 71 exposed to QualDash and 142 controls. This
23 yields 80% power to detect a change from 32% to 53%.
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BMJ Open

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation

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3 1 **Title: How, in what contexts, and why do quality dashboards lead to improvements in care**
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5 2 **quality in acute hospitals? Protocol for a realist feasibility evaluation**
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1 **ABSTRACT**

2 **Introduction:** National audits are used to monitor care quality and safety and are anticipated to reduce
3 unexplained variations in quality by stimulating quality improvement. However, variation within and
4 between providers in the extent of engagement with national audits mean that the potential for national
5 audit data to inform quality improvement is not being realised. This study will undertake a feasibility
6 evaluation of QualDash, a quality dashboard designed to support clinical teams and managers to
7 explore data from two national audits, the Myocardial Ischaemia National Audit Project (MINAP) and
8 the Paediatric Intensive Care Audit Network (PICANet).

9 **Methods and analysis:** Realist evaluation, which involves building, testing, and refining theories of
10 how an intervention works, provides an overall framework for this feasibility study. Realist hypotheses
11 that describe how, in what contexts, and why QualDash is expected to provide benefit will be tested
12 across five hospitals. A controlled interrupted time series analysis, using key MINAP and PICANet
13 measures, will provide preliminary evidence of the impact of QualDash, while ethnographic
14 observations and interviews over 12 months will provide initial insight into contexts and mechanisms
15 that lead to those impacts. Feasibility outcomes include the extent to which MINAP and PICANet data
16 are used, data completeness in the audits, and the extent to which participants perceive QualDash to
17 be useful and express the intention to continue using it after the study period.

18 **Ethics and dissemination:** The study has been approved by University of Leeds School of Healthcare
19 Research Ethics Committee. Study results will provide an initial understanding of how, in what contexts,
20 and why quality dashboards lead to improvements in care quality. These will be disseminated to
21 academic audiences, study participants, hospital IT departments, and national audits. If results show a
22 trial is feasible, we will disseminate the QualDash software through a stepped wedge cluster
23 randomised trial.

24 **Trial registration:** ISRCTN18289782

26 **Keywords:** Dashboard, audit and feedback, quality improvement, realist evaluation

28 **Word count:** 4,218

ARTICLE SUMMARY

Strengths and limitations of this study

- This study will assess the feasibility of a trial of QualDash, a quality dashboard; if a trial is feasible, the findings will be used to inform the design of the definitive trial, determining the components of QualDash to be preserved, appropriate outcome measures, and the contexts in which the trial should be undertaken.
- Through a controlled interrupted time series study and qualitative multi-site case study, the study will also provide an initial understanding of whether use of a quality dashboard leads to quality improvement, how, in what contexts, and why.
- The study will contribute to understanding of how realist methods can contribute to feasibility studies and the design of trials.
- Issues of data quality may be a limitation of the controlled interrupted time series study; data completeness, and whether this changes over the course of the study, will be assessed.

INTRODUCTION

National clinical audits (NCAs), which provide comparative data on the performance of healthcare providers, are one means by which health systems around the world monitor care quality and safety. In England, a programme of over 30 NCAs is managed by the Healthcare Quality Improvement Partnership (HQIP) and all healthcare providers that contribute to delivery of the National Health Service (NHS) are required to participate. Such audits are anticipated to reduce unexplained variations in healthcare quality by stimulating quality improvement (QI) [1 2]. While there is evidence of positive impacts of NCAs [3-5], variation within and between providers in the extent to which they engage with NCAs mean the potential for NCA data to inform QI is not being realised [6 7].

Quality dashboards are a form of audit and feedback (A&F) that provide visualisations of audit data with the aim of informing QI efforts [8]. Healthcare providers are increasingly using quality dashboards. For example, quality dashboard use has been reported in Canada [9], the UK [10], and the Netherlands [11]. While quality dashboards have been shown to have positive effects on some performance indicators [9], empirical evidence regarding their impact remains limited [12].

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3 **QualDash**

4 QualDash is an interactive web-based quality dashboard designed to support clinical teams and
5 managers to explore data from two national audits, the Myocardial Ischaemia National Audit Project
6 (MINAP) and the Paediatric Intensive Care Audit Network (PICANet), for the purpose of QI (Fig. 1).
7 Information used to inform design of QualDash was collected through interviews with 50 clinicians and
8 managers across five NHS Trusts (providers) and four healthcare commissioners, observations of
9 meetings where audit data are discussed, a workshop with NCA suppliers, and two co-design
10 workshops with clinicians and managers from one Trust.

11

12 Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using
13 simulated data).

14 [Figure 1 should go approximately here]

15

16 The interviews revealed that use of NCA data is largely at the clinical team level, with more limited use
17 at divisional and corporate (Board and sub-committees that report to the Board, such as Quality and
18 Safety Committees) levels. At all levels, a key constraint in use of NCA data for QI is lack of access to
19 timely data; there was consensus among interviewees that data should not be more than three months
20 old. QualDash seeks to improve access to timely data, providing users with a means to visualise the
21 data they collect for the NCAs, without having to wait for data to be returned to them from the NCAs.

22 There is variation between Trusts in the extent to which NCA data are used, often related to resources,
23 which in turn impacts on timeliness of data; Trusts that make greater use of NCA data tend to have
24 local databases from which they can generate visualisations of the data (e.g. bar charts) and audit
25 support staff who have the time and skills to be able to generate such visualisations. In contrast, where
26 such resources are not available, Trusts rely on the NCA annual reports, where data may be 15 months
27 old (e.g. one annual report published in June 2017 reported data from April 2015 to March 2016).

28 QualDash provides visualisations of key metrics, each metric being represented within a 'QualCard'
29 (Fig. 2), enabling Trusts to use NCA data for QI, regardless of existing resources. QualCards for MINAP

60

1 and PICANet are listed in Table 1; while there is only one set of QualCards for PICANet, for MINAP an
 2 additional QualCard is provided for teaching hospitals, as discussions with sites revealed that the
 3 metrics of interest are different between teaching hospitals and District General Hospitals (DGHs). Sites
 4 are also able to create additional QualCards, to reflect local priorities.

5
 6 Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the
 7 Mortality QualCard expanded (using simulated data).

8 [Figure 2 should go approximately here]

9
 10 Table 1: QualCards

	Metric
MINAP – all sites	Mortality Door (arrival in Accident and Emergency) to angiogram time Gold standard drugs on discharge Referral for cardiac rehabilitation Acute use of aspirin
MINAP teaching hospital specific	Call (by patient/relative to emergency services) to balloon (percutaneous coronary intervention) time
PICANet – all sites	Mortality 48 hour unplanned readmission Bed days and accidental extubation Specialty case mix Data quality (number of records with a missing value) Patient dependency

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 13 To load new data into QualDash, NCA data are either extracted from the site's database or downloaded
 14 from the NCA website and then fed to a small script (written in R), which in turn updates the dashboard.
 15 Users can add new data as often as they want, but at a minimum they will load data into QualDash at
 16 the same time as uploading to the NCAs (typically every three months).

17
 18 The benefits perceived from using QualDash may vary between sites, with under-resourced sites that
 19 previously made little use of NCA data for QI perceiving greater impact than those that already have
 20 the means to use NCA data for QI. There are also constraints on use of NCA data for QI that it may be
 21 difficult for QualDash to address. For example, in some Trusts, clinical team members perceive that
 22 relevant managers will not agree to provide the resources necessary for QI initiatives, which reduces
 23 motivation to engage with NCA data and may affect the extent to which QualDash is used. However,

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3 1 QualDash provides means for visualisations to be downloaded and incorporated into presentations and
4 reports, which may support clinical teams in making a stronger case for QI initiatives. Another constraint
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6 on use of NCA data for QI relates to clinicians' trust in the quality of the data. Interviews revealed
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8 variations across sites in processes for ensuring data quality. However, some interviewees also
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10 suggested that having the means to make more use of NCA data via QualDash would motivate them
11 5
12 to improve their processes for ensuring data quality, although this will be dependent on local resources.
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16 8 In this paper, we describe the methods for a realist feasibility evaluation of QualDash. The study
17 9
18 objectives are:
19 9

- 20 10 1. To develop an initial understanding of how, in what contexts, and why use of QualDash leads to QI;
- 21 11 and
- 22 11 2. To assess the feasibility of conducting a trial of QualDash.
- 23 12
- 24 12
- 25 12

26 13 As no checklists exist for reporting of realist evaluation protocols, in presenting this protocol we draw
27 14
28 on the RAMESES II reporting standards for realist evaluations [13] (Additional file 1).
29 14
30 15

31 16 **METHODS AND ANALYSIS**

32 17 **Study design**

33 18 Use of theory is needed for design and evaluation of A&F interventions [14-16], and QI initiatives more
34 19
35 generally [17-19]. This project draws on Realist Evaluation (RE), which involves building, testing, and
36 20
37 refining theories about how an intervention is supposed to work [20]. These theories are expressed in
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39 the form of Context Mechanism Outcome (CMO) configurations, where C+M=O, reflecting the realist
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41 understanding that it is recipients' responses to the resources that an intervention provides (the
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43 intervention mechanisms) that determine the impact of the intervention, and such responses are highly
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45 influenced by context [21]. Consequently, RE seeks to answer not only the question of 'what works?'
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47 but 'what works for whom, in what circumstances, and why?' [22]. It is concerned with both intended
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49 and unintended outcomes. RE is recommended for studying QI [23] and has been used for studying
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51 the implementation and impact of large-scale QI programmes [24]. There is increasing interest in use
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53 of realist methods in feasibility evaluations [25-27].
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3 1 We have drawn on a range of sources to develop CMO configurations which describe how, in what
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5 2 contexts, and why use of QualDash is anticipated to lead to QI (see Additional file 2). Data generated
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7 3 from the interviews, observations, and workshops described above have been essential to this, as have
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9 4 discussions with the designers of QualDash (ME and RAR) who, drawing on their expertise in
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11 5 information visualisation, have their own literature-informed theories regarding why certain features of
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13 6 QualDash will provide benefit to users [28 29]. We have also drawn on substantive theories regarding
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15 7 how A&F lead to QI at the micro [30 31], meso [32], and macro level [33 34].
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19 9 Data collection is designed to enable testing of the CMO configurations. Outcome data, in the form of
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21 10 key MINAP and PICANet measures, will be collected and analysed in a controlled interrupted time series
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23 11 (CITS) study, while a multi-site case study [35] will provide an initial understanding of the contexts and
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25 12 mechanisms that lead to those outcomes, as well as providing data on intermediate outcomes such as
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27 13 increased use of NCA data. A&F interventions, and QI interventions more generally, require longitudinal
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29 14 evaluation to allow sufficient time for staff to implement changes and incorporate them into their practice
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31 15 [36-38]. Similarly, evaluation of health IT (HIT) should allow time for staff to integrate the technology into
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33 16 their practices and evolve those practices to take advantage of the functionality offered by the technology
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35 17 [39]. Therefore, data will be collected over a 12 month period, from August 2019.
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19 **Public and patient involvement**

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21 20 A Lay Advisory Group has been established, which has contributed to the design of QualDash by
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23 21 reviewing the topic guide for the interviews that were conducted, providing their perspective on the
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25 22 findings of the interview study, and participating in the usability evaluation of QualDash. For the realist
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27 23 feasibility evaluation, they have provided advice on aspects to pay attention to when undertaking
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29 24 observations. They will contribute to analysis of a sample of the qualitative data, to provide a patient
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31 25 perspective. They will advise on dissemination of findings to relevant interest groups and will review
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33 26 outputs for comprehensibility.
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28 **Setting/context**

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30 29 The feasibility study will be conducted in the five NHS acute Trusts in which the interview study that
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32 30 informed the design of QualDash was undertaken. Three Trusts are teaching hospitals that participate
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3 1 in both MINAP and PICANet and have been selected to ensure variation in key outcome measures
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5 2 (MINAP: 30-day mortality for patients hospitalised with ST-elevation myocardial infarction; PICANet:
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7 3 risk adjusted standardised mortality ratio). Two Trusts are DGHs that participate in MINAP but do not
8
9 4 have a PICU and so do not participate in PICANet. These have been selected to ensure variation in the
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11 5 same key MINAP measure.
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14 7 **Multi-site case study**

16 8 In the multi-site case study, data will be collected through ethnographic observation and interviews.
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18 9 Ethnographic methods have been argued as essential for studying implementation of QI interventions
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20 10 [19] and introduction of HIT [40]. Ethnography is well suited to RE because it involves observing
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22 11 phenomena in context, supporting understanding of how context influences the response to an
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24 12 intervention [41]. We will follow the Biography of Artefacts approach [42], which is concerned with
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26 13 capturing how particular contexts and appropriations of a technology lead to different processes and
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28 14 generate different outcomes, a parallel to RE's concern with contexts, mechanisms, and outcomes [43].
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30 15 It involves longitudinal 'strategic ethnography' [42], where data collection is guided by a provisional
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32 16 understanding of the moments and locales in which a technology and associated practices evolve [43].
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35 18 **Data collection**

37 19 In the three teaching hospitals, we will undertake a minimum of 24 periods of observation per Trust, to
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39 20 be split across activities related to cardiology and the PICU, and in the two DGHs we will undertake a
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41 21 minimum of 12 periods of observation per Trust, to be spent observing activities related to cardiology.
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43 22 Each period of observation will be a minimum of four hours (total n=384 hours). While researchers will
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45 23 return to each Trust monthly, to understand how use of QualDash changes over time, more time will be
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47 24 spent in the first few months following the introduction of QualDash, because this is when users are
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49 25 most likely to engage with and explore the affordances of QualDash and establish new practices around
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51 26 it, generating information with implications for system enhancement [43]. Observations will be
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53 27 scheduled to take place at different times of day and on different days of the week, to ensure the account
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55 28 of what is observed is as complete and representative as possible [44].
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3 1 At each case site, an initial phase of general observation will provide an opportunity for researchers to
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5 2 become familiar with the setting and for those in the setting to become familiar with the presence of the
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7 3 researchers. Following a previous study of dashboards [10], observations will be undertaken in clinical
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9 4 areas to understand clinical teams' working practices and capture 'corridor committees' where issues
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11 5 of quality and safety are discussed more informally [45]. In the PICUs, initial observations will take place
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13 6 on the PICU, e.g. with the researchers positioning themselves by the nurses' station, as well as
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15 7 observing handovers, safety huddles, and ward rounds. Because activities related to cardiology tend to
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17 8 be more dispersed across hospitals, researchers will first shadow clinical team members (consultant
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19 9 cardiologists and acute chest pain nurses) to determine where it is most appropriate to conduct
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21 10 subsequent observations. These initial observations will also be used to record general details of the
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23 11 setting that may influence QualDash use, such as staffing levels and availability of computers.
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26 13 After this initial phase, observation will be guided by the CMO configurations under investigation. In
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28 14 addition to observing formal meetings where quality and safety are discussed, predominantly at ward
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30 15 level but also at divisional and corporate level, observation will involve shadowing staff members as
31
32 16 they undertake particular activities: collection and entry of NCA data, to see if and how this changes
33
34 17 over time; accessing and interrogating NCA data, whether using QualDash or some other means;
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36 18 preparation of reports and/or presentations using NCA data, again whether using QualDash or some
37
38 19 other means. Where visualisations from QualDash are incorporated into presentations and written
39
40 20 reports, we will follow the path of those documents, to identify staff members who may not use
41
42 21 QualDash directly but are receiving QualDash outputs. Attention will be paid to how, in what contexts,
43
44 22 and why QualDash and QualDash outputs are used or not, understood in the context of broader
45
46 23 practices and use of other sources of information for monitoring care quality, and how this changes over
47
48 24 time. We will also follow local QI initiatives, recording data on, for example, when and how the need for
49
50 25 the QI initiative was identified, contextual factors that appear to support and constrain its introduction,
51
52 26 how the impact of the QI initiative is monitored, and other contextual factors that appear to influence
53
54 27 the metric that the QI initiative is targeting. Researchers will record observations in fieldnotes, which
55
56 28 will be written up in detail as soon after data collection as possible.
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3 1 Brief interviews will be undertaken opportunistically during the course of conducting observations to
4
5 2 clarify aspects of practice that are not immediately intelligible to an observer, with participant responses
6
7 3 recorded in fieldnotes [46]. As data collection progresses, longer semi-structured interviews will be used
8
9 4 to discuss revisions to our CMO configurations. These will be undertaken using a particular approach
10
11 5 from RE, referred to as the teacher-learner cycle, whereby the theories under investigation are made
12
13 6 explicit to the interviewee so that the interviewee can use their experiences to refine the researcher's
14
15 7 understanding [47]. Being concerned with the reasoning of intervention recipients, mechanisms are
16
17 8 often not observable [21], so these longer interviews will also provide the opportunity to explore staff
18
19 9 reasoning about QualDash. These longer interviews will be audio recorded and transcribed verbatim.
20

21
22 11 Logfiles are widely used to evaluate visualisation tools [48]. QualDash logfiles will record information
23
24 12 about the user (job title, etc.), data used (audit, year), overall time spent using QualDash, time spent
25
26 13 interacting with different QualCards (including new QualCards that have been created), functionality
27
28 14 used, and whether QualDash visualisations were downloaded. In addition to providing data regarding
29
30 15 extent of QualDash use, how QualDash is used and by whom, and how this changes over time,
31
32 16 information from logfiles will be used to inform qualitative data collection (e.g. asking in interviews why
33
34 17 participants use particular QualCards and not others and the motivation behind the creation of new
35
36 18 QualCards).
37

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39
40 20 At the end of the data collection period, we will ask participants to complete a questionnaire based on
41
42 21 the Technology Acceptance Model, using well validated items that have been used in numerous
43
44 22 evaluations of HIT [49], including dashboards [50]. This will provide participants' perceptions of the
45
46 23 usefulness of QualDash and data on whether they intend to continue using QualDash after the study
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48 24 period.
49

50 51 26 **Analysis**

52
53 27 An iterative approach to data collection and analysis will be taken, to enable: ongoing testing and
54
55 28 refinement of the CMO configurations; gathering of further data in light of such revisions; and refinement
56
57 29 of QualDash in response to participants' feedback. Fieldnotes and interview transcripts will be entered
58
59 30 into NVivo 11. Narrative analysis will be undertaken to develop a 'biography' of QualDash, which will
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3 1 describe use of QualDash and its outputs by a range of stakeholders at different levels (clinical team,
4
5 2 divisional, and corporate) and the interconnections between them [10]. Narrative analysis is consistent
6
7 3 with a realist approach due to its emphasis on preserving connections within the data, thereby helping
8
9 4 to understand causality [51]. This analysis will be supplemented with analysis of the logfiles and
10
11 5 questionnaire data. Findings will be compared with the CMO configurations, to determine whether they
12
13 6 support, refute, or suggest a revision or addition to the CMO configurations.
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15 7

8 **Controlled interrupted time series study**

9 Interrupted time series studies provide a robust method of assessing the effect of an intervention and
10
11 10 have been used to assess effectiveness of a variety of complex interventions [52]. In a CITS, the
12
13 11 addition of a control group enhances causal inference because the presence of seasonal trends and
14
15 12 other potential time-varying confounders can be assessed [53]. Data will be collected across the five
16
17 13 Trusts, with two control Trusts per intervention Trust, providing a total of 10 control Trusts. Control
18
19 14 Trusts will be matched according to their size and outcomes pre-intervention. Having more than one
20
21 15 control site per intervention site increases power but, as the number of control sites per intervention site
22
23 16 increases, quality of matching decreases. Therefore, we have chosen to have two control Trusts per
24
25 17 intervention Trust to increase power while maintaining quality of the matching.
26
27 18

19 Given the study intention to determine the feasibility of and inform the design of a trial, a range of
20
21 20 measures will be considered. Initially, we selected two process measures, one for MINAP and one for
22
23 21 PICANet. For MINAP, we selected the composite process measure Cumulative Missed Opportunities
24
25 22 for Care (CMOC). This has nine components (pre-hospital ECG, acute use of aspirin, timely perfusion,
26
27 23 referral for cardiac rehabilitation, and prescription at hospital discharge of what are considered to be
28
29 24 the gold standard drugs – aspirin, thienopyridine inhibitor, ACE-inhibitor, HMG-CoA reductase inhibitor,
30
31 25 and beta blockers) and is inversely associated with mortality [54]. As some of these components, such
32
33 26 as pre-hospital ECG, are outside the direct control of the Trust, we will also explore the impact of
34
35 27 QualDash on the individual measures that make up CMOC. On the basis of the measures that
36
37 28 cardiology clinicians described in the interviews as being important for measuring care quality, we will
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39 29 also look at the percentage of patients who receive an angiogram within 72 hours from first admission
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41 30 to hospital, which is part of the Best Practice Tariff financial incentive scheme, and, for those hospitals
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3 1 that provide percutaneous coronary intervention (PCI), the proportion of patients who have a door-to-
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5 2 balloon time (the time from arrival at the hospital to PCI) of less than 60 minutes. Our CMO
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7 3 configurations (Additional file 2) suggest improvement will be seen in measures if: clinical teams
8
9 4 perceive them as being important indicators of care and/or they relate to financial incentives;
10
11 5 performance is not in line with expectations; they perceive the measure as being within their control;
12
13 6 and the team is resourced to introduce QI initiatives in relation to these measures.
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15 7

16 8 For PICANet, we selected use of non-invasive ventilation first for patients requiring ventilation, which
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18 9 has been shown to be associated with reduced mortality [55]. However, this was not raised as an area
19
20 10 of concern in our interviews with PICU clinicians. On the basis of this and two additional considerations
21
22 11 – it would require loading additional data into QualDash which would reduce the performance of
23
24 12 QualDash in terms of speed and it requires computation of the data, while the focus of QualDash is on
25
26 13 visualising the data – a QualCard has not been created for this metric. Therefore, while we will still
27
28 14 include this measure in the CITS, we do not hypothesise that it will change, unless other sources of
29
30 15 information, such as the PICANet annual report, draw a PICU team's attention to it. However, accidental
31
32 16 extubation and unplanned readmission within 48 hours were identified in our interviews with PICU
33
34 17 clinicians as being important indicators of care quality, so we will include these two measures in the
35
36 18 CITS. On the basis of our CMO configurations (Additional file 2), we would expect to see an
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38 19 improvement in these measures in sites where performance is not in line with expectations, if the team
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40 20 is resourced to introduce QI initiatives in relation to these measures.
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43 22 ***Sample size considerations***

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3 1 A CITS study requires data for a minimum of three time points pre-intervention and three time points
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5 2 post-intervention and must also allow for any seasonal effect on the outcomes [56]. Monthly data will
6
7 3 be obtained for 24 months pre-intervention and 12 months post-intervention. Consequently, for each
8
9 4 intervention Trust, there will be 72 data points prior to introduction (24 for the intervention Trust and 48
10
11 5 for the control Trusts) and 36 data points post intervention (12 for the intervention Trust and 24 for the
12
13 6 control Trusts). Sample size calculations were undertaken based on our two initial measures, CMOC
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15 7 for MINAP and use of non-invasive ventilation first for patients requiring ventilation for PICANet; full
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17 8 details are provided in Additional file 3.
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19 9

10 **Analysis**

11 Monthly MINAP and PICANet data will be extracted to spreadsheets for analysis with R software [57].
12 For both NCAs, each outcome will be regressed upon time and the intervention. The time component
13 will include a seasonal effect (quarterly effect) and will allow for a (linear) time trend. To account for
14 clustering of monthly observations within hospitals, a random intercept will be fitted, although a fixed
15 effect for hospital as a sensitivity analysis will be explored. Although the intervention is abrupt, its impact
16 may well be 'phased in' over a few months, perhaps three. The timing of the bedding in of the
17 intervention will be reported from the multi-site case study. Then a partial effect can be considered for
18 this period with the interaction effect stepping up in a linear fashion.
19

20 Results of the CITS analysis will be incorporated into the biography of QualDash, the analysis of the
21 data from the multi-site case study describing how contextual factors shape the evolution of practices
22 around QualDash and how this leads to the resulting outcome pattern.
23

24 **Trial feasibility assessment and design**

25 Our trial progression criteria are: (i) the number of people who engage with either MINAP or PICANet
26 data (via QualDash or some other means) is the same or higher than the number of people who engaged
27 with either MINAP or PICANet data prior to QualDash's introduction; (ii) data completeness in the national
28 audit improves or remains the same; (iii) 50% or more of participants in the questionnaire survey perceive
29 QualDash to be useful and express the intention to continue using it after the study period. Criteria (i)
30 and (ii) are concerned with ensuring the intervention does not have unintended negative consequences
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3 1 which would affect success of the intervention. Criterion (ii) is also concerned with feasibility of outcome
4 assessment. Criterion (iii) is concerned with acceptability and uptake of the intervention, and therefore
5 2
6 3 has implications for recruitment to a trial, as well as being concerned with participants' perceptions of the
7 4
8 5 impact of QualDash on care. While not formally assessed as part of the progression criteria, the impact
9 6
10 7 of QualDash on care as identified in the CITS will be considered in determining whether a future trial is
11 8
12 9 justified. A traffic light system will be used to determine if a trial is feasible (green), feasible with
13 10
14 11 modifications to QualDash (amber), or not feasible (red) [58 59].
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20 9 If the results show a trial of QualDash is feasible, we will design a stepped wedge cluster randomised
21 10
22 11 trial. Data from the CITS will be used to inform the selection of NCAs to be included in the trial (MINAP
23 12
24 13 and/or PICANet) and will provide information about variability of outcomes and about how long a trial
25 14
26 15 intervention period would need to be. Findings from the multi-site case study will be used to inform the
27 16
28 17 selection of categories of user to be included in the trial and, associated with this, the level of
29 18
30 19 randomisation (Trust, hospital, or ward). Using the understanding of the relationship between contexts,
31 20
32 21 mechanisms, and outcomes provided by the study, we will identify QualDash components associated
33 22
34 23 with mechanisms that produce the desired outcomes in order for them to be preserved in the trial, while
35 24
36 25 other components can be adapted to suit the local context.
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19 **ETHICS AND DISSEMINATION**

20 Ethics approval has been received from the University of Leeds School of Healthcare Research Ethics
21 Committee (Approval no.HREC16-044). Written consent will be obtained from participants for interviews
22 and for meeting observations.
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24 Study results will provide initial understanding of how and in what contexts quality dashboards may lead
25 to improvements in care quality. We will disseminate these results to academic audiences, study
26 participants, hospital IT departments, and NCAs. If we progress to a trial, in addition to providing further
27 understanding of the impact of quality dashboards on care quality, this will result in wider dissemination
28 of the QualDash software.
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6
7 3 are those of the presenter and do not necessarily reflect those of the HS&DR programme, NIHR, NHS
8
9 4 or the Department of Health.

10 5

11 6 **Data statement**

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14 7 The qualitative data gathered during the course of this evaluation will be kept until June 2030 and can
15
16 8 be accessed by other researchers during this time, subject to the necessary ethical approvals being
17
18 9 obtained. Requests for access to this data should be addressed to the corresponding author.

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22 11

1 **Authors' contributions**

2 RR is Principal Investigator for the study. She conceived, designed, and secured funding for the study
3 in collaboration with JG, RW, AF, CPG, RP, JK, RAR, JL, MM, and DD. NA and LM led the qualitative
4 data collection and analysis that informed the design of QualDash and the design of evaluation. ME
5 developed the QualDash software and contributed to the design of the evaluation. RP and RF provided
6 data for the testing of QualDash and provided significant feedback on its design. All authors provided
7 input into various aspects of the evaluation design and revised drafts of the protocol. RR led the writing
8 of this protocol manuscript. All authors read and approved the final manuscript.

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14 **Competing interests statement**

15 Chris Gale is a member of the MINAP Academic and Steering Groups. Richard Feltbower is Principal
16 Investigator for PICANet and Roger Parslow was previously Principal Investigator for PICANet. The
17 authors have no other competing interests to declare.

19 **Additional files**

20 Additional file 1: Checklist of RAMESES II reporting standards for realist evaluations (PDF)

21 Additional file 2: Context Mechanism Outcome configurations to be tested in the realist feasibility
22 evaluation (PDF)

23 Additional file 3: Sample size calculations for controlled interrupted time series (PDF)

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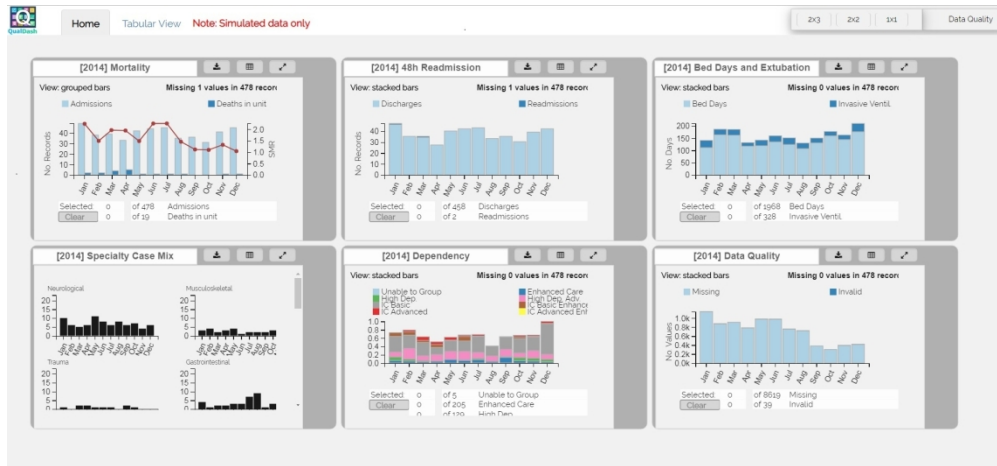


Fig. 1: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network (using simulated data).

161x74mm (300 x 300 DPI)



Fig. 2: Prototype of main dashboard view for the Paediatric Intensive Care Audit Network with the Mortality QualCard expanded (using simulated data).

161x85mm (300 x 300 DPI)

RAMESES II reporting standards for realist evaluations

How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation			Reported in document Y/N/NA	Page(s) in document	Comment
1		In the title, identify the document as a realist evaluation	Y	1	
SUMMARY OR ABSTRACT					
2		<p>Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions</p> <p>Where journals require it and the nature of the study is appropriate, brief details of respondents to the</p>	Y	3	

		<p>evaluation and recruitment and sampling processes may also be included</p> <p>Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined</p>			
INTRODUCTION					
3	Rationale for evaluation	Explain the purpose of the evaluation and the implications for its focus and design	Y	7	
4	Programme theory	Describe the initial programme theory (or theories) that underpin the programme, policy or initiative	Y	8 and Additional file 2	Placed in body of article, rather than Introduction, as more appropriate for protocol
5	Evaluation questions, objectives and focus	State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation	Y	7	
6	Ethical approval	State whether the realist evaluation required and has gained ethical approval from the relevant	Y	15	

		authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why			
METHODS					
7	Rationale for using realist evaluation	Explain why a realist evaluation approach was chosen and (if relevant) adapted	Y	7-8	
8	Environment surrounding the evaluation	Describe the environment in which the evaluation took place	Y	8-9	
9	Describe the programme policy, initiative or product evaluated	Provide relevant details on the programme, policy or initiative evaluated	Y	5-7	Description of intervention placed in Introduction as this seemed more appropriate in providing the context for the protocol
10	Describe and justify the evaluation design	A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation	Y	7-14	

		design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist			
11	Data collection methods	Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory Provide details of the steps taken to enhance the trustworthiness of data collection and documentation	Y	9-11	
12	Recruitment process and sampling strategy	Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory	Y	8-9	Sampling of sites, rather than individuals, is described; Recruitment will be described when reporting the results of the study
13	Data analysis	Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of	Y	11-12, 13-14	

		analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded			
RESULTS					
14	Details of participants	Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory	NA		Protocol so no results to report
15	Main findings	Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme theory	NA		Protocol so no results to report
DISCUSSION					
16	Summary of findings	Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience	NA		Protocol so no results to report
17	Strengths, limitations and future directions	Discuss both the strengths of the evaluation and its limitations. These should include (but need not be	4		Strengths and limitations of study design

		<p>limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged</p> <p>In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions</p>			
18	Comparison with existing literature	Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives	NA		Protocol so no results to compare with existing literature
19	Conclusion and recommendations	List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach	NA		Protocol so no results on which to base recommendations
20	Funding and conflict of interest	State the funding source (if any) for the evaluation, the role played by the	Y	16	

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		funder (if any) and any conflicts of interests of the evaluators			
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How, in what contexts, and why do quality dashboards lead to improvements in care quality in acute hospitals? Protocol for a realist feasibility evaluation

(Randell et al.)

Additional file 2

#	Context	+	Resource	Mechanism	Response	=	Outcome
1.	Teams previously constrained in their ability to use NCA data for monitoring service performance because data not considered to be timely, accurate, and/or complete	+	QualDash offers easy access to key metrics	Teams are able to see whether the data displayed are timely, accurate, and/or complete and, where they are not, adjust their data collection processes in order to benefit from QualDash	Teams use QualDash to embed NCA data within their monitoring processes e.g. in clinical governance meetings where data is presented visually via screens.	=	Improvement in data quality in terms of timeliness, accuracy, and completeness – as data quality improves, use of QualDash increases
2.	Teams previously using NCA data to monitor service performance routinely by extracting raw data and producing reports for review in meetings and by individuals	+	QualDash visualises key metrics in ways that clearly show whether service performance is within an expected range and provides functions to interrogate that data	Teams use QualDash to facilitate their existing processes for monitoring service performance using NCA data		=	Increased routine use of NCA data in performance monitoring, providing opportunities for its use in quality improvement
						=	Reduced time spent in accessing, and preparing visualisations of, NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
3.	Teams who want to use NCA data but were previously constrained by data quality and existing systems did not provide functions to easily access and interact with the data	+	QualDash provides functions that enable users to interact with NCA data and explore relationships between variables	Teams will use these functions to interrogate anomalies in the data, which will help them to understand what has impacted performance, thereby enabling them to identify appropriate strategies for improving performance		=	Introduction of QI initiatives in relation to metrics that teams consider important and where performance is not in line with expectations Over time, improvement in metrics that QI initiatives target
4.	Performance in key metrics, such as the Best Practice Tariff, is in line with expectations Relevant audit/IT support staff have time and willingness to support use of QualDash	+	QualDash offers teams the ability to quickly and easily add new QualCards (within NCA parameters)	Teams add new QualCards to be able to monitor and interrogate metrics they have chosen as important		=	Introduction of QI initiatives in relation to metrics shown on new QualCards when performance is not in line with expectations Over time, improvement in metrics that QI initiatives target

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#	Context	+	Resource	Mechanism	Response	=	Outcome
5.	Teams who previously did not, or were not able to, monitor key metrics routinely	+	QualDash provides quick and easy access to key metrics	Teams will become aware of discrepancies between performance and targets in key metrics, which they will take action to address		=	Introduction of QI initiatives in relation to key metrics Over time, improvement in those metrics
	Performance is not in line with expectations in key metrics						
	Teams are resourced to make practice changes						
6.	Teams are asked to produce reports and recommendations for managers and other groups about service performance, e.g. at the time of publication of NCA annual report	+	QualDash offers easy access to NCA data and visualisations that can be exported into reports	Teams will use QualDash to produce performance reports requested by other groups		=	Reduced time spent in report preparation Increased use of NCA data at divisional and corporate levels via outputs produced by QualDash Over time, use of QualDash at divisional and/or corporate levels, due to increased awareness of NCA data

#	Context	+	Resource	Mechanism	Response	=	Outcome
7.	Teams receive data requests from service managers	+	QualDash can be easily accessed via the web by multiple users	Service managers will use QualDash to access the information they need quickly and easily		=	Streamlines the use of NCA data for clinical managers Reduced time spent by audit support staff/clinical team in producing data reports for managers
8.	Teams need to evidence their performance to managers and other groups in order to support a case for practice change e.g. in business meetings with managers or in the NCA annual report summary	+	QualDash visualises performance metrics, which can also be exported into reports and presentations	Teams will use these functions to evidence service performance, in order to convince other Trust groups that change is needed		=	Other Trust groups, who are able to offer additional resource to teams, are convinced of the need for change based on the evidence provided. However, this is likely to be where those outputs are clearly associated with Trust priorities, e.g. relating to Trust reputation or avoiding penalties/gaining incentives.

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3 **How, in what contexts, and why do quality dashboards lead to improvements in care quality in**
4 **acute hospitals? Protocol for a realist feasibility evaluation (Randell et al.)**

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6 **Additional file 3**
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9 The average CMOC for patients on a ward will be averaged for each month, so that there are 36
10 observations clustered within each of 15 hospitals. Taking the intra-class correlation to be 0.15, this
11 yields a design effect of 6.25. Hence the effective number of observations is $15 \times 36 / 6.25 = 86.4$. Using
12 Cohen's approach to sample size calculation means an effect size of 0.17 can be estimated with 80%
13 given that there are six parameters in the model (including the coefficient for QualDash). Converting
14 this to the percentage of variation that can be explained by the model, this yields 20.5%. Translating
15 this back to CMOC, currently 49.6% of patients are discharged from hospital without missing any of
16 the nine opportunities for care, and we would be powered at the 80% level to detect an improvement
17 from an average of 8.33 opportunities achieved to 8.46. Thus our study has good power to detect
18 small but meaningful clinical improvements. For PICANet, 10% of the admitted population receive
19 non-invasive ventilation first [1]. On average there are 5.25 ventilation cases per month per hospital.
20 With a further design effect from patients clustered within hospitals, based on the reported intraclass
21 correlation coefficient of 0.065 giving a design effect of 1.276, the actual anticipated number of
22 patients is 1701 giving an effective number of 213: 71 exposed to QualDash and 142 controls. This
23 yields 80% power to detect a change from 32% to 53%.
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36 **References**
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- 38 1. Morris JV, Ramnarayan P, Parslow RC, Fleming SJ. Outcomes for Children Receiving Noninvasive
39 Ventilation as the First-Line Mode of Mechanical Ventilation at Intensive Care Admission: A
40 Propensity Score-Matched Cohort Study. *Crit. Care Med.* 2017.
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