

QUALITY IMPROVEMENT RESEARCH

Methods for evaluation of small scale quality improvement projects

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Evaluation is an integral component of quality improvement and there is much to be learned from the evaluation of small scale quality improvement initiatives at a local level. This type of evaluation is useful for a number of different reasons including monitoring the impact of local projects, identifying and dealing with issues as they arise within a project, comparing local projects to draw lessons, and collecting more detailed information as part of a bigger evaluation project. Focused audits and developmental studies can be used for evaluation within projects, while methods such as multiple case studies and process evaluations can be used to draw generalised lessons from local experiences and to provide examples of successful projects. Evaluations of small scale quality improvement projects help those involved in improvement initiatives to optimise their choice of interventions and use of resources. Important information to add to the knowledge base of quality improvement in health care can be derived by undertaking formal evaluation of local projects, particularly in relation to building theory around the processes of implementation and increasing understanding of the complex change processes involved.

purpose. Evaluations of small scale projects may encompass one or more of the following aims:

- (1) to monitor the success or impact of a local quality improvement project over time—for example, to make sure the project is achieving the desired results and to demonstrate the impact of the project to others;
- (2) to identify issues or problems as they arise within the project so that actions can be taken to change or redesign the project while it is in progress;
- (3) to compare similarities and differences in a number of local projects to draw out common lessons learnt and develop hypotheses for future research;
- (4) to collect more detailed information about the processes and outcomes of implementing a local quality improvement initiative as part of a bigger evaluation research project to help to explain the findings of this project.

Broadly speaking, the reasons for evaluation relate to two main types of learning—learning within the project (points 1 and 2 above) and more generalised learning about the implementation of quality improvement (points 3 and 4 above). The first type of learning is associated with the processes of clinical audit and quality improvement, while the second type is associated with research. This paper will outline a number of approaches and methods for the evaluation of quality improvement at a local level. Table 1 highlights the four main approaches that will be presented.

TYPES OF EVALUATIONS IN SMALL SCALE IMPROVEMENT PROJECTS

Focused audit studies

Local quality improvement projects typically involve implementing one or more specific changes that are designed to bring about improvements on a focused topic, such as a new way of treating a particular condition or a different way of organising delivery of care. Examples include a quality improvement project to ensure the provision of evidence-based pain management to patients following gastrointestinal surgery or a project to introduce more clinically and cost effective ways of organising patient-centred stroke services at a district or regional level. Within projects such as these, evaluation should comprise an integral part of the quality improvement process linked to an explicit assessment of the effect of implementing planned changes in practice. For example, in models of continuous quality improvement the third phase of the Plan-Do-Study-Act cycle¹ involves collecting data to

Many questions can be raised about the impact of quality improvement programmes in health care. Do they work? How can they be improved? What factors promote or inhibit their success? What can we learn from our local experiences? Why do they work in some settings and not in others? Different research designs are needed depending on the focus of the specific question the research is trying to answer, often involving the setting up of an external research project. But what about quality improvement initiatives that take place on a small scale such as a local ward, unit or departmental level: a clinical audit project, a process redesign effort or a unit that is participating in a breakthrough collaborative—should these be evaluated and, if so, how?

Evaluations of small scale quality improvement projects (defined as projects in a specific ward, unit or practice) can help both those who undertake such projects and researchers of quality improvement interventions. An important first step in any evaluation is the clarification of its

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Table 1 Types of evaluations in small scale improvement projects

Research designs	Aims	Approaches
Focused audit studies	Monitor impact of the activities over time	Evaluation as a component of quality improvement
Developmental studies	Identify issues and intervene when necessary, develop hypotheses	Evaluation linked to action by participants in the case of action research
Multiple case studies	Draw lessons and develop hypotheses	Case reports and comparisons across a number of local projects
Process evaluations	Explain the findings of a bigger research project	In depth analyses of projects as part of a bigger research project

evaluate whether changes introduced during the “Do” phase have actually realised improvements in practice or patient care. Similarly, in models of clinical audit the process typically includes an audit cycle in which a key stage involves evaluating how practice compares with expected standards and implementing changes accordingly. These changes are then re-evaluated by a process of re-audit.² The example illustrated in box 1 shows the role of evaluation within a project designed to improve the repeat prescribing process in a general practice setting.³

Measurements should be valid but simple.⁴ Chart reviews, surveys among patients, or simple observations of events are all examples of possible data collection methods. The relative simplicity of the measurements is perhaps most visible in the absence of complex case mix adjustments, as these would often require extensive additional data collection. Audit stud-

Box 1 Role of evaluation within a project designed to improve the repeat prescribing process in a busy general practice setting³

This project was established within a general practice in the UK to improve the service to patients in relation to ordering repeat prescriptions. A 48 hour target for processing repeat prescriptions was set. A multiprofessional team was established to work on the quality improvement initiative, using continuous quality improvement methods and supported by an external facilitator. Following the steps of the Plan-Do-Study-Act cycle, the team began by gathering information to assess their current practice and plan the necessary changes. This included the preparation of flow charts of the repeat prescribing process, and a baseline audit over a 1 month period to assess how many prescriptions were actually ready for collection within 48 hours and to identify the number that required medical records to be checked before they could be signed.

Information gained from the flow charts and the initial audit results helped the team to identify those areas where they could introduce changes that would have the most impact and to identify the measures they would use to evaluate the change process. Once planned, the changes were implemented in practice and repeat audits were undertaken at 6, 12 and 24 months. The resulting data were presented in two main ways: a comparison of results at baseline, 6, 12 and 24 months; and graphs plotting the turnaround times for consecutive prescriptions over time.

Analysis of the results helped the team to understand more clearly what was happening. Although 95% of repeat prescriptions were available within 48 hours at the baseline audit, the graphs illustrated considerable variation which led to frustration among staff. Repeated audits demonstrated improvements in turnaround times, significant reductions in the number of records that needed to be checked, and much greater staff satisfaction as the process became more consistent and more effective.

ies may comprise sampling of cases, such as patient records, so that statistical techniques can be used to indicate the reliability of figures. Generalisation to a larger population of clinicians or practices is, however, not sought. Focused audit studies help to close the loop of the quality improvement cycle, an area where many projects have been shown to fail in the past.⁵ Furthermore, information on the impact of the project aids learning from the local project, which is the aim of the approaches described next.

Developmental studies

Evaluation may also be beneficial with ongoing quality improvement projects to help assess what actions may be needed to refine or improve the design of the project, or specific interventions within the project. Evaluation mechanisms can be built into a local improvement project through both informal and formal methods. At an informal level, this might involve observation and discussion with colleagues about the process of how the project is going. Alternatively, the evaluation may employ a more formal developmental research method, particularly where there is a need to provide support, feedback, or help to the project team.⁶ One method is action research, which is broadly defined as an approach to research that actively involves participants and which has an explicit focus on promoting and facilitating change.⁷ It is an approach that has been used in a range of healthcare settings in the UK and has been the subject of a recent review to define the approach more clearly and assess its impact in practice.⁸ From this review a number of factors key to the success of action research were highlighted, including participation, maintaining a “real world” focus, resources, and project management.

Developmental approaches to evaluation may be particularly useful within the context of organisational learning⁹ and learning by professionals¹⁰ because of their action-orientated approach and the focus on personal and professional development. Within a quality improvement project, developmental research may form part of a flexible intervention programme—for example, a tailored educational approach to implement clinical guidelines, enabling actions to be planned on the basis of insight into the barriers for change. Box 2 illustrates the use of action research to introduce new wound management practices in a community nursing organisation.¹¹ This example also illustrates the use of a focused audit to assess the impact of the project as an integral part of the study design. The type of knowledge generated by developmental approaches is seen to be practical and propositional,⁸ and the focus is on generating and refining interpretations through inductive processes within repeated cycles of action research. As quality improvement projects studied through action research do not usually involve random or purposeful sampling, the generalisability of the knowledge generated may be limited to associations between different variables within the project under study.

Multiple case studies

In the approaches described above the focus has mainly been on learning within and about individual quality improvement projects. However, to draw out common experiences and lessons for the purpose of more generalised learning about

Box 2 An action research approach to introduce new wound management practices in a community nursing organisation¹¹

This project was set up to establish and encourage an improved approach to wound management in a community nursing organisation in South Australia. Within the organisation about 50% of client visits were related to wound care, hence the importance of promoting best practice in this area of care. Following an initial survey of wound management practices, participatory action research groups were established to address some of the issues identified.

Each group followed an action research approach with its three phases of planning, action, and evaluation being undertaken as part of a cyclical process. Volunteers were sought for the participatory action research groups, and core principles of action research including the group's responsibility for agenda setting, decision making about appropriate actions, and reaching consensus were emphasised. One group elected to focus specifically on evidence based practice relating to the care of leg ulcers, particularly appropriate methods for cleansing chronic leg ulcers. This involved comparing the use of tap water cleansing to an aseptic technique with sterile saline solution.

As part of the planning phase, an initial review of the literature was undertaken which highlighted the fact that the evidence base underpinning cleansing practice was limited and inconclusive. However, from this review and their own clinical experience, the group reached the conclusion that there was no evidence to suggest that tap water cleansing was ineffective. It also had the advantage of being more cost effective. Moving on to the action phase of the research cycle, the group examined the current cleansing practices used by their colleagues and reasons underpinning their chosen approach. This highlighted concerns around infection influencing the choice of the aseptic technique, so the group ran educational sessions to disseminate the research evidence on cleansing wounds. A repeat survey was subsequently carried out which showed an increase in the use of the clean tap water technique. As a spin-off from the action research and the identification of a lack of evidence to inform cleansing practices, a randomised controlled trial was subsequently set up to compare the use of warmed sterile saline with warm tap water for cleansing chronic leg ulcers.

quality improvement, it is most helpful to compare experiences across a number of local improvement projects to identify similarities and differences. This presents particular challenges in terms of identifying an appropriate research methodology for a number of reasons:

- each local project may be focused on a different topic for improvement and have different targets;
- there may be considerable variation in the processes of implementation as well as external influences across sites—for example, reasons for introducing the quality improvement initiative, membership of the quality improvement team, use of an internal/external facilitator or change agent;
- process and outcome indicators used to audit the progress and impact of the project are likely to be specific to each individual site.

Dealing with these context-specific issues requires an approach that is able to take account of local differences yet

Box 3 Key steps in the comparative case study approach

- Select individual cases relevant to the issues to be studied.
- Collect data within individual sites using a range of quantitative and qualitative methods.
- Analyse the data within individual sites using appropriate quantitative and qualitative methods of analysis—for example, descriptive statistics, thematic analysis of qualitative data.
- Compare data analyses across sites to draw more general conclusions and/or generate hypotheses for further testing.

can still compare across projects to draw out some more generalisable findings. One approach often used in these situations is the multiple case or comparative case study method.^{12–13}

Increasingly, the comparative case study approach is being applied in health care, notably within the field of evidence based practice and quality improvement. Here the focus is often on “why” questions, such as “why and under what conditions clinical professionals decide to adopt an innovation or change their clinical practice”.¹³ Recently published studies addressing questions such as this include an evaluation of the impact of guidelines on the management of adult asthma,¹⁴ the uptake of evidence based practice in elective orthopaedics,¹⁵ the management of glue ear,¹⁶ an evaluation of the ‘Promoting Action on Clinical Effectiveness’ initiative across 16 sites in England,¹⁷ and an evaluation of the six projects forming the Welsh Clinical Effectiveness National Demonstration Project.¹⁸ Box 3 summarises some of the key steps involved in the comparative case study approach.

Purposeful selection of cases to be included in the study contributes to its validity because a relevant diversity of cases is studied.^{13–15} In reality, however, the range of cases studied may be determined by what cases are available. The case study approach is not characterised by one specific method for data collection. Instead, a key feature is the use of data from a range of sources which are often collected using both quantitative and qualitative methods—for example, questionnaire surveys, semi-structured interviews, analysis of written documents, and direct observations. Combining data from multiple sources to study specific variables (known as “triangulation”) is recommended as it increases the validity of the data.¹⁹ It may, however, be expensive or impossible to achieve triangulation for all the variables studied.

The data analysis in multiple case studies is not characterised by one specific technique but by its overall approach. It is recognised that the cases are heterogeneous, so the analysis usually takes two approaches. Firstly, the cases are described in depth—comparable to detailed case reports of complex patients—including, for instance, both factual descriptions and the views of the participants. A systematic approach may then be used to derive lessons from such case reports—for instance, by verifying ideas on cases other than the one on which the idea was originally based.²⁰ Secondly, multiple case studies can be used to examine associations between variables and hypotheses on determinants of success, although formal statistical testing may be impossible. This requires that information on the impact of the projects is available from, for instance, focused audit studies.

Box 4 describes a project in which a number of hypotheses were developed a priori and then tested on the basis of the data available. Testing hypotheses is only valid for a limited number of predefined factors; if too many factors are studied, some associations will be found by chance. The associations found should be interpreted as hypothesis generating rather than testing. Although the heterogeneity of cases means that data cannot be pooled by more traditional methods such as

Box 4 Multiple case study approach to evaluate the implementation of 10 programmes to increase physical exercise in older adults²¹

Physical exercise improves the health status of adults, including older adults, but many adults perform very little physical exercise. A range of programmes in the Netherlands which focuses on walking, dancing, and aerobics aim to encourage older adults to become physically active for at least 30 minutes per day, at least five days a week. The clinical effectiveness of many of these programmes has been proven, so the focus is now on effective implementation in terms of setting up programmes and optimal participation of older adults in these programmes.

A multiple case study project has been undertaken to evaluate the implementation of 10 physical exercise programmes. This study has taken two approaches. Firstly, structured descriptions of the programmes were made and showed, for instance, that a variety of methods were used to improve participation in the programmes such as personal contact in case of absence, obligatory indication of check out, and provision of drinks to enhance social interaction. Furthermore, project leaders were asked to describe the most important barriers and facilitators to the success of the programme. Many mentioned, for example, the problem of convincing municipalities and welfare organisations of the relevance of the programme. These data were used to make structured descriptions of the cases.

Secondly, the study team proposed about 25 hypotheses on factors that influenced the success of implementation. For instance, it was hypothesised that the programme was more successful if there was a local tradition of collaboration between different organisations and if the physical exercise was three times a week (rather than five). Structured questionnaires were distributed to individuals involved in organising or delivering the programmes to collect data on the variables indicated by the hypotheses. Where possible, information on the success of implementation was derived from evaluations within the projects. These data were used to test the predefined hypotheses. The results indicated that successful implementation of physical exercise programmes was associated with larger investment by organisations in the programme, a prevailing view that audit and evaluation were relevant, and a local tradition of innovation in health care services. Although the number of cases is usually much lower than the number of variables, defining hypotheses a priori provides some protection against associations found by chance.

systematic reviews or meta-analyses, case study researchers are testing methodological approaches to pool results across similar studies. For example, Dopson and colleagues²² reported an attempt to pool data across a suite of seven related studies examining the diffusion of innovations in health care. This involved a multi-staged approach to critically review and summarise the findings of individual studies before identifying themes that were common across the studies. These themes were then verified by independent analysis of the data, followed by collective discussion and simultaneous analysis.

Process evaluations

Methods used for the in-depth study of local projects can also be helpful when undertaking evaluations of quality improvement initiatives using other research designs which explicitly aim at generalised knowledge. For example, a randomised controlled trial (RCT) may be set up to evaluate the effective-

ness of a particular approach to quality improvement. Within the design of the RCT, the research team may decide to collect more detailed qualitative data from a sample of the study sites involved in the trial to examine more fully what happens during the implementation process. This, in turn, may inform their subsequent understanding of the relationships between process and outcome data and provide information that helps to explain the trial findings in more detail. Another aim may be to provide examples of successful sites (“success stories”) that can be used to disseminate the message of the trial to a wider audience. A potential problem that needs to be considered, however, is the effect that additional measurements (collected as part of the in-depth evaluation) may have on the subjects participating in the quality improvement project, as these may be undesirable in the context of a controlled trial. If this is the case, it is important to find the right balance between learning about the programme and avoiding the test effect. Process evaluations of quality improvement have been discussed in detail in an earlier paper in this series.²³

DISCUSSION

All practitioners of quality improvement need to know the impact of specific programmes and possible ways to improve their effectiveness. Focused audit studies and developmental studies are designs that can help to structure these evaluations and provide information to determine the optimal choice of interventions and use of resources for quality improvement. Although the generalisability of the findings may be limited to the programmes evaluated, such evaluations can help to shed light on the more promising quality improvement methods and approaches.

An issue which is often debated is the extent to which clinicians and others who undertake quality improvement projects at a local level should use rigorous evaluation methods. For instance, how many cases should they study to get a reliable figure, should they adjust for case mix severity, and how extensive should the data collection on each case be? From a research point of view it is tempting to promote the use of rigorous approaches, but we believe that it is not realistic or necessary to evaluate each and every quality improvement project with the same level of rigour required by research. Simple evaluations can help to identify the methods that are most acceptable to clinical staff and appear to result in change of clinical performance. The probability that effective methods will be rejected on the basis of such evaluations appears to be small because rigorous evaluations such as randomised trials usually show smaller (and not larger) effects than simple evaluations.

Evaluations of small scale projects can also contribute to more generalised learning and inform scientific knowledge about quality improvement in health care. They can help to provide insight into causality if some sort of control is included in the design. A randomised trial is the ideal type of evaluation, but it is inefficient to trial interventions before they have been proved to be promising in small scale evaluation.²⁴ This is particularly relevant for organisational and structural changes which require large scale expensive trials. Multiple case studies may be particularly useful for testing the relevance of factors associated with a programme or its organisational context. Process evaluations help to understand the mechanism of causality better and contribute to the evidence on a specific intervention in this way. From a research perspective, these two designs can be used for studies that are equivalent to early phase studies in pharmaceutical research and are performed before large clinical trials.²⁵

CONCLUSIONS

Implementing change is complex and the processes involved are still not fully understood. Quality improvement projects are undertaken in many different settings and the knowledge

Key messages

- Focused audits of the impact of local quality improvement projects help those involved to learn from the project.
- In-depth study of local projects using developmental approaches to evaluation, case study methodology, or process evaluations can provide important insight into how and why programmes work in practice.
- These evaluations are characterised by their overall approach rather than by the use of specific techniques for sampling, data collection, or data analysis.
- Further development of the methodology for evaluation of local quality improvement projects is recommended.

gained from these projects is important to help increase our understanding of implementing effective change. It is useful to distinguish between evaluation undertaken to enable learning within the project and evaluation that aims to contribute to more generalised learning and inform scientific knowledge about quality improvement in health care. The appropriate methodology for evaluation needs to be elaborated, as not all interventions can or need to be tested in controlled trials.²⁶ A range of methods can be applied to evaluate small scale improvement projects, including focused audit studies, developmental research, multiple case studies, and process evaluations within RCTs. These approaches are characterised by their overall research approach rather than by the specific techniques for data collection or data analysis. Further development of the methodology for evaluation of small scale improvement projects is recommended.

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