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Fellowship Program Project Monograph

Implementation of evidence-based paediatric guidelines: evaluation of complex interventions based on a theoretical framework

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Implementation of evidence-based paediatric guidelines: evaluation of complex interventions based on a theoretical framework

Main messages

Greater understanding of 'how' and 'why' implementation interventions work is required to explain the variability in effectiveness, identify issues related to local context, enable generalisability beyond the study setting and enhance results by enabling targeted interventions. Two projects that involved implementation of paediatric guidelines were undertaken in a large health service in Melbourne. The NICS Fellowship aimed to link the outcomes of these projects to an investigation of the local determinants of effectiveness and a detailed evaluation of the process of change. The messages reported here reflect the results of application of the overall evaluation model. The detailed findings from each of the evaluation activities will be reported in separate publications.

A theoretical framework was developed to identify the factors to be investigated and provide a context for analysis and interpretation (Figure 1, Table 1). Mapping evaluation activities against a theoretical model was a clear, explicit and achievable approach to investigation of evidence-based implementation (Figure 2). It enabled assessment of the degree of coverage of the project evaluation, detection of gaps that need to be addressed to ensure validity of the conclusions and identification of opportunities for additional investigation.

An existing model of evaluation of complex interventions based on randomised controlled trials in a research context was successfully adapted for application to a local implementation project using predominantly qualitative methods for evaluation in a pragmatic context (Table 2).

An action research approach facilitated both implementation and process evaluation. Ongoing capturing of 'learnings' allowed iterative improvements in process design and implementation. Seeking to learn something out of every adverse event had an additional benefit, turning negative experiences into positive ones, and bolstering morale during the trying times of implementation.

Documentation of the implementation process using the classification and definitions of the Cochrane Effective Practice and Organisation of Care (EPOC) Data Collection Checklist was feasible and practical.

Documenting an Implementation Plan and keeping an Implementation Diary provided detailed information for evaluation and also improved the efficiency and effectiveness of the process.

Simple data collection methods yielded rich results. The framework 'What works, what doesn't, why, how can we improve it' was applied to many topics; used in surveys, interviews and focus groups; worked equally well with researchers, clinicians and consumers; and provided detailed information.

Simple structured surveys and focus groups worked well to identify many barriers and enablers, including the 'deal breakers'. However the participating target groups and stakeholders were not aware of some major organisational barriers. These must be sought creatively and proactively.

Simple evaluation methods contributed to all three research domains: conceptual (concepts, hypotheses and theories), substantive (context-specific factors) and methodological (design, measurement and analysis).

There are many high quality resources that outline the steps of guideline development, implementation and evaluation.[1-4] Although rigorous, comprehensive and user-friendly, they do not provide sufficient practical detail to enable application in a local health care setting. For each 'step' in the process, numerous smaller steps on rocky and unpredictable terrain are needed. This project discovered, tested and refined these processes and developed resources to assist others.

The current literature calls for more detailed information about implementation from case studies, pragmatic evaluations of 'real' projects, and observational studies to assess contextual factors. To achieve this, comprehensive evaluations need to be built into the health service systems that facilitate innovation and change.

Outside the relatively controlled world of research, projects in health services are particularly vulnerable to changes in the external and organisational environment. Changes in funding are always a possibility. Health service managers and researchers need to demonstrate the benefits of adequate evaluation of new activities.

Implementation of evidence-based paediatric guidelines: evaluation of complex interventions based on a theoretical framework

Executive Summary

Implementation research is defined as the scientific study of methods to promote the uptake of research findings.[5] The role of the National Institute of Clinical Studies (NICS) is to identify and test approaches that might improve evidence uptake across the healthcare system and that are feasible and affordable in Australia.[6] The opportunity provided by two existing guideline implementation projects and the NICS Fellowship enabled the scientific study of implementation methods that are, by virtue of their status in existing projects, both feasible and affordable in Australia. This project has provided considerable new information that will inform future guideline implementation projects and enhance sustainable evidence-based change.

There is a growing body of literature on the factors necessary for successful implementation of interventions to improve evidence uptake. However the effectiveness of these interventions is highly variable and often appears dependent on the local context. Now that there is some idea of 'what' works in implementation, there is a need to explore 'how' and 'why' these approaches work in order to explain the variability in success of implementation projects, identify issues related to local context, enable generalisability beyond the study setting and enhance results by enabling design of targeted interventions.

At the time NICS was establishing the Fellowship Program, the state health department of Victoria funded Health for Kids (HFK), a three year project to develop clinical practice guidelines and implement them via clinical paths. HFK provided a vehicle to test evidence-based interventions and the NICS Fellowship enabled additional detailed evaluation to explore the factors influencing change. This paper describes the overall approach and outcomes of applying a theoretical framework of evaluation to a large multi-faceted program of evidence-based change.

A theoretical framework was developed to identify the factors to be investigated and provide a context for analysis and interpretation. This model outlines three domains to be considered in the evaluation of complex interventions; determinants of effectiveness, process of change and final outcomes (Figure 1), and includes a detailed list of potential factors within each domain (Table 1). Evaluation activities were then mapped against the theoretical framework.

The project design was derived from a model of evaluation for complex interventions which, although based on randomised controlled trials in a research context, was potentially relevant to observational studies. The model was successfully adapted for application to an existing project, and was based on predominantly qualitative evaluation methods in a pragmatic context (Table 2).

The initial hypotheses would be tested through detailed evaluation of the development and implementation of the four paediatric guidelines within the HFK project. Further testing and refining of the hypotheses would require an additional project. The Newborn Services (NBS) department of the participating health service wanted to develop a guideline for care of preterm infants and approached the HFK team for assistance. The two projects had many factors in common as they were both centered on hospital-based paediatric guidelines within the same health service, but also several key differences which are outlined in Table 3. These points of difference provided an opportunity to test the influence of local factors on the success of implementation. Additional funding for the NBS project was obtained from a philanthropic foundation.

An 'action research' approach was adopted which included features of the 'Plan, Do, Study, Act' model where the data is collected, analysed and acted upon in short, iterative cycles; the 'researcher as facilitator for change' model where the project team was instrumental in developing and conducting the implementation strategies while simultaneously researching the change process; and the 'action evaluation comparative' design where detailed descriptions of the change process can facilitate a theory-building approach to evaluation.

The HFK and NBS projects included analyses of barriers and enablers and assessment of outcomes. The NICS Fellowship enabled additional, more detailed, evaluation. Five evaluation activities were selected to provide broad coverage across all three domains of the theoretical framework, be achievable within the scope of the HFK and NBS projects and resources of the Fellowship, and provide additional information in the areas of identified gaps in current knowledge (Figure 2).

The results reported here reflect the outcome of application of the overall evaluation model. The detailed findings in each area will be reported in separate publications. Due to a number of unexpected events, both projects encountered significant delays. In most cases the results relate to HFK. The NBS guideline has recently been completed but the implementation process has not yet commenced.

Analysis of barriers and enablers: Potential barriers and enablers, the likelihood of their occurrence, level of impact and possible ways to overcome the problems were identified through surveys, focus groups and existing reports. This information was compiled with known generic and topic-specific barriers and enablers from the literature and then analysed in a focus group of key leaders from the relevant clinical areas to determine 'deal breakers' that could potentially prevent implementation. In addition to the anticipated barriers that are common to all guideline implementation projects, this process identified some unexpected local issues which were addressed with targeted strategies. Some organisational barriers were not identified by this process and later caused significant disruption to the project.

Predetermined project evaluation: An extensive evaluation of process, impact and outcome measures was planned for HFK, however the state health department changed the funding priorities and decided that HFK funds would be withdrawn. They were clear that this was not a judgment of the project, which they considered to be excellent, but reflected a change of direction for the department. After some persuasion, funding was continued to enable completion of the project activities, however the amount was significantly reduced and would not enable the evaluation. Philanthropic funding was obtained for process analysis of pilot implementation of the clinical paths. Unless further funding is obtained, there will be no evaluation of practice change, health outcomes or health service utilisation arising from HFK guidelines.

Documentation of observable characteristics of the determinants of effectiveness: Features of the organisation and external environment, descriptions of the potential adopters and patients in the relevant target groups, details of the innovation itself and implementation strategies were documented in a structured framework. Funding for the Project Officer who undertook this work was provided by the Monash Institute of Health Services Research. When the incumbent left the organisation the funding was directed elsewhere and this work was not completed.

Formal assessment of organisational culture: An appropriate validated instrument was identified and permission to use it was obtained. Just prior to implementation of the survey, the participating health service announced their own survey to assess organisational culture. The survey tool to be used by the health service covered a majority of the questions in the project survey tool. Since it was unlikely that staff would respond to a second survey based on the same questions, an attempt was made to gain access to the results of the health service survey. The information was de-identified and the request was granted however aggregation of information across departments meant that it was unable to discriminate between the clinical areas in the respective projects. No formal assessment of organisational culture was achieved.

Ascertainment of perceptions of project participants, potential adopters and consumers: Perceptions of those participating in project development and activities, potential adopters and consumers (in this case parents of children attending the participating health service) were ascertained through surveys, focus groups and interviews. Feedback was provided on their project roles; time spent on various activities; expectations and whether these were met; overall satisfaction; implementation process; format, content and utility of clinical paths; and suggestions for improvement.

Detailed documentation of the process: All project activities were documented and a database was maintained with information about all the implementation interventions. The Cochrane EPOC Checklist was used where possible. Implementation Plans recorded the nature of each planned intervention, how it would be undertaken, target groups of potential adopters and barriers to be addressed. An Implementation Diary recorded the person responsible for each intervention, time, place and catering needs. Attendance at dissemination and educational interventions was recorded.

Reflective self-evaluation of project team's experience: Project team observations and 'learnings' were captured and recorded at all regular team meetings and specific team retreats at the end of each guideline development phase. Evaluation of 'what worked, what didn't, why and how it could be improved' was a continuous activity. Decisions and actions were recorded and summaries were developed at the end of each 12 month period. Seven main themes emerged: systems and documentation, project context, communication, project functioning, working with clinicians, working with managers and working with consumers.

Many messages for future guideline implementation projects emerged from this work. They can be described in two categories. The first is from the 'learn from the mistakes of others, you don't have time to make them all yourself' school. A series of key recommendations that reflect major lessons learnt by the project team highlight pitfalls to be avoided and enabling factors to assist others embarking on implementation projects was developed.

The second relates to a significant body of information that can be used in a more systematic way to facilitate the guideline process in local health service settings. There are many manuals that set out the steps required for guideline development, implementation and evaluation.[1-4] However the steps are often broad and fairly non-specific with limited practical information. It became clear that for each 'step' in a guideline manual, there are numerous smaller steps required to make it happen. Over the course of five guidelines, the project team discovered 'what worked well and what didn't' and developed a number of resources to facilitate the process. These are being collated and developed into a companion document to complement the existing guideline manuals.

This research makes a contribution to implementation science in each of the three research domains.

Conceptual: A theoretical framework was developed to identify the factors to be investigated and provide a context for analysis and interpretation. Mapping evaluation activities against a theoretical model was demonstrated to be a clear, explicit and achievable approach to investigation of evidence-based implementation. It enabled assessment of the degree of coverage of the project evaluation, detection of gaps that need to be addressed to ensure validity of the conclusions and identification of opportunities for additional investigation.

Substantive: Comparison of the HFK and NBS projects allowed greater understanding of the context in which these projects were undertaken. While the external and organisation-wide factors remained the same, and many features of the target professional and patient groups and the innovation itself were also common to both projects, differences in the participants' perceptions, the process and impact measures and the project team's experiences might be explained by the factors in which the two projects vary.

Methodological: This project has tested existing methods and also developed new ones. An existing design for research evaluation of complex interventions was successfully adapted for pragmatic application to a local implementation project. The action research approach worked very well, facilitating both the process of change and the evaluation. This work demonstrated that it is feasible and achievable to use the Cochrane EPOC Checklist framework and that simple data collection methods can yield rich results.

Withdrawal of funding had a major impact on this project but it is not such an unusual occurrence in health service programs. It reflects the vulnerability of researchers working with project funding. Health service managers and researchers need to convince governments of the benefits of adequate evaluation of new activities. The current literature calls for more detailed information about implementation from case studies, pragmatic evaluations of 'real' projects, and observational studies to assess contextual factors. If we are to achieve this, comprehensive evaluations need to be built into the health service systems that facilitate innovation and change. This will require funding to ensure that the appropriate time, skills and resources and available.

Until recently, it would have seemed almost inconceivable that resources for evaluation could be built into the health system at the local level. However the health service participating in the HFK and NBS projects has recently committed to developing organisation-wide systems to support and encourage use of clinical practice guidelines and other evidence-based decision-making processes. These systems will include specific requirements for implementation and evaluation and will provide resources to support the process. It is incumbent on those involved to demonstrate the value of rigorous implementation and evaluation programs in evidence-based change processes in order to use this opportunity to influence policy making at both government and health service level.

This project has provided considerable new information that will inform future guideline implementation projects and enhance sustainable evidence-based change. The challenge ahead is to produce the detailed findings of this research in formats that are suitable and accessible to guideline implementers and researchers worldwide.

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Background

There is a growing body of literature on the factors necessary for successful implementation of interventions to improve evidence uptake.[7-10] However the effectiveness of these interventions can be highly variable and often appears dependent on the local context. Now that there is some idea of 'what' works in implementation, there is a need to explore 'how' and 'why' these approaches work in order to explain the variability in success of implementation projects, identify issues related to local context, enable generalisability beyond the study setting and enhance results by enabling targeted interventions.[11-15]

There are two noticeable gaps in the current implementation literature: insufficient detail about implementation processes and lack of consideration of the complexity within organisations in which interventions are implemented. Although there are many studies reporting outcomes of interventions that aim to increase uptake of evidence, most of them do not provide sufficient details of the activities undertaken, the degree of implementation actually achieved or independent factors in the organisation that may have influenced the results in order to explain the outcomes or replicate the process.[5 11 13] Without this information it is impossible to tell whether successful outcomes were due to the strategies implemented or to other coincidental influences. Or whether outcomes were unsuccessful because the strategies used were ineffective or because the implementation process did not reach the target audience. Health care services are complex adaptive systems where individuals are free to act in ways that are not totally predictable, and whose actions are interconnected, so that the behaviour of individuals or groups changes the context for others.[12 16 17] More detailed information about what actually happened and greater understanding of the context in which it happened might help to explain the variability in effectiveness of change management interventions.

In 2003, the state health department of Victoria, Australia, funded the Health for Kids (HFK) project to improve health outcomes for children in the south east of Melbourne.[15] Established as a partnership between hospitals, general practice and community health services, the focus of HFK was evidence-based change though implementation of clinical practice guidelines and innovative models of health service delivery. Also in 2003, the National Institute of Clinical Studies (NICS), Australia's agency for closing the gaps between evidence and practice in health care, established a fellowship program to develop and support future leaders in evidence-based practice. The role of NICS is to identify and test approaches that might improve evidence uptake across the system and that are feasible and affordable in Australia.[6] HFK provided a vehicle to test evidence-based interventions and the NICS Fellowship enabled additional detailed evaluation to explore the factors influencing change. Both HFK and the NICS Fellowship were funded for a period of three years.

This paper describes the overall approach and success (or lack thereof) of applying a theoretical framework of evaluation to a large multi-faceted program of evidence-based change.

Methods

Theoretical framework

This was a pragmatic investigation built around a previously defined project, rather than a trial where the features are determined *a priori* by the researchers. A theoretical framework was developed to identify the factors to be considered and provide a context for analysis and interpretation of the findings. A number of existing models were reviewed. The 'Determinants of Innovation' model by Fleuren et al[18], the 'Ottawa Model of Research Use' by Logan and Graham[19] and the model for inducing change by Grol and Wensing[20] were combined and adapted to form a framework (Figure 1). Relevant factors within each domain were compiled from the work of these authors and others (Table 1). [10 18-23] To enable conclusions about the effectiveness of the innovation, information is required from each of the domains: determinants of effectiveness, process of change and outcomes.

Figure 1. Theoretical framework for evaluation of implementation of an evidence-based innovation

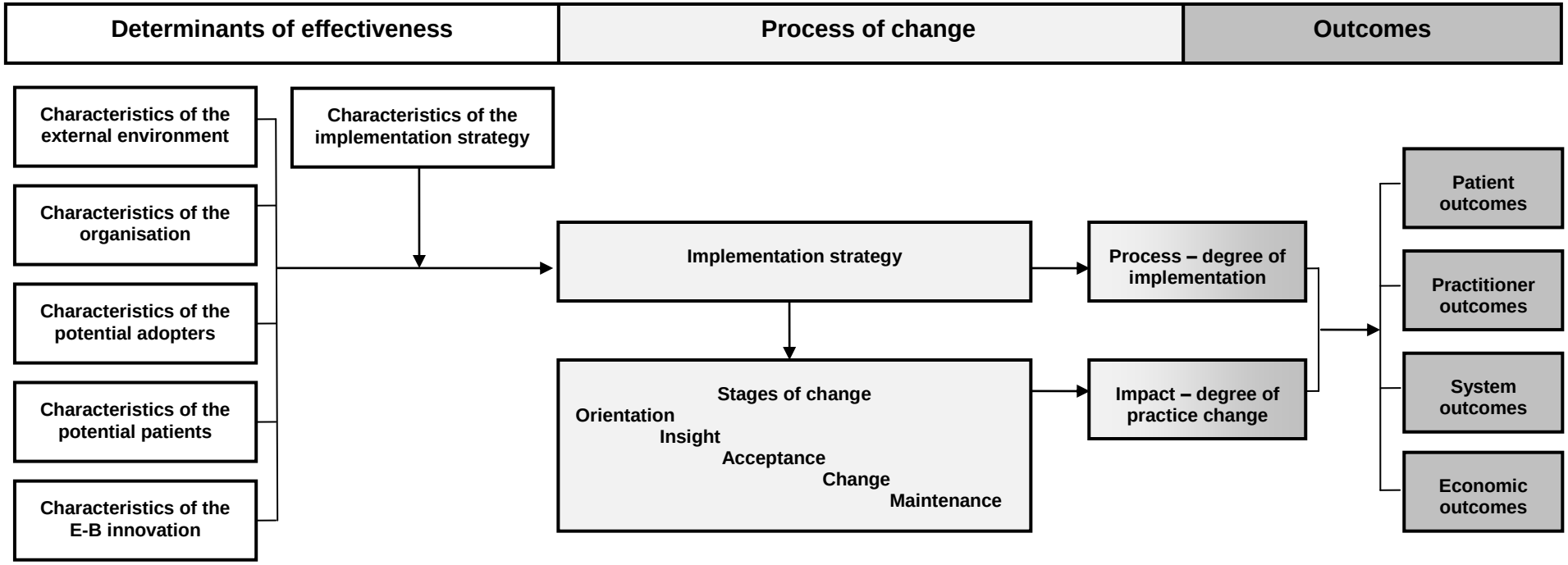

Figure 2. Evaluation of implementation in the Health for Kids and Newborn Services projects

	Determinants of effectiveness	Process of change	Outcomes
HFK NBS	1. Analysis of barriers and enablers		2. Process, impact & outcome evaluation
NICS	3. Documentation of observable characteristics	5. Ascertainment of perceptions of project participants, potential adopters and patients	
	4. Formal assessment of organisational culture	6. Detailed documentation of implementation and evaluation process	
	7. Reflective self-evaluation of project team's experience		

Table 1: Factors with potential influence over implementation of an evidence-based innovation

Characteristics of determinants of effectiveness*					
External Environment	**Organisation**		**Potential Adopters**	**Potential Patients**	**Evidence-Based Innovation**	**Implementation Strategy**
Structure Financial Physical Political Patients	**Levels** Health network Site/Campus Program Unit/Department Team Individual **Structure** Size Relationship to other organisations Collaboration between departments **Culture** Values Beliefs Assumptions Personalities **Leadership** Management style Hierarchy	**Staffing** Skills & knowledge Support Capacity Changes Orientation Modelling Role definition **Processes** General logistics Administrative Use of information Communication Decision-making Change – Adaptability – Linking – Saturation – Willingness	**Demographics** Professional groups Specialties Level of training Age Time since graduation Size of group **Expertise** Attitudes Knowledge Skills Self-efficacy **Other** Motivation Ownership Perceived support Leadership Team planning Measurement of progress Resources	**Demographics** Age Gender Ethnicity Other relevant **Reason for targeting** Clinical problem Risk factor Population group	**Evidence** Research Clinical perspective Patient perspective **Procedure** Clarity Appeal Relative advantage Compatibility Coordination User involvement Relevance Time Complexity Trialability Observability Cost benefit	**Interventions** Tailored to barriers & enablers Based on relevant theory Format **Facilitation** Purpose Roles Skills and attributes Knowledge **Procedure** Complexity Compatibility Advantage Trialability Cost benefit **Resources** Financial Administrative Time Facilities

Details of process of change*	Outcome measures*
Type of intervention Professional, financial re professional/patient, organisational, patient-oriented, structural, regulatory **Type of targeted behaviour change** Preventive service, diagnosis, test ordering, referrals, prescribing, management, patient education, communication, record keeping, resource use, discharge planning **Implementer** Professional status, opinion leaders, authority **Setting** Reimbursement system, location of care (eg inpatient, outpatient, community, etc), country, proportion of eligible providers participating **Methods/quality** Study design, unit of allocation, unit of analysis, power calculation, concealment of allocation, blinding, follow up, data collection processes **Controls used** **Other** Source of funding, ethical approval	**Degree of implementation** Target groups reached, activities delivered as planned **Health professionals** Practice changes, satisfaction **Patient** Health outcomes, health service utilisation (eg attendance, admission, length of stay, re-presentation rates, etc), satisfaction **System changes** Clinical/organisational practices, clinical/organisational documentation, changes to service provision, other process changes **Economic** Patient costs, health service costs, cost reallocation, local/global economic implications, cost of implementation **Timing** Length of time after initiation of intervention, length of post-intervention follow up, possible ceiling effect **Comparison between intervention and controls**

***** Use definitions from Cochrane Effective Practice and Organisation of Care (EPOC) Data Collection Checklist where applicable[24]

Project design

Evaluation of complex interventions can be challenging and a phased approach involving qualitative and quantitative methods to understand settings, behaviours and interactions is advocated in the literature.[11 14 25 26] The principles used by Campbell et al in their framework for design and evaluation of complex interventions were applied to the HFK setting (Table 2). The steps outlined in this framework are based on the traditional phases of pharmaceutical research adapted to reflect the complexity of many non-pharmacological interventions. This model is recommended by the UK Medical Research Council for randomised controlled trials but the authors also acknowledge its relevance to observational studies of complex interventions.

Table 2. Project Design

UK Medical Research Council Model[25]	Adaptation for HFK/NICS project
1.'Pre-clinical' (Theoretical phase) Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues	**Step 1** Undertake literature review Consult with national and international leaders in the field Identify hypotheses and research questions
2. Phase I (Modelling) Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other	**Step 2** Map existing practice Consult with stakeholders Identify target areas Develop tools for capturing information
3. Phase II (Exploratory trial) Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative	**Step 3** Develop, implement and evaluate interventions for HFK project Undertake mixed methods evaluation Analyse and interpret available information Refine hypotheses
4. Phase III (Main trial) Compare a fully defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power	**Step 4** Replicate Step 3 for additional project in different setting Test hypotheses
5. Phase IV (Long term surveillance) Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term	**Step 5** Identify & understand the factors that are specific to the local setting and those that are relevant to all healthcare organisations Make recommendations for enhanced strategies that will facilitate successful implementation and sustainability of change

Project conduct as 'action research'

This design is well suited to the 'action research' methodology defined by Meyer where the researcher is also the facilitator for change.[27] Ovretveit and Gustafson describe an 'action evaluation comparative design' that enables some degree of control, allowing possible inferences about critical factors and developing a 'theory-building' approach.[11]

The HFK project involved development and implementation of four clinical practice guidelines and several new clinical services. Many of these activities were undertaken sequentially, allowing Step 3 to be repeated in several iterative cycles. Using the theoretical framework above the project team collected, reflected on and analysed the data in an ongoing way; making appropriate changes to the implementation processes throughout the project. The success of the changes was evaluated in the subsequent cycles.

Setting and target groups

The HFK project was set in emergency departments (ED) and inpatient wards across three hospital campuses; one tertiary paediatric hospital with a designated paediatric ED and two general hospitals with large paediatric populations. HFK project strategies were also undertaken in general practice and community health services however, since the NICS investigation was limited to the hospital setting, the community-based activities are not addressed in this paper.

The additional project to be undertaken in Step 4 was not initially determined. Once the HFK project was underway, a number of factors specific to local situations were identified as potential barriers and enablers, generating hypotheses about the determinants of effectiveness of implementation in these settings. Around this time, the senior medical and nursing staff of the Newborn Services (NBS) department at the

participating paediatric hospital approached the HFK team and requested assistance to develop a new guideline. The NBS department differed from the original HFK settings in many of the factors identified (Table 3) and provided an opportunity to test additional hypotheses. Separate funding was obtained from a philanthropic foundation to undertake this project.

The main focus of the NICS study was on the interventions relating to clinical practice guidelines. However additional data were collected regarding participant's perceptions and project team learnings for several of the other HFK and NBS activities, particularly those relating to consumer involvement.

The target groups for practice change were medical, nursing and relevant allied health staff for both the HFK and NBS projects.

Table 3. Points of difference between the Health for Kids and Newborn Services projects

Features	Health for Kids	Newborn Services
Location	Three EDs and four inpatient wards across three hospitals	Single department consisting of Neonatal Intensive Care Unit and Special Care Nursery at one hospital
Guidelines	Asthma, croup, bronchiolitis and diarrhoea Acute, usually uncomplicated, short-lived conditions	Management of enteral feeding in preterm infants Chronic and complex conditions, long-term admissions
Clinical implementation tool	Guideline covers whole episode of care, standard clinical path model can be used for implementation tool	Guideline for only part of care, standard clinical path not applicable, clinical implementation tool must integrate with other clinical documentation
Role of senior staff	Medical Program Directors requested guidelines and paths but had no ongoing involvement in process. Nursing Directors not involved	Medical and nursing department heads requested guidelines and expressed commitment to involvement in whole process
Medical staff	Sessional paediatricians only in hospital for six hours per week Junior staff rotate at 10 weekly intervals	Full time neonatologists Junior staff rotate at 6 or 12 monthly intervals
Nursing staff	Only a small number of ED nurses have paediatric training and all rotate through both adult and paediatric areas.	Highly trained specialist nursing staff
Decision-making	Multiple levels of decision-making, medical and nursing decisions made independently	Medical and nursing decisions made together for NBS department
Education	Medical and nursing staff share some education sessions in ED but not in wards	Medical and nursing staff joint education sessions encouraged

Data collection and analysis

The use of action research methodology meant that data were collected and analysed continuously throughout the project. This was mainly qualitative information that identified whether implementation strategies were successful or not. The data were analysed thematically and discussed by the project team and other project participants. Iterative changes were made to the implementation processes based on these findings and the changes were re-evaluated.

Data was collected through two parallel processes: the HFK and NBS projects undertook analyses of barriers and enablers and routine evaluation activities and the NICS Fellowship provided additional, more detailed evaluation. Within the scope of the Fellowship it was not possible to report on all the factors in the framework. Five activities were selected to provide broad coverage across all three domains, be achievable within the scope of the HFK and NBS projects and resources of the Fellowship, and provide additional information in the areas of identified gaps in current knowledge (Figure 2).

1. *Analysis of barriers and enablers*
   - Potential barriers and enablers, the likelihood of their occurrence, level of impact and possible ways to overcome the problems were identified through:
     - A locally-developed survey sent to staff in target clinical areas (nursing staff surveys were stapled to their payslips, senior medical staff surveys were sent with a personalised note)
     - Focus groups (nurses during in-service time, junior medical staff during routine meetings)
   - This information was compiled with additional information from
     - other local sources eg internal surveys, reports, etc
     - known generic and topic-specific barriers and enablers from the literature
   - The information summary was analysed in a focus group of key leaders from the relevant clinical areas to determine 'deal breakers' that could potentially prevent implementation

2. *Predetermined project evaluation*
   - Evaluation of process (degree of implementation), impact (degree of practice change) and outcome (change in patient health and health service utilisation) measures was undertaken through:
     - Medical record audit (proportion of eligible patients on clinical paths, proportion of clinical paths completed appropriately, measures of clinical practice change as determined for each guideline)
     - Routinely-collected hospital data (admission rate, length of stay, re-presentation rate)
     - Surveys (patient and staff satisfaction)
   - Quantitative data analysed using chi squared and t tests
   - Qualitative date analysed thematically

3. *Documentation of observable characteristics of the determinants of effectiveness*
   - Project team observations and investigations documented in a structured framework to include:
     - Identification of processes, policies or features of the organisation and external environment that may influence the project outcomes
     - Descriptions of characteristics of the potential adopters and patients in the relevant target groups, details of the innovation itself and implementation strategies.

4. *Formal assessment of organisational culture*
   - Factors related to organisational culture to be evaluated through:
     - Validated survey instrument
     - Focus groups

5. *Ascertainment of perceptions of project participants, potential adopters and consumers*
   - Perceptions of those participating in project development and activities (clinicians, managers and consumer representatives involved in guideline development groups, committees and working groups), potential adopters (clinicians targeted to change their practice) and potential consumers (in this case parents of children attending the participating health services) ascertained through:
     - Locally-developed surveys
     - Focus groups
     - Interviews
     - Informal contact

6. *Detailed documentation of the process*
   - Documentation of all general project activities and maintenance of a database of all implementation interventions (reason for choice of intervention, target audience, setting, timing, attendance, feedback, what, when, where, who, how many)
   - Recording of changes to implementation plans based on feedback and 'learnings'
   - The Cochrane EPOC Data Collection Checklist classifications and definitions used where possible[24]

7. *Reflective self-evaluation of project team's experience*
   Regular capture and utilisation of team observations and 'learnings' from day-to-day activities and an ongoing evaluation of 'what worked, what didn't, why and how it could be improved'
   - Team meetings held fortnightly
     - 'Learnings' captured, discussed and analysed at beginning of each team meeting
     - Actions determined and recorded directly into a spreadsheet
     - Summary of themes developed at the end of each 12 month period
   - Team retreat held at the end of each guideline development phase (Appendix 8)
     - Nominal Group Technique to identify positive and negative aspects of the guideline development process and successful and unsuccessful strategies
     - Actions determined
     - Summary developed for each guideline

Both qualitative and quantitative data from the HFK and NBS projects were to be evaluated in the context of the theoretical framework to assess the relationships between the determinants of effectiveness, the implementation process and the project outcomes.

Ethics

The HFK, NBS and NICS projects received approval from the Southern Health Human Research Ethics Committee as Quality Improvement activities.

Results

Results are reported as at the end of the three year funding period. Due to circumstances beyond the control of the project team, none of the activities had been fully completed at this time. In addition to the numerous barriers encountered in implementing change in seven departments across three hospital campuses, the HFK project was significantly delayed due to new document control processes introduced at the time of implementation of the clinical paths, lack of access to the health service printer while the needs of a newly opened hospital were met and changes to the funding stream in the final year of the project. Development of the NBS guideline was suspended for six months due to staff shortages within the department. Funding for a Project Officer to assist with the additional activities related to the NICS Fellowship was also withdrawn before completion.

The results reported here reflect the outcome of application of the overall evaluation model. The detailed findings in each area will be reported in separate publications.

1. *Analysis of barriers and enablers*
   The surveys and focus groups undertaken within the HFK project yielded rich data from all stakeholder groups including senior and junior medical staff, nurses in management and education roles as well as ward and ED nurses, allied health practitioners and GPs. A survey on readiness for quality management processes had been commissioned nine months earlier and provided additional useful information.

   In addition to the anticipated barriers that are common to all guideline implementation projects, this process identified some unexpected local issues. One example was an existing protocol in one of the three EDs which prevented use of spacers for delivery of bronchodilators in acute asthma based on concerns about sterilisation. A targeted strategy was developed which identified up-to-date information about sterilisation procedures and engaged the infection control team in development of the new protocol before implementation at the particular site.

   Although the anticipated barriers and some additional local issues were raised, a number of barriers that had a significant detrimental effect on the implementation process were not identified through this process.

   At the time of writing, analysis of barriers and enablers in the NBS project was about to be undertaken.

2. *Predetermined project evaluation*
   An extensive evaluation of process, impact and outcome measures was planned for HFK, however two years after commencement of the three year project, the state health department changed the priorities for the funding stream to concentrate exclusively on chronic disease. The fund managers decided that HFK funds would be withdrawn since the focus of the project was on acute paediatric conditions. They were clear that this was not a judgment of the project, which they considered to be excellent, but reflected a change of direction for the department. After some persuasion, funding was continued to enable completion of the project activities, however the amount was significantly reduced and would not enable the evaluation.

   The project team obtained additional funding from a philanthropic source which allowed a detailed process analysis of pilot implementation of the clinical paths.

   Unless further funding is obtained, there will be no evaluation of practice change, health outcomes or health service utilisation arising from HFK guidelines.

   At the time of writing, implementation of the NBS guideline had not commenced.

3. *Documentation of observable characteristics of the determinants of effectiveness*
   Potentially relevant characteristics of the participating health service and external environment were identified by the project team, grouped into categories and developed into a matrix. After further investigation of the various factors, the matrix was populated with details of the processes, policies and other features that might influence the project outcomes.

   Funding for the part-time Project Officer who undertook this work was provided by the Monash Institute of Health Services Research where the project team was based. When the incumbent left the organisation the funding was directed elsewhere and this work was not completed.

4. *Formal assessment of organisational culture*
We identified an appropriate validated instrument to measure organisational culture and obtained permission to use it.[28] The tool was adapted to include the names of the various clinical areas where it would be applied and was re-formatted to two double-sided pages. No changes were made to the questions themselves. Extensive discussions were held with experienced researchers outside the project to determine the best way to implement the tool to maximise the response rates. Targeting of a random sample of staff in each area, separation of the tool into its three component parts and administration of one element via focus groups and the other two as separate surveys were planned.

In the final stages of decision-making about implementation of the survey, the participating health service announced a survey of all staff to assess organisational culture. The survey tool to be used by the health service covered a majority of the questions in the project survey tool.

Since it was unlikely that staff would respond to a second survey based on the same questions, an attempt was made to gain access to the results of the health service survey. The information was de-identified and the request was granted. However the hypotheses of this project required a comparison of the information from the target clinical areas – emergency departments, paediatric wards and neonatal services. In the participating health service the emergency departments are part of a different clinical program to the paediatric services, and responses from staff in both areas were aggregated with their colleagues from other departments within their respective programs, so no comparison between the emergency departments and paediatric wards could be made. The paediatric wards and NBS department are both in the same program so their data were aggregated together and no comparison could be made between them.

No formal assessment of organisational culture was achieved.

5. *Ascertainment of perceptions of project participants, potential adopters and consumers*
Perceptions of those involved in project activities were identified through surveys, interviews and informal meetings. Participants included members of the four HFK Guideline Development Groups, two Project Management Committees and occasional working parties (all included clinicians, managers and consumer representatives), plus four paediatric nurses seconded to the project team as 'Clinical Scholars in Evidence-Based Practice'. The participants provided feedback about their project roles, training in EBP where relevant, time spent on various activities, their expectations and whether these were met, their overall satisfaction and suggestions for improvement.

The views of potential adopters, clinicians in the target settings, were sought through focus groups, surveys attached to the clinical paths during the pilot phase, invitations to contact the implementation coordinator in their area and informal contact with the project team. They provided feedback about the implementation process and the format, content and utility of the clinical paths.

Potential consumers were represented by the HFK Consumer Advisory Group comprised of parents interested in health service delivery for their children. They provided feedback on their experiences, the participation process and how it could be improved through surveys and at Advisory Group meetings. They also participated in development of a model for an ongoing Consumer Participation Program within the Children's Program of the participating health service.

At the time of writing these activities had not been repeated within the NBS project

6. *Detailed documentation of the process*
All HKF project activities were documented, minutes were taken at GDG and committee meetings, and decisions and actions were recorded at project team meetings. This process is ongoing in the NBS project.

Specific attention was paid to documentation of the implementation process. Implementation Plans recorded the nature of each planned intervention, how it would be undertaken, the target group of potential adopters and the barriers that would be addressed. An Implementation Diary recorded the person responsible for each intervention and the time, place and catering needs if appropriate. Attendance at dissemination and educational interventions was recorded. Details were captured using the classification and definitions of the EPOC Data Collection Checklist.[24]

Detailed recording of the implementation process was achieved in the HFK project but has not yet commenced in the NBS project.

7. *Reflective self-evaluation of project team's experience*

a. Team meetings

Reflective self-evaluation of the project team's experience was undertaken continuously throughout both projects and was a priority for team meetings. The first activity of each meeting, prior to discussion of any agenda items, was presentation and discussion of any 'learnings' since the previous meeting.

Any experiences thought to have an influence on the project were identified. The perceived influence could be either an effect on project activities such as timelines, deliverables and other outcomes or an effect on members of the project team in areas such as workload, job satisfaction and personal stress. This was followed by discussion about how the situation came about and any relevant issues. The project team were very aware of the need to support each other, particularly during key stages in implementation, and the discussion often focused on helping a colleague work through an unpleasant experience. The team then reflected on 'what have we learnt from this, how will we prevent it happening again, or if we can't prevent it, how will we minimise its impact on the project and on ourselves?' Changes were made to the relevant processes and future activities based on the discussion, and all decisions and actions were recorded.

A large amount of detail was ascertained in this way. At the end of each 12 month period, the data was analysed thematically and a summary document was produced. Seven main themes emerged:

- Systems and documentation
- Project context
- Communication
- Project functioning
- Working with clinicians
- Working with managers
- Working with consumers

b. Team retreats

The HFK guidelines were developed sequentially. Asthma was commenced as a pilot, croup and diarrhoea were undertaken in parallel following completion of asthma, and bronchiolitis was developed in the final phase. At the end of each of the first two phases, the project team spent a day off-site to reflect on the process using the model 'what worked, what didn't, why and how can we improve it'. Based on the findings from this discussion changes were made to the process for subsequent guidelines. Details were recorded throughout the day and a report produced.

Discussion

The aim of this research was to link outcomes of evidence-based change, in this case implementation of clinical practice guidelines, with characteristics of the determinants of effectiveness and details of the implementation process to understand how and why strategies were, or were not, successful. An additional comparison between the HFK and NBS projects would enable testing of the research design and exploration of the role of local factors.

In both projects, external factors caused major delays and even prevented some aspects of the project being completed. Lack of outcome evaluation due to reduction in funding for the HFK project means that the overall aim of linking outcomes to determinants of effectiveness will not be met. Understanding how and why certain strategies were successful or unsuccessful in achieving the desired outcomes cannot be assessed without the final evaluation.

However, although some of the planned outcomes were not achieved, much can be learnt from the rich information available.

Considerations for guideline implementation projects

Many messages for future guideline implementation projects emerged from this work. They can be described in two categories.

The first is from the 'learn from the mistakes of others, you don't have time to make them all yourself' school. A series of key recommendations that reflect major lessons learnt by the project team highlight pitfalls to be avoided and enabling factors to assist others embarking on implementation projects. Examples include:

- Build ‘capturing learning’ into your workplan and use the information
- Start small, resist implementation at multiple sites
- Beware of making assumptions and consider the impact if you are wrong
- Re-think your timelines to allow plenty of time for activities beyond your control
- Seek out the ‘deal breakers’ actively – your stakeholders may not be aware of them
- Seek help from both clinicians and consumers
- Remember to thank people for their help or input, it’s always worth it
- Acknowledge feedback and clearly demonstrate how you act on it
- Be prepared for the worst, don’t let it surprise you!

The second relates to a significant body of information identified by the project team that can be used in a more systematic way to facilitate the guideline process in local health service settings. There are many manuals that set out the steps required for methodologically rigorous development, implementation and evaluation of guidelines.[1-4] These are very comprehensive and quite user-friendly documents. However the steps they outline can often be broad and fairly non-specific such as ‘establish a multidisciplinary group’ or ‘involve consumers’ with limited practical information to assist the local project team in how to actually go about the task and complete each step effectively and efficiently. It became clear that for each ‘step’ outlined in a guideline manual, there are numerous smaller steps required to make it happen.

An illustration of this is development of clinical questions. Each of the manuals has a section on ‘Clinical questions’. They vary slightly in content and degree of detail provided, and between them cover the number and types of questions that might be asked and how to translate them into the required research format. However none of them describe how to actually ascertain the questions. Over the course of five guidelines (four HFK and one NBS), the project team discovered, developed and refined methods of eliciting clinical questions from multidisciplinary GDGs that included consumers. Each guideline process improved upon the one before and it became clear ‘what worked well and what didn’t’. This learning was repeated in numerous other contexts across all the project activities.

A number of resources were developed in response to process changes following this team learning. For example terms of reference, memoranda of understanding and letters of agreement were developed to confirm participant and stakeholder roles and agreed actions and expectations. Letters of invitation, flyers, newsletters, posters, methods to both capture and provide feedback, quick guides to running meetings and methods for taking minutes were also developed, tested and refined through the life of the project.

The project team has collated the resources and is in the process of developing a companion resource to the guideline manuals. This will not duplicate the information in the existing documents, but will provide the practical details that will enable others to develop and implement guidelines readily in their health services and avoid the pitfalls encountered by the project team.

Considerations for implementation research

This research makes a contribution to implementation science across each of the three research domains: conceptual (concepts, hypotheses and theories), substantive (context-specific factors) and methodological (design, measurement and analysis).

1. *Conceptual*

   A theoretical framework was developed to identify the factors to be investigated and provide a context for analysis and interpretation. This model outlines three domains to be considered in the evaluation of complex interventions; determinants of effectiveness, process of change and final outcomes (Figure 1), and includes a detailed list of potential factors within each domain (Table 1).

   This project demonstrates that mapping evaluation activities against a theoretical model provides a clear, explicit and achievable approach to investigation of evidence-based implementation. It enables the researcher to see the degree of coverage of their evaluation, detect gaps that need to be addressed to ensure validity of their conclusions and identify areas of opportunities for additional investigation.

   Unfortunately, without the final HFK outcomes data we are unable to add to existing theories about the influence of specific determinants of effectiveness or the process of change.

2. *Substantive*

   This domain considers context-specific factors and enables deeper understanding of the implementation setting. By testing hypotheses in contexts with some similarities (hospital-based paediatric guidelines within the same health service) but also key differences (outlined in Table 3) we

can learn more about the influence of local factors. While the external and organisation-wide factors remain the same, and many features of the target professional and patient groups and the innovation itself are also common to both projects, differences in the participants' perceptions, the process and impact measures and the project team's experiences might be explained by the factors in which the two projects vary. All of the points of difference listed in Table 3 have theory-based links to well-established barriers and enablers to change.

Due to the various project delays, there is relatively little detail regarding the NBS guideline process, but data collection will continue throughout the project. Even without the final HFK results, the rich data from the qualitative studies of both projects will provide insights into the influence of local determinants of effectiveness and the process of change in the context of hospital-based paediatric guidelines.

3. *Methodological*
This project has tested existing methods and also developed new ones.

a. Project design
The project design for evaluation of complex interventions by Campbell et al is based on randomised controlled trials in a research context. This design was successfully adapted for application to an existing multi-faceted project using predominantly qualitative methods for evaluation in a pragmatic context. The model worked as planned in this setting, and although there were problems with completion of some of the activities, these were all due to external factors and not related to the project design.

The richness of the data ascertained will still enable completion of Step 5 even though the HFK final outcome evaluation will not be available. The recommendations for enhanced strategies for successful implementation will be based on a different perspective than that expected. Rather than arising from comparison of the determinants of effectiveness and implementation process against the outcome measures, they will be based on the findings of the detailed process evaluation and refinement of project methods.

b. Project conduct as 'action research'
A combination of three models of 'action research' was used:
- 'Plan, Do, Study, Act' approach where the data is collected, analysed and acted upon in short, iterative cycles
- 'Researcher as facilitator for change' model where the project team was instrumental in developing and conducting the implementation strategies while simultaneously researching the change process[27]
- 'Action evaluation comparative' design where detailed descriptions of the change process can facilitate a theory-building approach to evaluation[11]

This approach worked very well, achieving both the expected results and some unexpected additional benefits. It facilitated both the process of change and the evaluation.
- By collecting, analysing and acting upon the data as we received it, the systems and processes employed were continuously improved, making the project more efficient and effective
- Documentation of this ongoing testing and refinement process enabled evaluation of the factors influencing change
- Overtly discussing the positive and negative issues as they arose contributed to a stronger team ethos with a shared sense of experience
- Seeking out 'learnings' made it clear that the team did not have to know everything about the growing area of implementation science and that problems encountered in the implementation process were not necessarily avoidable or due to mistakes
- Every negative experience was turned into a positive one by finding the 'learning' and acting to prevent it happening again. The project team felt that this contributed significantly to maintaining team morale during some difficult times in the implementation phase.

c. Standardisation of documentation
This project has demonstrated that it is feasible and achievable to collect implementation data using the Cochrane EPOC Checklist. The detailed documentation was undertaken as a research exercise however, despite initial perceptions that it was overly time consuming, it actually made the process more effective. The matrix of all target groups and identified barriers that formed the basis of the Implementation Plan ensured that development of implementation strategies addressing all relevant issues was efficient and comprehensive. The Implementation Diary made the complex itinerary of

numerous activities delivered across three campuses more explicit, easier to implement and reduced the likelihood of something being overlooked.

d. Data collection methods
Several methods of data collection were tested and refined during this project. These are available from the authors on request. Details will be provided in separate publications.

Simple, but structured surveys were developed for assessment of barriers and enablers and ascertainment of participant's perceptions. The structures were based on relevant theoretical considerations. The surveys were completed as expected, the responses were appropriate and the results were very useful.

The format of 'what works, what doesn't, why and how can we improve it' was also used in surveys as well as focus groups and interviews. In surveys these questions formed the column headings in a table of cells for free text answers. The format was readily adapted for different purposes by changing the row headings in the surveys and the verbal prompts in the focus groups and interviews. This simple format proved to be very successful in providing useful information in considerable detail. In addition to guideline implementation, this format was used with success in development and evaluation of a number of innovative clinical services. It worked equally well with the project team, clinicians and consumers.

Considerations for health policy
This research provides another example of what is already well known to health service managers and researchers – that government departments do not make all of their decisions based on sound evaluation. Programs and projects are funded for a variety of reasons, which is appropriate. Effectiveness is only one consideration alongside others such as access, equity, and economic, cultural and political implications. In this case large amounts of money were used to develop and implement evidence-based guidelines for the four most common paediatric conditions for presentation to emergency departments and admission to hospital. But with funding for evaluation withdrawn, we cannot assess if they have had any effect on health outcomes or health service utilisation. This means that in order to find out the process will have to be duplicated somewhere else. Health service managers and researchers need to find ways to convince governments of the benefits of adequate evaluation of new activities.

Most of the work in implementation research is conducted on a project basis, making it vulnerable to the vagaries of 'soft funding' and limiting the sustainability of innovative programs. The current literature calls for more detailed information about implementation from case studies, pragmatic evaluations of 'real' projects, and observational studies to assess contextual factors. If we are to achieve this, comprehensive evaluations need to be built into the health service systems that facilitate innovation and change. This will require funding to ensure that the appropriate time, skills and resources and available.

Until recently, it would have seemed almost inconceivable that resources for evaluation could be built into the health system at the local level. However the health service participating in the HFK and NBS projects has recently committed to developing organisation-wide systems to support and encourage use of clinical practice guidelines and other evidence-based decision-making processes. These systems will include specific requirements for implementation and evaluation and will provide resources to support the process. It is incumbent on those involved to demonstrate the value of rigorous implementation and evaluation programs in evidence-based change processes in order to use this opportunity to influence policy making at both government and health service level.

Conclusions
Implementation research is defined as 'the scientific study of methods to promote the uptake of research findings'.[5] The role of NICS is to identify and test approaches that might improve evidence uptake across the system and that are feasible and affordable in Australia.[6] The opportunity provided by two existing guideline implementation projects and the NICS Fellowship program has enabled the scientific study of implementation methods that are, by virtue of their status in existing projects, both feasible and affordable in Australia.

This project has provided considerable new information that will inform future guideline implementation projects and enhance sustainable evidence-based change. Unfortunately, due to factors beyond our control, the main aim of the research is not likely to be achieved. Without the HFK final outcome evaluation, the success of implementation strategies, and the influence of the determinants of effectiveness on that success, cannot be determined.

Other contributions from this work include development of a theoretical model and mapping of the evaluation plan to this framework; adaptation and implementation of a project design for evaluation of complex interventions; and development, testing and refinement of a number of data collection methods. We have demonstrated that simple qualitative techniques can produce rich and informative data and that application of standard data collection frameworks such as the Cochrane EPOC Checklist is feasible in this project context.

The challenge ahead is to produce the detailed findings in formats that are suitable and accessible to guideline implementers and researchers worldwide.

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