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1. Introduction

There is a growing body of evidence to suggest that training and/or supporting patients to develop effective self-management strategies can reduce the burden of chronic disease and improve the health and well being of patients with chronic diseases, their families and their carers. These strategies, based on social learning and behavioural theories, are thought to contribute to better health by improving:

- patients' knowledge, confidence and skills in managing their chronic conditions; and
- communication between health professionals, family carers and patients.

The 1999 Commonwealth Budget provided for the Department of Health and Aged Care (DHAC) to initiate the Enhanced Primary Care Package as one part of its strategy to address the growing burden of chronic disease in the Australian community. The Chronic Disease Self-Management Initiative was part of this package. The objectives of the Chronic Disease Self-Management (CDSM) Initiative are to:

- Improve the health-related quality of life for people with chronic diseases, particularly those with co-morbidities;
- Improve the use of the health care system by people with chronic diseases; and
- Encourage collaboration between individuals, their families and health care professionals in the management of chronic conditions.

The CDSM initiative was subsequently renamed the Sharing Health Care (SHC) Initiative. In this document, we use the term Chronic Disease Self-Management when referring to historical documents and references and the term Sharing Health Care to refer to the current and future program.

The Sharing Health Care Initiative has five components:

- a) The Sharing Health Care demonstration projects.
- b) Guidelines for General Practitioners and other health professionals.
- c) Education modules to train General Practitioners, professionals and lay workers on the objectives, benefits and ways to use self management strategies for patients with chronic diseases.
- d) A database of accredited self-management/self-help programs that can be used by health service providers and participants at the locally based self-management demonstration projects.
- e) A communication strategy encompassing workshops, information sheets, publications, articles and a website.

The Department called for submissions from groups wanting to conduct projects to demonstrate how Sharing Health Care programs could be operated in Australia. Over 140 submissions were received and in October 2000 the Minister for Health and Aged Care announced that five submissions had been accepted, with more projects likely to be funded.

1.1. Objectives in Evaluating the Sharing Health Care Initiative

The Department is funding the evaluation of the Sharing Health Care Initiative to provide it with information for future policy and program development in relation to the better management of chronic diseases. It is seeking to develop an evidence base from which it can develop a national program to support patients in developing their self-management capacity and to encourage changes in the health sector to support patient self-management.

The Department is aware of the limitations of existing knowledge about self-management initiatives. In particular, little is known about how to reach those people in the target population who have the greatest need for improving their self-management skills. So, while the projects are funded as *demonstration projects* and not formal trials, the Department expects that project sponsors will contribute to improving understanding about how to most effectively provide self-management programs in Australia.

The objectives set out by the Department in the Request for Tender for the development of the Evaluation Framework, and in subsequent discussions with the Centre for Health Service Development require research and evaluation at four levels:

- evaluation of individual projects;
- evaluation of major elements of projects¹;
- research to answer questions for which there is currently little research evidence; and,
- to provide information on costs and sustainability of self-management projects.

The Centre for Health Service Development (CHSD) was contracted by the Commonwealth Department of Health and Aged Care to develop the Evaluation Framework². The Evaluation Framework was to 'allow the key aspects of the evaluation (including the data requirements) to be built into the demonstration projects, the education modules and the communication strategy'. The Department envisaged that 'the demonstration projects will need to be evaluated at both the local and national levels'.

There is some tension between the Department's commitment to the project sponsors that the projects be *demonstration projects* and its desire to learn from the projects so as to improve its understanding of program options for the future. This Evaluation Framework seeks to outline an approach to refining the design of projects that achieves a reasonable balance between the two objectives.

2. The Sharing Health Care Model

The term Sharing Health Care is not routinely used in the literature. The most commonly used term is 'Chronic Disease Self-Management' although even when that is used the interventions described are widely different. In many cases activities that could be described as chronic disease self-management are referred to by different names such as health promotion and case management. To provide some degree of comparability for evaluation purposes, the design team has developed a model of Sharing Health Care derived from the literature (see Appendix 2). **The**

¹ Elements are identifiable activities such as method of involving patients in self-management, the education programs for patients and providers etc

² Throughout this document, the CHSD is referred to as the design team.

intention in proposing the Sharing Health Care Model is not to impose a rigid framework on all project designers, but to:

- provide a guide to Local Evaluators and project sponsors when refining the design of their projects;
- encourage consistency in the description of projects;
- facilitate discussion between the local evaluators and the national evaluators when considering 'across project' evaluation issues;
- assist both groups to specifying the variations in elements to be incorporated in different projects; and
- assist in defining the measures to be adopted to evaluate the elements of projects.

By specifying a model, the design team does not expect that the projects will necessarily remain unchanged for the whole period of the projects. In fact, it is likely that during the course of the projects, project managers (assisted by local evaluators and national evaluators) will make changes to fine-tune the performance of their projects. However, it is expected that the changes will be carried out in such a manner to allow such changes to be evaluated.

2.1. Terminology

The following terms are used in this paper:

- Program:** All of the individual Sharing Health Care projects, plus the modules to develop guidelines, educational modules, database, etc defined in the Sharing Health Care Initiative.
- Project:** The individual self-management demonstration projects to be funded under the SHC Initiative.
- Elements:** The component parts of the Sharing Health Care model that can be subjected to evaluation.
- Modules:** The different components of the SHC Initiative - education, guidelines development, database and communications strategy - that are being developed nationally and are not the responsibility of an individual project.
- The SHC model:** The set of **elements** that are used to describe all projects and that form the basis of design of the projects during the second phase of project development.
- Variations:** The different ways in which **elements** can be implemented. For example, a self-management education program may be delivered by a lay person, a nurse, a doctor, or through a programmed learning book or computer program. The purpose of the self-management education program will be the same regardless of how it is delivered. However the cost and effectiveness of the element may vary significantly depending on how it is delivered.

The basis for these features are derived from the model represented in Figure 1 (see page 34). The SHC model has two types of elements:

2.2. Patient focussed elements

- Engagement/recruitment – the strategy to be used to engage patients in the projects;
- Clinical assessment – during the Engagement Phase and during the life of the project;
- Patient self-management education;
- Involvement in self-help groups and community services;
- Support and follow-up during life of project;
- Involvement in Activity Planning; and
- Collaborative problem solving between patients and providers.

2.3. Health system elements

- Definition and maintenance of links between service providers, community services, self help groups and other organisations involved in the project;
- Provider education;
- Agreements on development and use of guidelines to be used by all providers when working with patients, including development and use of treatment plans;
- Protocols for the exchange of information between health and community service providers; and
- Agreement on funding responsibilities within the project.

For most of the elements, there are a number of possible **variations** that could be appropriate to evaluate. For example, patient self-management education could be provided by lay persons, health educators, nurses, GPs. The education could be provided on a one-to-one basis, in groups of people with the same (major) chronic condition, in groups with different chronic conditions, in groups of similar ages; the courses could be short or long; or could be provided by the internet or other computer based system.

While the funded Projects are diverse in the activities that they plan to undertake (and in their target populations), there are a number of 'generic' features that most of the projects will have in common.

It is recommended that, early in the design phase for second round projects, the national evaluators should conduct a workshop with key informants to determine the variations in elements to be tested in the projects. An example of some of the variations is shown below. For example, the design team considers that recruiting patients with high burden from chronic illnesses from Hospital Emergency Departments and inpatients should be trialed, as people who are not managing their illnesses well often attend Emergency Departments or are admitted.

Table 1: Elements of the SHC Model and Possible Variations

Elements	Variations	Significance
Patient focussed – Recruitment/engagement	Self Referral; Systems Referral – GP, allied health professional, nurse, Aboriginal health worker– hospital inpatient and emergency department – community agency; Funder – health insurer.	Many studies report low rates of participation by NESB, low income and other groups. Different recruitment/engagement strategies may be successful with different target groups
Self-management education for patients and carers.	Education provider – Lay, allied health professional, Aboriginal health worker Nurse, Health Educator, GP; Groups or one-on-one; Groups with Mixed or Single Conditions; Long and short courses. Setting for courses - home, hospital, other; Language in which courses are conducted; Internet/computer based education.	As above – the type of education program offered may have a significant impact on the participation rates of different target groups. The type of program can influence costs of providing the service.
Patient support and follow-up	By GPs, allied health professional, Aboriginal health worker, Nurse, Other; In person or telephone; Frequency of follow-up.	Some studies have found that the effect of Self-Management education declines over time.
Education for providers	Face-to-face sessions with education provided by professional peers (eg Divisions of General Practice to provide courses for doctors) or by other health educators involved in allied health, Aboriginal health workers, Nurse education; Provision of written material; Computer assisted learning material.	There is little literature on how best to provide Self-Management training for multidisciplinary groups who may have to work together in developing care plans etc. It could be an important component in providing consistent support to patients across health and community service settings.
Target population and local context	Socio-economic mix; age mix; people with a single (main) chronic condition. Ethnicity mix (Australian general, NESB, ATSI). Occupation. Roles.	Selection of a suitable group for intervention should be based on what works for which groups, as well as the local population mix.

3. Hypotheses to be Tested, Key Evaluation Questions, and Other Research Issues

This section outlines the hypotheses against which the demonstration projects are to be evaluated, the key questions, and other research issues to be addressed in the evaluation.

These hypotheses and evaluation questions determine the data needed to conduct the evaluations.

3.1. Hypotheses against which the projects are to be evaluated

The Department specified three hypotheses against which the projects are to be evaluated. The Expected Outcomes, also specified by the Department, effectively specify the types of data necessary for the evaluations.

3.1.1. Patient and Family Hypothesis

Hypothesis

That Sharing Health Care will help improve health-related quality of life for people with chronic conditions, particularly those with co-morbidities.

Expected Outcomes

- Participants in the CDSM will experience improvements in areas such as: managing their daily lives, communication with family and health service providers, emotional health, nutrition and physical activity, medication management and decision making abilities;
- The health and well being of patients will be improved;
- Patients will be more empowered to take an increased role in making decisions regarding their own health;
- Patients will be more knowledgeable about their condition/s and about ways of managing it/them; and
- Patients' families may experience improvements in a range of areas such as communication with the patient and health care service providers, emotional health, and decision-making abilities.

3.1.2. Health Service Provider Hypothesis

Hypothesis

That Sharing Health Care will help to facilitate improvements in awareness and understanding about the benefits of self-management, as well as improving communication and collaboration between General Practitioners, people with chronic conditions and their families, and other Health Professionals.

Expected Outcomes

- Improved quality care (eg. care planning, care pathways, recall systems);
- Satisfaction with the Sharing Health Care initiative;
- Increased support for patient self-efficacy principles and incorporation of these principles into their management; and
- Increased referrals to chronic disease self-management programs.

3.1.3. Health Services Hypothesis

Hypothesis

That the Sharing Health Care Initiative will result in more appropriate use of health services.

Expected Outcomes

- Improved use of GP and Specialist clinicians;
- Improved use of community services;
- Appropriate use of EPC MBS items; and
- Appropriate pattern of use of hospital services.

3.2. Key Evaluation questions

The Department proposed a range of issues to be addressed in the evaluation:

- Patient issues, such as how to assess the benefits to patients of self-management and which particular patient groups benefit;
- The effectiveness of recruitment and assessment methods, and the levels of satisfaction of both the patient and carers/family;
- Health service provider satisfaction with the impact of the program;
- Organisation and management issues, including the cost of different models and the level of stakeholder involvement;
- Approaches to self-management, covering issues such as the use of self-management protocols, the suitability of different self-management approaches to different patient groups, the suitability and effectiveness of the education modules and guidelines for General Practitioners and other Health Service Providers, and the development and/or use of assessment tools, training and self-management interventions; and
- Examination of accessibility problems including those facing patients in rural and remote areas.

Through the process of consultations described in Appendix 1 the design team developed a number of questions which expanded on these issues:

Evaluation Question 1: Which recruitment strategies are most successful in recruiting which target groups?

Evaluation Question 2: Can patient related characteristics be identified so that the service providers can offer education programs that patients are most likely to accept? This should include identifying patients who can self manage effectively without specific education.

Evaluation Question 3: Are some forms of SHC education more acceptable to some population groups than others - and hence influence the participation rate in the program?

Evaluation Question 4: How does the form of self-management education influence the health behaviours and health outcomes of patients?

Evaluation Question 5: Are the health outcomes associated with high cost programs better than those associated with low cost?

Evaluation Question 6: How does the type, intensity and frequency of patient support and follow-up influence health behaviours and health outcomes?

Evaluation Question 7: Does the type and intensity of patient support and follow-up influence the costs of service utilisation?

Evaluation Question 8: Does the type and extent of carer and community support influence patient outcomes and the costs of service utilisation?

Evaluation Question 9: What factors do patients identify as contributing to their engagement and continuing involvement with self management initiatives or to them not becoming involved or dropping out?

Two other questions were derived by the design team from the Departments 'possible' evaluation questions:

Evaluation Question 10: What are the *actual* and *sustainable* costs of variations of elements of the Sharing Health Care Model ('elements' defined in Section 4)?

Actual costs are the costs incurred during the live phase of the projects of the elements of the projects.

Sustainable costs – Based on their experience of operating the projects, project sponsors and local evaluators will be asked to make estimates of the costs of elements that would be incurred *if* the element was to be included as part of the continuing provision of health services.

This will provide some capacity to assess the cost-effectiveness of, for example, different methods of engaging patients in different target groups in self-management activities.

During the design phase, the national evaluators should identify those elements of the Sharing Health Care Model for which costs estimates are considered most important.

Evaluation Question 11: Projects should identify those *changes* necessary to make the elements of their project sustainable (ie part of the continuing provision of health services).

Changes necessary could include changes to:

- organisations,
- financing methods,
- relationships between existing parts of the health and community sectors (including establishing new services); and/or
- methods of developing and/or strengthening the links between health services and community and/or self help groups (including the need for financial support for self-help groups).

3.3. Other Research Issues

The SHC initiative includes modules designed to provide resources to, and support for, the funded projects. These modules, as well as the demonstration projects themselves, are to be evaluated:

- the Education Module;
- the Guidelines Module; and
- the Database of Accredited Self-Management/Self-Help Programs.

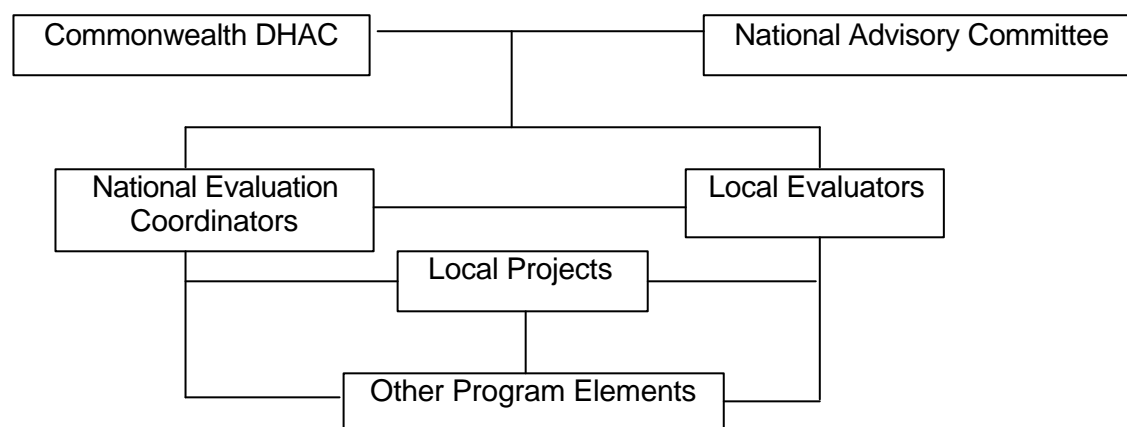
At the time of writing this report, the contract for developing the Database had not been finalised, so the evaluation proposed for this may need further refining when the actual content and supporting systems are known.

4. Organisation and Management Issues

4.1. Structure and roles in evaluation

It is proposed that the Chronic Disease Self-Management Initiative be evaluated at the individual project level (local evaluation) and as an entire program (national evaluation) if resources permit. The coordination of the evaluation would be carried out under the auspice of the Public Health Branch of the Commonwealth Department of Health and Aged Care with the advice of a National Advisory Committee, a National Evaluation Coordinator and Local Evaluators. These arrangements are shown in Figure 1.

Figure 1 Proposed evaluation arrangements



The **National Advisory Committee** will provide advice on the local project proposals and comment on the way that the projects inform the national framework, including:

- local demonstration project feasibility and scope;
- the scope of the set of demonstration projects, including the alternative interventions that might be tested across the projects
- arrangements for governance and ensuring that checks and balances are in place;
- privacy issues for providers, both public and private;
- ethics and the implications for consumers;
- how the projects make an impact on State concerns;
- the impact of government policy on the projects;
- the design features of the national evaluation, including the collection of routine consumer outcomes, consumer feedback and other evaluation data.

The National Advisory Committee will have a mix of clinical, consumer and research skills and provide for input from health authorities on policy and organisational issues.

The **National Evaluation Coordinators** will:

- advise the Commonwealth on the design issues to be incorporated in the local projects to ensure that evaluation questions requiring 'across project' analysis are adequately addressed;

-
- work with Local Evaluators on issues of ‘across project’ evaluation;
 - work with Local Evaluators to develop agreements on project design issues or measurement issues that require a uniform and consistent approach (such as data collection, outcomes measures etc);
 - specify the data collection and analysis necessary to evaluate the Key Questions that require ‘across project’ analysis;
 - specify the data collection and analysis necessary to assess the impact of the Modules (Education, Guidelines etc);
 - undertake a synthesis of evaluation findings across local projects.

The **Local Evaluators** will be jointly selected by the local project developers and the Commonwealth, but are to be responsible to the Commonwealth and National Advisory Committee for the conduct of the evaluation. The main tasks of the Local Evaluators are to:

- advise the local project sponsor in designing the local project;
- evaluate the local project as required by the National Evaluation Framework and/or as agreed with the Commonwealth;
- work with the National Evaluation Coordinators on issues of ‘across project’ evaluation;
- work with National Evaluation Coordinators to develop agreements on project design issues or measurement issues that require a uniform and consistent approach (such as data collection, outcomes measures etc);
- undertake the data collection on behalf of the National Evaluation Coordinators necessary to evaluate the Key Questions that require ‘across project’ analysis;
- collaborate in the data collection and analysis necessary to evaluate the Modules (Education, Guidelines etc).

5. Evaluation Methods

The logic underpinning the Sharing Health Care Initiative and incorporated in the Sharing Health Care Model is that patients experience improved functional, clinical and health outcomes if they are able to self-manage their own health conditions. Those who are not natural self-managers can be assisted to become ‘activated and informed patients’ (in the terminology of the Sharing Health Care Model described in Appendix 2) by assisting them to develop their self-management skills and supporting them to continue as self-managers.

Patients’ capacities to self-manage effectively can be increased by providing them with formal education on self management, continuing support and encouragement by health service providers, involvement in self-help groups, and support from community services providers.

According to the research outlined in Appendix 2, patients are more likely to effectively self-manage if they are supported by a ‘proactive, prepared, practice team’. While in the Australian context ‘team’ is likely to be less structured than in the USA where the terminology was coined, the functionality of a ‘proactive, prepared, practice team’ may be achieved by provider education, and the establishment of formal and informal links between public and private health sector providers, community services and self-help groups.

The program logic of Sharing Health Care is that a project to develop ‘informed and activated patients’ should:

- Engage patients in a process to develop their self-management skills;
- Provide formal education to develop these skills;
- Collaborate with patients in developing and following an activity plan which involves a mix of self directed activities and a medical care plan;
- Assist patients to continue to use these self-management skills by professional follow-up;
- Establish review and monitoring activities; and
- Encourage patients to be involved in self help groups.

These are the 'patient focussed activities' in the Sharing Health Care Model.

Activities to develop 'proactive, prepared, practice teams' should:

- Establish a team-like environment by establishing links between public and private health service providers, community services and other organisations;
- Undertake provider education supportive of patient self-management;
- Develop agreements on the use of evidence based guidelines to be used by all providers when working with patients; and
- Develop protocols for the exchange of information between health and community service providers.

These are the health system elements in the model.

5.1. Evaluation of hypotheses

The patient and family hypothesis was given in Section 3.1.1. This hypothesis will be supported if it can be shown that patients and families in the intervention group of a Sharing Health Care Project experience improved health and/or quality of life (or a slower rate of decline in these variables) than patients in a control group who receive 'usual care' during the period of the project (where the results have been adjusted for patient characteristics).

The evaluation of this hypothesis requires the following broad sets of data:

- Measures of health status and quality of life of patients and families at the start of the intervention (t_0) and at the end of the period (t_n) for patients in the intervention and control groups where the projects have control groups (these are the measured listed in Table 2, Section 6.1); and
- Measures of the activities that constitute the intervention (to demonstrate that an 'intervention' took place) and to test for any 'dose' response effect (these are the Impact and Process measures listed in Table 2, Section 6.1).

The patient outcome measures can only be attributed to whole projects, while many of the impact and process measures can be associated with the elements of projects (e.g. self-efficacy measures may be associated with patient education interventions).

The health service provider hypothesis (3.1.2) and health service hypothesis (3.1.3) are also evaluated at the project level.

As discussed in Section 5.2, each project **should consider establishing** formal intervention and control groups, randomised where possible, to allow comparison of the outcomes, impact and process measures, both within projects and between projects. This will not be possible in all cases. For some of the measures proposed in Section 6 it will not be possible to have an intervention/control experimental design as some of the systems change issues are all-or-nothing interventions (discussed further in Section 6). Analysis of process and impact across projects will provide comparative data on the effectiveness of some elements of different interventions.

Analysis of these measures will permit comparisons between projects to see if some interventions are more or less effective in bringing about change than others. Each local evaluator will be responsible for evaluating the extent to which their own project meets the patient and family hypothesis while the national evaluators will be responsible for comparing effectiveness across projects.

The national evaluators, with the assistance of local evaluators, will be responsible for comparing performance of the elements of the demonstration projects using process and outcomes measures.

The proportion of patients who participate in different aspects of each project will provide a good guide to the effectiveness of elements in the projects, and can be directly related to the Key Evaluation Questions:

- The proportion of the target population who initially engage in activities offered by the projects (including self-management education programs) (Evaluation Question 1);
- The proportion of the enrolled population who fully engage in the activities offered (eg. complete the self-management education program where this is offered) (Evaluation Question 3);
- The proportion of the fully engaged population who are empowered by the activities and education program (ie experience improved self-efficacy) (Evaluation Question 4);
- The proportion of the fully engaged population who change their health behaviours (in both the short term and long term) (Evaluation Question 4);
- The proportion of the fully engaged population who experience improved health outcomes (in both the short term and long term)(Evaluation Question 6).

Each of these measures must be adjusted for the characteristics of the population cohorts. Unless the numbers and characteristics of people in the target population are known it is not possible to answer Evaluation Question 1 – perhaps the most important question that the Initiative should address. If the characteristics of only those who take part in some form of self-management educational activity is known, it will not be possible to know if people with high need and high burden of disease are participating to the extent that they should.

A number of the patient focussed and health service elements will influence the proportion of patients who participate in the projects. The attitudes of health service providers to Sharing Health Care may influence the willingness of patients to undertake self-management education, or may influence the persistence of patients in seeking to manage their own conditions. But the attitudes of health service providers can also be influenced by education programs designed for them, or by policies, practice or incentives within the health system. Patients may be more or less willing to undertake self-management education depending on the specific type of course offered.

5.2. Evaluation of Projects

It needs to be recognised by project sponsors that individual projects are being undertaken as part of developing an understanding of the range of what interventions work in the Australian context. While the projects will provide services to people, they are primarily being undertaken for the purposes of evaluation.

When projects are refined specific consideration will have to be given to how the hypotheses specified by the Department and the Key Evaluation Questions can be evaluated. To do this will require that each project explicitly consider the following issues in their project designs:

- Definition of target population;
- Project design factors relating to evaluation;
- Definition of management responsibilities with respect to clinical issues, service delivery issues and evaluation issues and the relationships between them;
- Review and monitoring activities;
- Processes for collection of data for evaluation and monitoring purposes;
- Ethical issues.

As a first step, projects should identify those key evaluation questions that they believe their projects can contribute to the evaluation of, and any evaluation questions that are specific to their projects. Other issues that require specific consideration are:

5.2.1. Definition of target population

To undertake the evaluation in a manner that allows the Key Evaluation Questions (especially Questions 1,2, 3) to be evaluated, projects will need to be able to define the target group that the project seeks to recruit and be able to compare those who engage with the project with those who do not. (See Appendix 2 for justification for importance of Key Evaluation Questions 1-3).

5.2.2. Evaluation method

If conclusions derived from projects are to have any scientific or policy significance, they should be derived from a credible evaluation method. The more rigorous the evaluation methods used, the more credible will be the findings derived from them.

Project sponsors should consider the hierarchy of evaluation designs possible - randomised/controlled trials, controlled trials, case controlled studies, before and after studies etc – and chose the most effective research **designs** consistent with their projects. Where projects are contributing to the evaluation of a number of key evaluation questions, they may be able to incorporate a number of different evaluation methods into their project depending on the specific question and on their project.

When considering the evaluation method, project sponsors should consider that there will be 'noise' in the system due to other changes that are occurring concurrently. These include the increasing use of Enhanced Primary Care items, the RACGP disseminating its tools and materials on the use of Enhanced Primary Care items, and various State and Territory health authority initiatives. Rigour in project design will be necessary to separate out the effects of the SHC project

from the effects of other changes.

Lessons from the Coordinated Care Trials should also be incorporated into the project – for example GPs should be the unit of sampling rather than patients since GPs are unlikely to differentiate the care they provide to patients who are in or out of the project.

Project sponsors should consider if it is possible to incorporate some elements of randomised/control design into evaluating the key evaluation questions.

Where a randomised/control model is not appropriate for cultural or logistic reasons the project sponsors and local evaluators will have to develop a project design that allows for the rigorous testing of the hypotheses and Key Evaluation Questions.

5.2.3. Sample size

There is an extensive research literature on the impacts and outcomes of different types of self-manage educational interventions. In some cases, studies with small sample sizes have been able to demonstrate statistically significant, or nearly statistically significant, effects. Though many projects will use continuous recruitment rather than selection of a single sample, the sample size issues remain the same for estimating the scientific validity of conclusions reached.

Project designers should explicitly describe the research evidence that justifies the sample size of their projects. (See Section 5.2.5 below).

5.2.4. Definition of management responsibilities

Projects will need to establish clear lines of responsibilities with respect to clinical issues, service delivery issues and evaluation issues and the relationships between them. Quality assurance processes will need to be established for each one of these activities.

5.2.5. Review and monitoring

Projects will be expected to have mechanisms to review and monitor their activities during the course of the project so as to take corrective action if necessary. The review and monitoring process should ensure that changes made to the project during its course are undertaken in a manner to ensure that the evaluations can continue.

5.2.6. Process for collection of data

Data will have to be collected for evaluation and monitoring purposes. Where possible data collected for management, monitoring and evaluation purposes should be from the same data sets to minimise respondent burden and to avoid the potential for conflict between those responsible for different activities.

5.2.7. Ethical Issues

Each project will need to examine the ethical issues that its particular processes raise. A document relating to issues of confidentiality of information and data should be prepared and where necessary, informed consent should be obtained for the inclusion of personal data in research data sets.

Section 4 describes the Organisation and Management Issues for the evaluation. This will need to be considered by project designers when considering their relationships with local and national evaluators, and for the transfer to data to these groups.

5.3. Evaluation of the Education Module and Guidelines Module

The Education Module has been developed 'for Practitioners who assist patients in the Self Management of a Chronic Disease'. The initial Module is being developed for General Practitioners and will be adapted for the needs of other health professionals.

The Guidelines Module includes a detailed Guideline that provides details of the relevant literature and the levels of evidence that support the recommendations, a short Guideline in the form of a flip chart that the clinician can use when discussing self management issues with patients, and a two page chart for use by the clinician. All of the information in the Education Module will need to be consistent with that in the detailed guideline.

Since these two Modules have been developed using similar data sources and have to be consistent and mutually reinforcing, the dissemination of the Guidelines and the Education Module are not 'independent' activities. It was agreed at the first meeting of the Chronic Disease Self-Management Education Modules and Guidelines Technical Advisory Committee meeting on 18 October 2000 that the Education Module and Guidelines would be evaluated for their *impact* on the outcomes of the Sharing Health Care Projects.

A single strategy needs to be developed to evaluate both modules. The evaluation should assess the impact of three different implementation strategies:

- The 'passive' distribution of the detailed guideline to clinicians (ie distribution with little other activity to promote the use of the guideline). 'Passive' dissemination of detailed guidelines has been found to have little impact on the uptake of guidelines. In the context of these evaluations, the distribution of guidelines could include information to let GPs know that the projects are being undertaken. This group of doctors could act as a control group for the other education strategies;
- Distribution to clinicians of the short Guideline and related material with some promotional fanfare; and
- Offers of formal education to clinicians using the Education Module and tools within it.

The distribution of the short Guidelines and offers to take part in the Education Module should be randomised if at all possible to allow for more rigorous evaluation.

The Department, with the assistance of the national evaluator, should ask several projects to use the Education Module as the basis of education for at least some of the health professionals involved in their projects. The three implementation strategies could be evaluated by comparing the impact of each strategy on those factors identified in the Health Service Provider Hypothesis.

In addition, the national evaluator should conduct a survey of projects not formally involved in evaluating the Education and Guidelines Modules and Divisions of General Practice to ascertain the extent to which these groups used the material developed.

5.4. Evaluation of the Database of Accredited Projects

The Department is funding the development of a database of self-help groups and local support and training activities that can be accessed by anyone in the community - health service providers, patients, family etc. The contract for the project had not been let as at 27 October 2000, so detailed discussion is not possible at this stage.

It is possible to develop an experimental design to evaluate the database project for its impact on health outcomes as a stand alone project, but it is likely that it would be expensive and that it would be difficult to detect the impact in the context of the other activities being promoted relating to patient self-management. The database project should be evaluated using measures of access and acceptability to providers, patients and families, and self-help groups.

The evaluation should consist of a survey of patients and families, providers and self-help groups to measure the proportions of these groups who access the material and the frequency with which they access the material. The results should be analysed by characteristics of patients and providers already collected for other purposes (eg how does the use of the database by GPs who have use the Education and Guidelines Modules, compare with that of GPs who have not used the modules?). The local evaluators should undertake the survey for demonstration projects. The national evaluators should examine the use of modules in those projects and Divisions of General Practice which are not funded in this program.

The 'home page' of the database should incorporate an 'evaluation questionnaire' to identify the characteristics relevant to the people who visit the site.

6. Data requirements to Evaluate the Hypotheses and Evaluation Questions

To ensure a consistent evaluation of the Sharing Health Care Initiative it is important to have a clear set of priorities to guide activity. The evaluation hierarchy is as follows:

- 1 Outcomes for patients (and families/carers)
- 2 Impact on providers
- 3 Impact on the health system

The Evaluation Framework proposes a nested design to allow the evaluation of four levels of activity simultaneously:

- the evaluation of **each project** against the three hypotheses;
- the evaluation of **elements** of each project against the Key Evaluation Questions;
- the evaluation of the Education and Guidelines **Modules**; and
- the evaluation of other **research issues**.

The data required for the evaluation will be a mix of quantitative, qualitative and descriptive data with patient data being largely quantitative, health systems data being largely descriptive, and health service provider data being a mix of quantitative and qualitative.

The proposed data sets represent the 'ideal' for the purposes of the evaluation of the Sharing Health Care Initiative. Because of the differences in the projects funded so far, the issue of how data are collected and by whom will have to be determined on a project by project basis.

Some projects will not cover all elements of the Sharing Health Care Model. These projects will not need to collect the data specified below, unless they require it to answer evaluation questions addressed in their project.

The data are defined in the following groups:

- Patient and family data;
- Provider data; and
- Health systems data.

6.1. Patient data

Evaluation of the patient and family hypothesis (3.1.1), and the Key Evaluation Questions 1-9 requires five sets of data:

- Descriptors of the patients (and families where appropriate);
- Measures of the health of patients at the start, during and end of the project;
- Measures of activities undertaken by the patient (where activities include self-initiated activities such as exercise, involvement with self-help groups etc, or health services received);

- Measures of health service use;
- Data for Key Evaluation Question 9 - structured interviews with patients and carers, and with people in the target group who did not participate in the activities of projects, to assess their perceptions of barriers to entry to the project, experience with different elements of the projects and other factors relevant to the success of individual elements and the entire project.

Five sets of data will need to be collected. These are shown in Table 2.

Table 2: Recommended data items for evaluating outcomes for patients and carers

Data Type/ Data Item	Patient	Carer	Target Population	Type of Measure (a)
	Collected?/ When	Collected?/ When	Collected?/ When	
Descriptor Items				
Age, Sex	✓ Baseline	✓ Baseline	✓ Baseline	
Role (eg employed), Pension Status, Income, Carer Support	✓ “	✓ “	✓ “	
Ethnicity, Language spoken at home, ATSI	✓ “	✓ “	✓ “	
Health Status				
Health related quality of life	✓ 0,12,24, 36 mths. (b)	✓ 0, 12, 24, 36 mths (b)	✓ 0, 12, 24, 36 mths	O
Chronic Conditions	✓ “		✓ “	O
Self-rated health	✓ “		✓ “	O
Disability	✓ “		✓ “	O
Social/role activities	✓ “			O
Pain/physical discomfort	✓ “			O
Psychological well-being	✓ “	✓ “		O
Energy/fatigue	✓ “			O
Symptoms checklist (eg Shortness of breath)	✓ “			O
Clinical measures - conditions specific	✓ “			I
Health behaviours				
Exercise	✓ “			I
Stretching	✓ “			I
Communication with clinicians	✓ “			I
Participation with self-help groups	✓ “		✓ “	I
Self-efficacy ³	✓ “			I
Knowledge, attitudes, beliefs regarding SHC	✓ “			I
Reasons for exiting formal self-management processes (d)	✓ “			
Health Service Use				
Stays and nights in hospital	✓ “		✓ “	P
Visits to Hospital outpatient/ emergency/ clinic	✓ “		✓ “	P
GP visits	✓ “			P
ID of ‘usual’ GP (c)	✓ “			P

³ At the Sydney Chronic Disease Self-Management Conference, Lorig stated that self-efficacy was best treated as an indicator of change not as an outcome.

Specialist Visits	✓	“		✓	“	P
Allied health contacts	✓	“				P
Prescriptions filled	✓	“				P
Use of community services	✓	“				P
Use of Enhanced Primary Care MBS items	✓	“		✓	“	P
Self-management education	✓	“		✓	“	P
Care Plan	✓	“				P
Support and follow-up activities	✓	“				P
Other						
Patient's perceptions of GP attitudes to self-management.	✓	“				I

- Used to calculate measures of O = Outcome, I = Impact, P = Process.
- The '0' month will be determined by the nature of the project. If the project recruits by cohort, all patients will have the same '0' month. If there is on-going recruitment, '0' month is determined by the month the patient enrolled.
- It will be necessary to be able to link patients and GPs in some projects to measure the effectiveness of the provider Education Modules
- The details of exit from formal self-management processes will need to be developed with the projects.

6.2. Health Service Provider Data

The health service provider data required to answer the hypothesis (3.1.2) and the associated evaluation questions will depend, in part, on the structure and staffing of the projects. For example, to address Evaluation Question 10 (the *actual* and *sustainable* costs of variations of elements of the Sharing Health Care Model - see Section 4) requires data on the time and costs to service providers in delivering the agreed elements (eg. in providing patient education). The data necessary for this costing have not been included here.

The focus here, as in the Departmental brief, is on General Practitioners and the recommended data items are shown in

Table 3 Recommended data items for evaluating the impact on providers

Data Item	When collected	Notes	Type of Measure (a)
GP participation in formal patient self-manage education programs	During the life of the project	Timing, duration and intensity of course	P
Self-guided learning activities	✓	✓	P
Use of project provided materials (posters, leaflets, referral forms etc)	✓		P
Activities identified from Guidelines (b)	(b)		P
Use of Enhanced Primary Care MBS items	By month (ex HIC)		P
Knowledge , attitudes, beliefs re self-management	0, 6, 12, 24,36 months		I
Referrals to patient self-manage courses	0, 6, 12, 24,36 months	By type of patient	O
Referrals to self-help groups	0, 6, 12, 24,36 months	By type of patient	O
Use of care plans (other than required for billing for EPC items.	0, 6, 12, 24,36 months	By type of patient	O
<ol style="list-style-type: none"> Used to calculate measures of O = Outcome, I = Impact, P = Process. Activities considered to be 'best practice' to be identified from Guidelines once guidelines development is complete. 			

In addition structured interviews should be conducted with GPs, and other health professionals to assess their perceptions of the self-management in general (at baseline) and of project specific initiatives (6, 18, 36 months).

6.3. Health Services Data

The Health Services Hypothesis is that ‘the Sharing Health Care Initiative resulted in more appropriate⁴ use of health services’.

Two approaches are planned to address this hypotheses:

- A 2x2 analysis of the data collected on patient service use where one ‘pair’ is patients who have been actively involved in self-management activities (education, self-help groups etc) compared to people who did not participate in the project, and the other ‘pair’ is General Practitioners who did or did not formally engage with the project and its education activities.
- Reports from project managers covering changes that have occurred in the formal and informal organisational arrangements and relevant communications within their area as a result of the project.

6.4. Data to evaluate the Education and Guidelines Modules

As discussed in Section 5.3, the evaluation of the Education and Guidelines Modules will be conducted by inclusion of formal ‘sub-projects’ within a number of funded projects.

The data specified above for collection will be sufficient for these evaluations.

⁴ What constitutes ‘appropriate’ use of health services is always a vexed question since it implies that some patterns of service is inappropriate.

7. Applying the Evaluation Framework

This section provides an overview of the Evaluation Framework and of how the elements fit together in the Sharing Health Care Initiative.

7.1. A Complete Overview of the Evaluation Framework

The Evaluation Framework has three main elements:

- the hypotheses and Key Evaluation Questions which give purpose and direction to the evaluation;
- the Sharing Health Care Model which provides a structure for describing and comparing the different projects that are to be funded; and;
- the experimental design necessary to test the hypotheses and evaluation questions.

The 'real world' may be regarded as a fourth element which informs the evaluation designer through the vast, but still inadequate research literature, and yet constrains what can be done because of existing institutional, professional and social arrangements.

The key evaluation questions are derived from the Commonwealth's desire to improve the well being of people with chronic disease and the absence of any operating national Sharing Health Care Program elsewhere in the world that could be used as a model. Because of the gaps in the research literature, it has been necessary to identify a limited number of policy relevant evaluation questions and to build a research agenda around them.

The Sharing Health Care Model provides a basis for describing the Sharing Health Care projects that are funded in a manner that allows the projects, and their elements, to be evaluated separately, but to allow the effectiveness of similar elements in different projects to be evaluated - 'across project' evaluation.

The elements in the Sharing Health Care Model are the 'interventions' that are evaluated to answer the key evaluation questions. It is then necessary to develop a design that allows a rigorous evaluation to be undertaken and to establish a process that ensures that the planned evaluation takes place. The following section develops a work program built around the Evaluation Framework.

7.2. The Work Program

Task No.	Month	Task
Pre Project Phase		
1		Department selects a National Evaluation Coordinator (or national evaluator for short) and a National Advisory Committee (the functions of these are specified in Section 4). The proposed steps in the evaluation are described below.
Project and Evaluation Development Phase		
The tasks for the national evaluators are to:		
2		Review the funded projects and map each project against the elements of the Sharing Health Care Model.

Task No.	Month	Task
3		Provide advice to the Department and the project sponsors in choosing local evaluators for each project (the local evaluators are to report to the National Advisory Committee);
4		<p>Conduct a workshop with project sponsors, local evaluators and key informants to carry out the following tasks:</p> <ul style="list-style-type: none"> ▪ For each element of the model, determine if there are any variations likely to be particularly relevant to Australia that have been omitted from all projects⁵. Initiate discussion with project sponsors to include important variations in one or more of the projects; ▪ Review the target groups and conditions in the projects and select a limited set of health outcomes measures to be used across the studies (these should include a limited number of condition-specific clinical measures); ▪ Review the types of data likely to be available to projects, and assess the need to undertake a comparison of the reliability of collecting health service use data by patient diary, recall, and from administrative data sources. Plan a cross-project study if appropriate; ▪ Identify those groups of carers from which projects should collect data on health status (see Section 6.2); ▪ Initiate the evaluation of Education and Guidelines Modules within projects (See Section 5.2). ▪ Review with project sponsors and local evaluators the issues of evaluation design necessary to undertake the evaluation of elements necessary for their projects.
5		Local evaluators and project sponsors develop their revised project proposals in light of task 4 above.
6		The national evaluators meet with each project team, at the project site, and review the project plan: the definition of elements, method of inclusion of national evaluation issues into plan; project specific key evaluation questions; project design, data collection methods. A report would be produced for the National Advisory Committee on the evaluability of each project, based on these meetings. Agree on data to be provided by the local evaluators to the national evaluators.
7		The project sponsors and local evaluators develop the project infrastructure, patient and clinician recruitment processes, and such other activities necessary for the projects to start. The national evaluators establish data systems necessary to collect data.
Phase 0 – 8 months after start up		
8	Month 0	National evaluators develop a pro-forma for a baseline report to be provided by projects
9	Month 1	Project sponsors and local evaluators provide a base line report to the national evaluators detailing the local health service infrastructure and the ways in which their projects activities fit and planned activities to carry out the process (after negotiation with local stakeholders on the specifics)
10	Month 3	The national evaluators provide to the National Advisory Committee a National Baseline Report based on the local reports
11	Month 6	Data Quality Study: The national evaluators, local evaluators and project sponsors conduct a data quality study at each project site. Local evaluators to provide data from the first 6 months to the national evaluators. Project sponsors to provide to the national evaluators a short report on activity and impressions of the first six months operation of the project

⁵ For example, in the projects that the design team reviewed to develop an appreciation of the projects being submitted, there was no project that sought to offer courses on self-management to people with chronic illness who attended Emergency Departments, or who were admitted to hospital. This seems a likely place to engage just those people who the literature suggests are not easily engaged in self-management education.

Task No.	Month	Task
12	Month 8	Short Report to NAC on Data Quality Study and Activities and First Impressions of the first 6 months operations
13	Month 12	Survey by national evaluators of Divisions of GPs and Projects which used Education and Guidelines Modules material for training purposes, other than as part of the formal evaluation
14	Month 12	Local evaluators survey non-participants and persons who left the projects
15	Month 12	Local evaluators survey patients, families, GPs and local self-help groups to assess usefulness of Accredited Database Project
16	Month 13	Project sponsors and local evaluators review the performance of their projects, taking into account the results of the survey in Task 15 and analysis in Task 17, and make such changes as are considered appropriate (subject to the evaluability of the changed project). Changes to be reported in Task 15.
17	Month 13	Projects analyse and report on the conduct of the project over the first 12 months of operations, and on findings to date against hypotheses and evaluation questions. Project data provided to national evaluators.
18	Month 15	National evaluators to provide to the National Advisory Committee a consolidated report on the results of the first 12 months of operations including comparisons of performance against key evaluation questions of projects and changes in project design resulting from the review of performance.
19	Month 17	Second data quality study to be carried out by project sponsors and local evaluators in consultation with the national evaluators
20	Month 18	Local evaluators transfer project data to the national evaluators
21	Month 19	Report to National Advisory Committee by national evaluators on second data quality study
22	Month 24	Survey of, or consultations with, non-participants, persons who have exited the project, service provides, self-help and community services.
23	Month 24	Survey by national evaluators of Divisions of GPs and Projects which used Education and Guidelines Modules material for training purposes, other than as part of the formal evaluation.
24	Month 24	Local evaluators survey of patients, families, GPs and local self-help groups to assess usefulness of Accredited Database Project
25	Month 25	Local evaluators transfer 24 month data to national evaluators
26	Month 25	Project sponsors and local evaluators provide 24 month report on projects to NE and National Advisory Committee
27	Month 25	Project sponsors to review projects in view of results of Task 26
28	Month 26	National evaluators to prepare 24 month report to National Advisory Committee
29	Month 31	Local evaluators transfer 30 month data to National evaluators
30	Month 35	Survey of, or consultations with, non-participants, persons who have exited the project, service provides, self-help and community services.
31	Month 35	Survey by national evaluators of Divisions of GPs and Projects which used Education and Guidelines Modules material for training purposes, other than as part of the formal evaluation
32	Month 35	Local evaluators conduct survey of patients, families, GPs and local self-help groups to assess usefulness of Accredited Database Project
33	Month 37	Local evaluators transfer final data to national evaluators
34	Month 37	Project sponsors and local evaluators prepare final project reports
35	Month 38	National evaluators prepare consolidation of project reports and report on cross-project

Task No.	Month	Task
		studies

8. Risk Analysis

There are 6 risks to be managed in the evaluation of the SHC initiative:

- a) Significant elements, or important variations in elements, of the Shared Health Care Model may not be included in the program of demonstration projects.
 - This is a substantial risk and could threaten the learning that results from the program.
 - It could be managed by asking first round projects to include additional elements or by commissioning second round projects to broaden the range of elements addressed.
- b) Project interventions are implemented inconsistently such that they cannot be evaluated or projects change interventions and compromise evaluation.
 - This is a serious risk that eventuated in the first round of coordinated care trials.
 - It can be managed by developing close relationships between projects and the local and national evaluators.
- c) Evaluation monies are spread too thinly such that key questions cannot be reliably answered.
 - If funds do not permit adequate evaluation to take place then the entire program is threatened.
 - It would make more sense to evaluate a small number of projects properly than to attempt to evaluate a larger number of projects that do not provide a satisfactory vehicle for learning.
 - DHAC should critically review the number of key questions and set priorities.
- d) Demonstration projects submit poor quality data.
 - Poor quality data threatens the ability to address questions directly.
 - A combination of local evaluator support and National data quality reviews should prevent this problem and enable improvements in data quality through the projects.
- e) Projects recruit clients who are not representative of program target groups eg without co-morbidities, or from higher socio-economic status populations.
 - This threatens two distinctive features of the proposed Sharing Health Care program.
 - Local and National Evaluators should pay particular attention to the clients recruited at the earliest opportunity and projects should change their recruitment strategies if necessary.
- f) Projects and evaluators have difficulty following up clients in order to measure outcomes and impacts.
 - This would make it difficult to address the patient/client hypothesis.
 - Projects should pay particular attention to explaining purpose of the projects to clients at recruitment to facilitate understanding and follow-up.

Appendix 1: Process of Consultation

Design team activities

The main activities undertaken by the CHSD to develop the framework were:

- A literature review;
- Attendance and presentation at the National Chronic Disease Self-Management Conference;
- Development of a Discussion Paper on the Development of the Evaluation Framework;
- Circulation of the Discussion Paper to stakeholder groups;
- Meetings, telephone follow-up and correspondence with stakeholders on the Discussion paper (See Appendix 2 for a summary of these responses);
- Discussions with members of the Sharing Health Care Technical Advisory Committee;
- Discussions with members of the project teams developing the Education and Guidelines Modules;
- Discussions with officers of DHAC.

Process of consultation and level of response

The Stakeholder Discussion Paper - Development of the Evaluation Framework for the Sharing Health Care Initiative was circulated to a number of stakeholders organisations and informed individuals during the week 1-8 September. Stakeholders were offered three mechanisms for providing feedback: by meeting with a member of the design team (Roy Harvey) and other stakeholders (initially, meetings were proposed to be held in Sydney and Melbourne during the week 18-22 September); by email, fax or hard copy; or by telephone discussion with the consultant. It was requested feedback be provided by 22 September.

The Melbourne meeting was held on 20 September which was attended by 4 stakeholders. The Sydney meeting did not eventuate because of lack of response from Sydney based stakeholders - presumably due to the Olympics. Instead a meeting was held in Canberra on 22 September which was attended by 3 stakeholders (another stakeholder had advised that a representative would attend but did not. Attempts were made to obtain feedback from that stakeholder but no response was received to any of the 3 follow-ups).

It is not possible to calculate a response rate because some organisations circulated the Discussion Paper to a number of people resulting, in some cases, in more than one response per organisation. It was not always clear whether people were replying on behalf of organisations or in their own right.

A total of 21 responses (counting attendances at meetings) were received as shown in Table 4 and Table 5.

Table 4 Responses received during the consultation process from health issue organisations

	Responses	Involvement			
		Email	Meeting	Phone	Follow-ups

	Responses	Involvement			
		Email	Meeting	Phone	Follow-ups
Arthritis	2		1	1	
Asthma	1		1		
Diabetes	1		1		
Heart	4	1	3		
Kidney	0				3
Aboriginal Health	1	1			
Consumer	1			1	
Total replies	10	2	6	2	

Table 5 Other responses received during the consultation process

	Responses	Involvement		
		Email	Meeting	Phone
State Health Authorities (1)	6	4	1	1
RACGP - Rural Health	2	2		
Academic	2	2		
CCT1 Evaluator	1	1		
Total	11	9	1	1
(1) NSW, Qld, SA, Tas, ACT, NT				

The Stakeholder Discussion Document asked for comment on 19 questions on evaluation design issues, 9 Evaluation questions, and one 'any other comment'. In general respondents tended to concentrate on a few questions or on issues of particular interest to them. The overview of these responses is presented here as: issues raised that did not fit well into the general 'questions' posed; and, a summary of responses by group of questions (broad comment about 'medical model vs consumer focus').

Broad issues

Consumer issues: A number of consumer respondents were concerned that the framework had a medical model bias instead of a consumer focus which they perceived as the fundamental basis of the patient self-management.

Need to ensure that the consumer experience is investigated – it will help to identify **why** some elements and projects are successful, not just **which** ones were. Requires questionnaire/interviews on barriers (physical, psychological or financial) to self-management.

Concern that the model assumed that there would be a formal education element for patients. The approach suggested was to monitor patient activity to see if they were already self-managers or took on the self-management role without formal education. The effect of 'informal' education by providers was acknowledged as a possible element in developing the self-management role.

Wanted to see role of self-help groups given greater prominence – referrals by health providers to self-help groups etc.

General Issues: Strong support for use of a uniform set of instruments to measure health and quality of life of patients with condition specific subsets (including a few key clinical measures) where appropriate. There were no strong views one way or another about using the Stanford instruments.

Table 6 Summary of issues raised in consultations

Topic	Question Numbers	Comments
Evaluation Framework issues		
Generic Sharing Health Care Model	1-3	Need to recognise 'community' - self-help groups and support.
Patient hypothesis and measurement issues	4-10	<p>Include 'participation instrument' being developed by WHO.</p> <p>Include 'readiness to change' as a baseline measure for patients and providers.</p> <p>Should 'self-efficacy' or 'empowerment' be included as an 'outcome' or a 'process measure'?</p> <p>Terminology - use Activity Plan instead of Care Plan</p> <p>Some support for the use of the Stanford instruments if adapted to Australian use.</p> <p>Carer outcomes – Care Giver Strain Index</p> <p>Patient characteristics should include measures of 'social connectedness'</p>
Provider hypothesis and measurement issues	11-12	
Health Service hypothesis and measurement issues	13-14	<p>Seek to include measures of 'trust' between patients and providers and providers and providers.</p> <p>Audit chronic disease services at baseline and over time and link to patients self-management status at baseline and over time.</p> <p>Desirable if programs resulted in development of 'new' health services through a process of capacity building involving clients, communities and established providers.</p>
Measurement of patient participation rate in education	15-16	Strong (essential/vital) support for follow-up of patients not taking up offers of self-management education. Need to understand 'patient experience' and specific barriers that may inhibit involvement in Self Management.
Patient follow – models of	17	Strong support for trialing phone, mail, Internet follow-up methods
Possible conflict between patient preferences and best clinical practice	18	Some concerns about this but no solutions or options suggested.
Model for Management of Evaluation	19	No comments.
Any other	20	No comments not elsewhere discussed.
Evaluation questions		
Effectiveness of recruitment strategy and patient characteristics	1-2	<p>Measure patient's social environment, knowledge, 'readiness to change'</p> <p>Modify EQ 2 to be 'how well can patient related characteristics..'</p>
Patient Education strategies, effectiveness, outcomes and costs	3-6	<p>Modify questions to read 'how does...'</p> <p>EQ 4 covered by EQ2.</p>
Patient support, carer support and outcomes	7-9	SA RDNS Carer Stress instrument possibly useful to the evaluation. One suggestion that an instrument to assess depression in carers could be used.

Appendix 2: Foundations of the Sharing Health Care Model

Self-management approach has been defined by Lorig (1993) as enabling:

‘Participants to make informed choices, to adopt new perspectives and generic skills that can be applied to new problems as they arise, to practice new health behaviors, and to maintain or regain emotional stability’

Von Korff (Von Korff, 1999 p552) defined self-management as:

‘an approach aimed at encouraging people with chronic illness to:

- *Engage in activities that promote health and build physiologic reserve*
- *Interact with health care professionals and systems and adhere to recommended prevention and treatment protocols*
- *Monitor their own physical and emotional status, using the results to make appropriate management decisions*
- *Manage the impacts of illness on their emotions, self-esteem, relations with others and ability to function in important roles.’*

There is a growing body of research that shows that Self Management Programs can assist people with chronic conditions to improve the quality of their lives and to reduce health service use. Much of this research has focussed on disease specific programs (arthritis [Lorig 1998, Taal 1997], asthma and lung disease [Gallefoss,2000] , heart disease [Sawicki, 1999], etc) but Lorig (1999) has shown that a self management program can be run for people with different chronic conditions and with different co-morbidities and provide improved quality of life and reduced health service use. But the literature also raises a number of potential problems that need to be planned for if there are to be overcome.

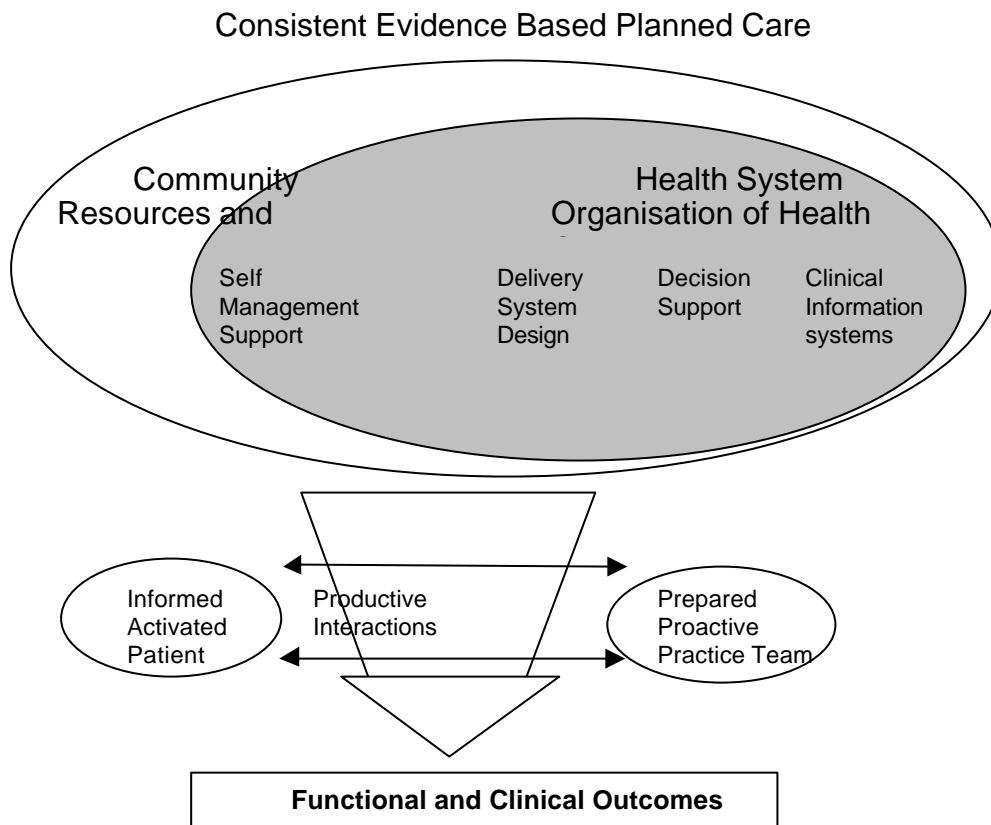
The research literature on self-management may be loosely grouped into ‘narrow’ focussed and ‘wide’ focussed studies (this dichotomy will cause injustice to some studies). The ‘narrow’ focussed studies tend to concentrate on chronic disease self-management *training* activities (Lorig, 1998) and are mainly patient education focussed studies. The ‘wide’ focussed studies place the patient education activities in a broader *systems* context, often involving health care providers in the training and sometimes involving modifications to health systems.

There is an extensive (‘narrow’ focus) literature that reports on various forms of self-management education interventions that have produced improvements in well being and some reductions in the use of health services (Lorig 1999). Some of these interventions have focussed on self-management of single chronic conditions, while others have provided self-management education to groups of people with different and sometimes multiple chronic conditions. There is growing support in the literature for the view that there is a generic set of self management skills that are applicable to people with different conditions (Clark 1991, and numerous Stanford publications) – relating to exercise, nutrition, monitoring medications, relaxation skills etc. Such generic self-management skills can be supplemented with condition specific knowledge. Some of these ‘narrow’ focus interventions had patient support activities that reinforced the self-management skills of the patients. While most studies report on planned educational interventions, there is also evidence to show that involvement of people in self-help networks, with no formal educational interventions, can also result in improvements in well being. A number of studies have commented on the concerns about the participation rates and attrition, and the potential bias in self-management education programs (Glasgow, 1996; Dodge 1993).

Some of the 'narrow' focus studies were of relative small scale and were conducted in environments in which the health system was probably aware of the conduct of the study and was generally supportive of self management principles.

The literature on 'broad' focus is varied in the content. Some report on studies that establish training programs for health providers (Clark 1998), others report on systems that provided structured support to patients over longer time periods, while some studies report on factors that inhibit the provision of support to self-managing patients.

Figure 2 The SHC Model



Reference Wagner EH, Davis C, Schaefer J, Von Korff M, Austin B (1999) 'A survey of leading chronic disease management programs: are they consistent with the Literature' **Managed Care Quarterly** 7 (3), 56-66.

There is no conflict between the two sets of literature – the differences are matters of emphasis. The significance of the breadth of the self-management literature is that the Evaluation Framework must also be capable of evaluating widely differing projects.

In Wagner (1999), a model was developed (Figure 1) which sought to show the underlying relationships necessary to achieve successful functional and clinical outcomes by self-managing patients. Two essential elements were identified as necessary:

- 'informed activated patients', and
- 'prepared, proactive practice teams'.

Informed and activated patients can either be spontaneous self managers or persons whose self management skills are developed through formal or informal training and networks. The 'narrow' focus literature provides a wealth of research describing how patients can be encouraged to be 'informed and active'.

The development of prepared, proactive teams was seen as requiring change not only through the health system (the shaded area in Figure 2), but also by developing better links between the formal health system and community resources and policies. While the activities of patient self-help groups is not explicitly identified in the diagram, they were regarded as important element in linking the health and community sectors.

Von Korff (1999) describes the elements necessary to develop and sustain self management by patients:

- a) Interventions that strengthen the patient's role
 - Self-management education
 - Clinical assessment conducted in such a manner as to inform providers about the individual patient's life situation and preferences, and to allow the matching of treatment recommendations to patient's needs and preferences;
 - Collaborative treatment planning which involves:
 - Sustained follow-up
 - Collaborative problem solving
 - Individualising treatment approaches
- b) Interventions to ensure that the health system is supportive of self management, including
 - Provider education
 - Recognition of the role of allied health professionals
 - Coordinated and consistent primary and specialist care;
 - Information systems to support patients and providers
 - Better links between the health sector and the community resources, especially formal and informal self help groups.

The Model has been developed to reflect this literature. The Education Module also makes reference to the material in Wagner (1999) and Von Korff (1999).

Appendix 3: Developing the Key Evaluation Questions

The Key Evaluation Questions were first developed by the design team after reviewing the literature, discussing issues with a limited number of key informants, and considering the Department requirement that the evaluation focus on effectiveness research (that is identifying what actually works in routine practice).

There is a large literature on chronic disease self-management covering not only the narrow and broad focus literature referred to before, but extending into management and organisational theory, health promotion methods, theories of learning and behaviour change and issues of cultural studies.

The research literature shows that chronic disease self-management education has been efficacious in many limited trials, engaging specific target populations, and delivered in a variety of settings (hospital, ambulatory settings, community settings). It has been shown that it can work with patients with single chronic conditions and mixed groups of patients. However, there appears to be no country with a national SHC program.

At the Chronic Disease Self-Management Conference in Sydney in July-August this year, there was a report on the experience of Arthritis Care in England. Arthritis Care has been developing lay person-led education programs for about 5 years; in that time it has provided education to 5000 patients, and expects to provide education to another 3000 people in the coming year: it appears to be one of the largest routine Self Management education providers in the world. However, it was stated that there are about 8 million people with arthritis who could potentially benefit from this program. It is a long step from providing services on a largely voluntary basis to thousands of people to providing services to hundreds of thousands of people annually.

The research literature also shows that some Self Management education trials have had relatively high rates of non-participation, while others have experienced significant rate of attrition during the education program or in a relatively short time after the education programs (Glasgow, 1996, Dodge, 1993). Some trials have reported that the benefits of the Self Management education appear to decline after six months while others reported sustained benefits for up to four years. Other trials have reported that low intensity education and patient follow-up have been as successful as more intense and expensive interventions.

The design team identified two sets of issues that seemed most important to providing a basis for developing a national program. The first set concerned the uncertainty that surrounded the matching of self management interventions to the needs of patients, particularly patients with multiple chronic conditions and patients in socially and culturally disadvantaged groups. The second set concerned the type of support and follow up services/activities necessary to sustain patients as effective self managers. These were incorporated into nine evaluation questions.

The Key Evaluation Questions were included in the Discussion Paper that was circulated to stakeholders (see Appendix 2 for details of feedback) and stakeholder were asked to comment on the Key Evaluation Questions proposed and to suggest additional questions. There was strong support for issues chosen and one additional issue raised in one way or another by several consumer stakeholders. This issue concerned developing an understanding of WHY patients responded to the Sharing Health Care projects in the ways they did. Their concern was that the success of any self management project to engage patients in self management activities and to sustain them in these activities, may be determined more by patient characteristics in that individual trial than to the elements of the intervention itself. To this end they proposed that an attempt should be made to identify the factors that patients saw as important in engaging and continuing with the projects:

- Why did they chose not to participate in self-management activities offered to them (cultural, social, financial, environmental);
- What were the factors that lead patients to participated in self-management education programs or self help groups, to develop activity plans, and to implement (or not) their activity plans.
(*it was suggested by a consumer stakeholder that the term 'activity plan' was more appropriate than 'care plan' on the grounds that 'care plan' has a strong clinical focus while the outcomes of much self management educations is activity chosen, undertake and directed by patients themselves, and the clinical elements may only be a small part of this activities).

Following consultation, it is proposed that there should be nine Key Evaluation Questions relating to the three issues:

- Participation in the projects
- Methods of sustaining the practice of self-management
- Factors that patients identify as influencing their decisions.

The Key Evaluation Questions are:

Evaluation Question 1: Which recruitment strategies are most successful in recruiting which target groups?

Evaluation Question 2: Can patient related characteristics be identified so that the service providers can offer education programs that patients are most likely to accept? ?
This should include identifying patients who can self manage effectively without specific education.

Evaluation Question 3: Are some forms of SHC education more acceptable to some population groups than others - and hence influences the participation rate in the program?

Evaluation Question 4: How does the form of self management education influence the health behaviours and health outcomes of patients?

Evaluation Question 5: Are the health outcomes associated with high cost programs better than those associated with low cost?

Evaluation Question 6: How does the type and intensity and frequency of patient support and follow-up influence health behaviours and health outcomes?

Evaluation Question 7: Does the type and intensity of patient support and follow-up influence the costs of service utilisation?

Evaluation Question 8: Does the type and extent of carer and community support influence patient outcomes and the costs of service utilisation?

Evaluation Question 9: What are the factors that patients identify as contributing to their engagement and continuing involvement with self management initiatives or to them not becoming involved to dropping out.

Evaluation Question 10: Determine the *actual* and *sustainable* costs of variations of elements of the Sharing Health Care Model (see Section 4).

Evaluation Question 11: Projects should identify those changes necessary to make the elements of their project sustainable (ie part of the continuing provision of health services).

Evaluation Questions 10 and 11 were derived directly from those posed as 'possible' questions by the Department in its Request For Tender. Most of the other 'possible' questions posed by the Department will be able to be answered from the data already collected for these 11 Key Evaluation Questions.

Bibliography

- Anderson RM et al (1995) 'Patient empowerment: results of a randomized controlled trial' *Diabetes Care*, 18, 943-949.
- Clark NM et al (1992) 'Impact of self-management education on the functional health status of older adults' *Gerontologist* 32, 438-443.
- Clark, NM, Gong, M, Schork, M A, Et al (1998) *Impact of education for physicians on patient outcomes* Pediatrics 1998 V 101, I 5, pp831-6.
- Dodge, JA, Clark, NM, Janz, NK (1993) *Nonparticipation of older adults in a heart disease self-management program* Research on Aging 1993 Vol 15, i2, pp 220-237
- Gallefoss, F Bakke, PS (2000) *Impact of patient education and self-management on morbidity in asthmatics and patients with chronic obstructive pulmonary disease* Respiratory Medicine 94, pp279-287.
- Glasgow, RE, Eakin, EG, Toobert, DJ.(1996) *How generalizable are the results of diabetes self-management research? The impact of participation and attrition* Diabetes Educator Vol 22, i6, pp 573-4, 581-2, 584-5
- Gruman, J. and M. Von Korff (1999). *Self Management services : their role in disease management.* Disease Management and Health Outcomes 6(3): 151-158.
- Lohr KN (1988) *Outcome measurement : concepts and questions* Inquiry, 25:37-50.
- Lorig K, et al (1996) *Outcome Measures for Health Education and other Health Care Interventions* Sage Publications.
- Lorig, K, Gonzalez, VM, Laurent, DD et al (1998) *Arthritis self-management program variations: three studies* Arthritis Care & Research v11, I6, pp 448-54
- Lorig, K. R., D. S. Sobel, et al. (1999). *Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial.* Medical Care 37(1): 5-14.
- Provan KG, Milward HB (1995) *A preliminary theory of interorganizational network effectiveness: a comparative study of four community mental health systems.* Administrative Science Quarterly, March 1995.
- Sawicki PT (1999) *A structured teaching and self-management program for patients receiving oral anticoagulation: a randomized controlled trial* JAMA Jan 13, 1999 v281 i2 p145(1)
- Taal E, Rasker JJ, Wiegman O (1997) *Group education for rheumatoid arthritis patients* *Arthritis and Rheumatism* 1997, 26 (6) pp805-816.
- Von Korff, M., J. Gruman, et al. (1997). *Collaborative management of chronic illness.* Annals of Internal Medicine 127(12): 1097-102.
-

Von Korff, M. and E. Wagner (1999) *The role of the older person in managing illness*. New Ways to Care for Older People: Building Systems Based on Evidence. E. Calkins, C. Boulton, E. Wagner and J. Pacala. New York, Springer Publishing Company.

Wagner EH et al (1996) Organizing care for patients with chronic conditions *Milbank Quarterly* 74, 511-544.

Wagner EH, Davis C, Schaefer J, Von Korff M, Austin B (1999) *A survey of leading chronic disease management programs: are they consistent with the Literature* Managed Care Quarterly 7 (3), 56-66.