The Medical Research Handbook

Planning a Research Project

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PREFACE

Research is vital to the understanding of problems that affect individuals, communities or health systems. It allows for a systematic and scientific assessment or evaluation of the problem and often provides knowledge that allows for change to occur – change that can improve the quality of health and health care. No organisation or health institution can grow or develop without the use of research.

The major problems facing research today is the lack of application of research findings. Conducting research for "research sake" or the "publish or perish mentality", has resulted in a flood of research publications that have little impact on health – the 10/90 gap in medical research (only 10% of global research funding is spent on health problems that affect 90% of the world's population). What is required today is applied research – research that impacts the health of the individual and the community, resulting in meaningful improvement in health status.

With this in mind, we have produced this research handbook. We hope it assists health care professionals to identify important health needs. The style we have used is a step by step approach to preparing a research proposal. In addition, we have provided examples and two summaries of completed proposals.

This research handbook was initiated by the lead author in 1990 and revised numerous times since. It began as lecture notes and has gradually evolved into a brief handbook, aimed at giving the reader the "basic skeleton" or components of research methodology and provides a guide to conducting a research project. Much of the contents have been developed and revised based on numerous research training workshops conducted over many years. It has currently been extensively revised and re-written with the view to offer a practical handbook to health professionals interested in conducting research.

Although the handbook has a special focus on Health Systems Research (HSR), the principles expressed here can be used for Clinical Research, Quality Assurance (QA) Research, Clinical Audit or other forms of research.

The authors would be happy to receive feedback and constructive criticism on improving this handbook. Please see contact (emails) details on the inside of the back cover.

Note: **This is the FIRST VOLUME of the research handbook and it will be expanded subsequently to include Analysing Data, Report Writing and Publication.**

Learning points:
It is important to note that research is best learnt by actually conducting a research project, rather than by reading or attending lectures

This handbook is aimed to be used in conjunction with the user doing an actual research project.

Learning points:
This handbook has two examples of research proposals in the appendices.

Please refer to the relevant parts of the examples to aid your understanding as you read the various sections of the handbook.

The Authors
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We would like to thank the many researchers who have attended our research workshops over the past 15-20 years. They have helped to shape the contents of this handbook and given valuable feedback. They allowed us to try out many research approaches that enriched our repertoire of research methodology, data analysis and how data can be best presented.

A special thanks to the authors of two research proposals who allowed us to reproduce the core summaries of the proposals here as examples.

We would also like to thank, in advance, readers of this book who we hope will provide critical feedback for its improvement.

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COMPONENTS OF A RESEARCH PROJECT: *QUESTIONS WE SHOULD ASK*

SECTION	COMPONENTS	KEY QUESTIONS TO ASK
Proposal: Introduction	1. Identifying & prioritizing problems	What are the important problems? Which of these need research? Which one of these problems is most important to answer?
	2. Problem statement & analysis	Why do we need to do this study? What exactly is the problem?
	3. Literature review	What have other people done? In what areas is research still required for this problem? How do we organize and refer to the literature?
Proposal: Objectives	4. Objectives	What do we want to include in the study?
Proposal: Methodology	5. Overview of Research Design	What is your plan to answer the research objectives?
	6. Study type	What is the best way to do it?
	7. Ethics in research	Any ethical considerations for: • Respondents? • Researchers?
	8. Variables	What do we want to measure? How do we measure it?
	9. Sampling	Who do we measure? How many should we measure? How do we select them?
	10. Techniques for data collection & pre-testing	What techniques will best answer the objective? How should we train data collectors? How can we check whether the data collection technique is the best for our study?
	11. Plan for data analysis & interpretation	What will we do with the collected data?
	12. Project management	Who does what & when? What resources do we need? Where will the resources come from?

The actual study	13. Data collection & monitoring	Is the data collection according to plan?
	14. Data entry	Is the data entry according to schedule? Have we ensured the quality of the data?
	15. Data analysis & interpretation	Did the findings answer the objectives? What do the results show? What statistics are required?
Utilising the study to make clinical, health & policy changes	16. Report writing	How can we best present the methods & results?
	17. Recommendation and potential utilisation	How can the findings be used? What aspect of the results can be used to improve care?
	18. Dissemination	How can we best inform others? (e.g. discussions with policy makers, presentations, policy brief, publications, etc.)
	19. Using study results to make changes	How can we use the findings to institute health change?

Learning points:
Steps in this schedule are inter-related. When we complete a step, review previous steps to ensure consistency in planning.

OUTLINE FOR WRITING A RESEARCH PROPOSAL

Please ensure that the following are covered when preparing a research proposal:

1. **TITLE PAGE** – include
   - The Title
   - Author(s)
   - Details Of Department
   - Date

2. **INTRODUCTION**
   Write this as one cohesive section that includes the following components:

   - Identifying & prioritising problems
     – write this in terms of why this study is chosen
   - Problem statement & analysis
     – Important to include problem analysis chart
   - Literature review
     – this may be incorporated into the introduction if brief, or written as a separate section

3. **OBJECTIVES**
   - General
   - Specific

4. **METHODOLOGY**
   - Overview of Research Design
   - Study type
   - Ethical considerations
   - Variables
   - Sampling
   - Techniques for data collection & pre-testing
   - Plan for data analysis & interpretation (include dummy tables)
   - Project management (including Gantt Chart)

5. **REFERENCES** – include all references used

6. **APPENDICES** – these include
   - the tools
   - relevant supplementary documents

THE INTRODUCTION

This section contains:

- **IDENTIFYING & PRIORITISING PROBLEMS**
- **PROBLEM STATEMENT & ANALYSIS**
- **LITERATURE REVIEW**

Although they are discussed separately here, they should be merged into one write up in the proposal.

The introduction sets the stage for the beginning of the proposal.

The researcher uses this section to crystallize the problem and justify why it is necessary.

A manager or research funding agency wants a clearly outlined argument before funding or approving it.

WHY THIS?
To utilise limited resources to answer the most pressing problem

COMPONENT 1:
IDENTIFYING & PRIORITISING PROBLEMS

What are the important problems?
Which of these need research?
Which one of these problems is most important to answer?

IDENTIFYING PROBLEMS

What are my important problems?

Identify important problems by:

1. Dialogue and discussions with
   a. Managers/Colleagues
   b. Feedback from others
2. Felt needs and working experience
3. Magnitude/severity of issues/conditions
4. Joint discussions with colleagues
   a. Brainstorming
   b. Delphi
   c. NGT (see below)

DIFFERENTIATE BETWEEN RESEARCH AND NON-RESEARCH

Which of these need research?

If any of the following is true for your problem, then you don't need to research it

1. Can the problem be solved by administrative change?
2. Are there already solutions available that can be used?
3. Is the problem due to lack of manpower and resources?
4. Is there data showing that it is not a significant problem?

PRIORITIZING PROBLEMS

Which one of these problems is most important to answer?

1. Use a scientific method to prioritise, e.g.
   a. NGT (see below)
   b. Delphi (see below)
2. Manager's most urgent concern that needs research

Learning points:
Eliminate non-research problems before prioritizing research problems.
Pick the most crucial problem that needs research.

PROBLEM IDENTIFICATION

Identification of a problem for study can be done in various ways. A manager may commission a study on a problem he/she perceives as important. Similarly an individual researcher may choose an area to study. This may not reflect the most important problems in the community; in addition, difficulties arise when a group of persons try to select a research project.

Some method of agreeing on what problem is important to study is useful. One common method used is the nominal group technique (NGT). This method allows every member in a group or organisation to have an equal say in decision making.

NOMINAL GROUP TECHNIQUE (NGT)

Use the NGT to identify problems for study:

1. Appoint a chairperson and rapporteur.
2. Spend 10 minutes in silence thinking of important problems that you have at work or in the community. Focus on problems not solutions (a problem is a perceived gap between what is and what should be).
3. The chairman then lists all the problems on a flip-chart in round-robin fashion until all problems are exhausted (if time is a limitation allow each member to list only his/her two most important problems). No comments are to be made at this stage.
4. The problems are then open for discussion, clarification, dispute, duplication. Every member is given an opportunity to express their view and some problems may be dropped/excluded.
5. The group then has a list of problems for possible research.

Use NGT to prioritize a research problem for study:

1. The group identifies criteria to prioritise problems
    a. Limit to 5 important criteria. Possible criteria to use & their meaning is below.
    b. For each criterion, specify the scoring system to use (e.g. “1” lowest to “3” highest; or “1” lowest to “5” highest).
    c. Each problem’s score is independent of the other problems (e.g. you may give two problems the score “5” for the criterion “relevance”).

2. Every member then ranks each problem individually according to perceived importance.
3. Total all the scores from the members.
4. The total score for each problem is then discussed. The one with the highest score is accepted. There may be a need to re-clarify, elaborate, defend, and dispute the score if
   a. More than one problem obtained the highest score
      or
   b. Members object to the problem that obtained the highest score
5. Repeat steps #2 and #3 if there is a dispute.

CRITERIA FOR PRIORITISATION

1. **Relevance**
   How important is the problem?
   Size, severity, health & social consequences.
   Problems that affect communities or involve health systems are ideal.

2. **Duplication**
   Establish that the answer is not already available by some other study.

3. **Feasibility**
   Is it feasible to carry out remedial actions? Are the manpower, time and resource requirements available?

4. **Applicability**
   Will the potential solution be effective for solving the problem under ideal conditions?
   Will managers accept and use the solutions?

5. **Cost Effectiveness**
   Are the resources invested in doing the study worth the outcome? Will the solution be too expensive to implement?

6. **Timeliness**
   Will we get an answer quick enough?

7. **Ethics**
   Will the project be acceptable to those who are studied?

8. **Political acceptability**
   Will the managers and the community accept the results?

EXAMPLE OF CRITERIA FOR SELECTION OF PROBLEM

Problems identified	Relevance	Duplication	Feasibility	Application	Cost effectiveness	Timeliness	Ethics	Political acceptability	Total Score
a.									
b.									
c.									
d.									
e.									

WHY THIS?
Problem statement: You need to justify why you are doing this study.
Problem analysis: You need to understand the problem in depth.

COMPONENT 2

PROBLEM STATEMENT & ANALYSIS

Why do we need to do this study? (Problem statement)
What exactly is the problem? (Problem analysis)

PROBLEM STATEMENT

Why do you need to do this study?

Write a narrative introduction. Include the following:

1.	Why was this problem identified?
2.	How bad is the problem? (magnitude / severity)
3.	Who is affected?
4.	Where is the problem?
5.	What is the impact of the problem?
6.	How do you anticipate the study to help overcome the problem?

PROBLEM ANALYSIS

What exactly is the problem?

Use a problem analysis method (e.g. problem analysis chart/bubble diagram, Ishikawa/fish-bone chart, mind-mapping) to identify the following:

1.	What factors might contribute to or cause the problem?
2.	What are the relationships between the various factors contributing to the problem?
3.	If the scope of the study is limited to only a few areas, justify and give reasons why (see no. 6 under Problem Analysis Chart).

Learning points:
The problem analysis chart will guide the direction of the study. Make sure the brainstorming is comprehensive.

You will use it to identify:
- Scope of the study (i.e. also the areas not studied)
- Objectives, and
- Variables (areas to be covered in the tools for data collection).

PROBLEM ANALYSIS CHART

Use a problem analysis chart to analyse a research problem:

1. Draw a centre bubble that contains the problem stated in a negative manner (the primary bubble).

2. Identify key problems that contribute to the problem (the secondary bubbles). Cover these areas: patient, staff, environmental and system factors.

3. For each secondary bubble, identify contributing factors (tertiary bubbles).

4. Continue expanding the levels of bubbles until all contributing factors identified.

5. The arrows all point towards the primary bubble. In addition, arrows may connect between secondary and tertiary bubbles. This provides the possible relationships between factors.

6. Not all factors identified need to be studied. But you must be comprehensive in identifying factors.

The figure represents the factors and indicates their relationships.

Factors may be interrelated or may contribute to more than one intermediate factor. Some of the factors identified will be the variables to be studied. In practical terms the problem analysis is best done by a “brainstorming” session using a flip-chart.

The primary bubble (central bubble) is drawn containing the perceived problem. Secondary bubbles are then drawn for key factors contributing to the problem and so on.

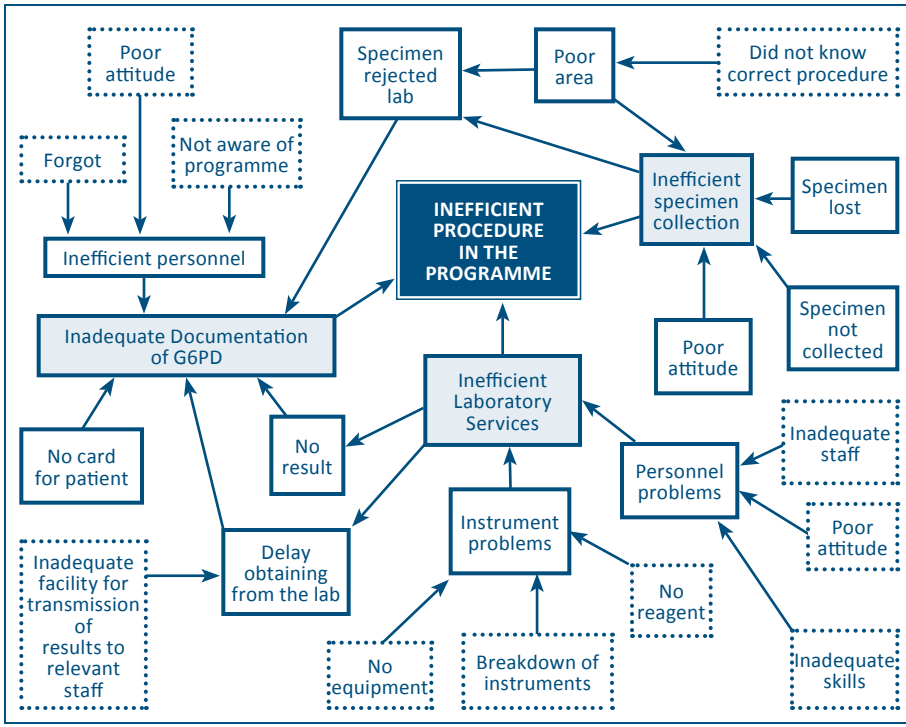

Figure 1: Evaluation of problems faced in the running of the G6PD screening programme [Source: Chong KM, Amar HSS, Ling HM, Meftahuddin T, Lee BC. An Evaluation of the glucose-6 phosphate dehydrogenase screening procedure in selected hospitals in Perak. Medical Practice Hospital Ipoh 1998; 4(1):17-21]

WRITING THE PROBLEM STATEMENT & ANALYSIS

The problem statement attempts to put into words the entire thinking process involved in choosing the problem and identifying the factors related to it. It is important to write the statement in a logical and concise fashion.

The argument for why we should conduct this research or why the research problem is important should be clearly outlined. All data quoted or supporting evidence should be referenced.

The relevant studies identified during the literature review are also incorporated into the problem statement.

Conclude your introduction with a final paragraph clearly stating the importance of the problem and what we aim to do.

WHY THIS?
To avoid doing what others have already done (prevent duplication of work)
To guide your methodology
- clarifying the issues
- identifying what still requires research

To use for discussion/compare with your study on various aspects (problem statement, methodology, discussion)

COMPONENT 3

LITERATURE REVIEW

What have other people done?
In what areas is research still required for this problem?
How do we organise and refer to the literature?

AVAILABLE INFORMATION & EVIDENCE

What have other people done?

In what areas is research still required for this problem?

This is a search for published / unpublished work and experts in the area to guide you in planning your study. The literature review should be incorporated into the introduction, methods and discussion.

1.	Search for current work related to the problem you are studying. a. Experts in the area. b. Literature & reports.
2.	Evaluate the articles you obtained for: a. relevance & applicability. b. auality (critical appraisal).
3.	Identify issues by relating them to your secondary bubbles: a. areas already addressed (if viable solutions are present – do not need to be studied). b. areas not adequately addressed (may need study). c. new secondary bubbles not previously identified (add to your problem analysis chart and may need study as well).
4.	Identify possible methods others used to study the problem.
5.	Always acknowledge the source of your ideas as references.

ORGANISING AND REFERENCING LITERATURE

How do we organise and refer to the literature?

It is important to have a good and systematic method to keep useful articles and reference them in the text.

1.	Keep hard copies and organise them in files. Sort by relevance to sections of the proposal/report e.g. method, discussion. Alternatively use a proprietary software.
2.	Reference them according to one of two international standard formats - Vancouver or Harvard styles.
3.	Cite articles used in the text of your proposal/report/publication, according to the format selected.
4.	Use the Harvard method initially in your text (proposal), and convert to Vancouver if required (for publication). (See below & appendix.)

VANCOUVER & HARVARD STYLES

- Vancouver style – This style will have a superscript number in the text and references will be arranged in numerical order (as they have appeared in the text). Example: Altman DG, Gore SM. Statistical guidelines for contributors to medical journals Br Med J 1983; 286:1489-1493. (NB: Examples available in the appendices).

- Harvard style – This style will have the authors and year (of publication) in the text and references will be arranged in alphabetic order. Example: Altman D.G., Gore S.M., 1983. Statistical guidelines for contributors to medical journals Br Med J; 286:1489-1493.

Learning points:
Do this before starting your study.
Don't duplicate work.
You may need to do this continuously.

Learning points:
This will help you identify many things, such as:
- definitions of terms.
- relevant tools for data collection.
- approach to analyses.
- problems in designing/implementing similar studies.

DOING A LITERATURE SEARCH

1. Request help from an expert in the area to:
   a. help in problem analysis and method design.
   b. point out relevant articles (especially unpublished and local studies).

2. Use the internet (electronic data bases of medical literature).
   a. Identify key words for your search.
   b. Search from current year, backwards.
   c. Vary / modify the words if you cannot find sufficient useful articles.
   d. Use the references listed in a relevant article to extend the search.

3. If possible, search for systematic reviews in the area. It will give you an overview, and many articles on the problem. The following table shows some Internet search sites:

Name	Site	Resource
Google Scholar	http://scholar.google.com/	Good search engine for scientific (academic) papers and results.
Medscape (also for Medline search)	http://www.medscape.com/	Free resource for Physicians, with customized CME, medical journal articles, MEDLINE search, medical news, etc.
PubMed (includes links to full text articles and other related resources)	http://www.pubmedcentral.nih.gov/	PubMed service of U.S. National Library of Medicine. Includes more than 16 million citations from MEDLINE and other journals going back to the 1950s.
Biomail	http://www.biomail.org	Customised new references from MEDLINE to your email account.

Name	Site	Resource
Free Medical Journals	http://www.freemedicaljournals.com	Free Medical Journals
National Library of Medicine	http://www.nlm.nih.gov/database/	Up-to-date, accurate information about effects of healthcare. Systematic reviews of healthcare interventions.
Cochrane Collaboration	http://www.cochrane.org	
Cochrane Health Promotion and Public Health (CHPPH) Field	http://www.ph.cochrane.org/en/index.html	
UK Evidence-Based Medicine Centre	http://www.cebm.net/	
National Guideline Clearing House – a public resource for evidence-based guidelines	http://www.guideline.gov/	
The Community Guide. Evidence-based recommendations for programmes and policies to promote population health.	http://www.thecommunityguide.org/	
Centre for Health Evidence	http://www.cche.net/	

4. Use a local database to identify unpublished work:

Name	Site
National Medical Research Registry (NMRR)	https://www.nmrr.gov.my/
Institute for Health Systems Research	http://www.ihsr.gov.my/
Clinical Research Centre, Ministry of Health Malaysia	http://www.crc.gov.my/
Institute for Medical Research (IMR) "Reports & Documents" for past copies of MOH research	http://www.imr.gov.my/; http://ilmusvr.imr.gov.my/index.php
Medical Journal of Malaysia (MJM)	http://www.mma.org.my/Publications/MedicalJournalofMalaysia/tabid/69/Default.aspx
Ministry of Health Publications	http://www.moh.gov.my/MohPortal/pubPublic.jsp
Also use proceedings of local conferences (abstracts) & annual reports	

5. Hand search the relevant journals in a library (useful to examine the December issues) if you have no internet facilities or looking for older publications.

   The extent of the search depends on your resources. It may be ideal but not always a practical way to conduct a detailed search.

THE OBJECTIVES

WHY THIS?
To guide what you want to accomplish in the study

COMPONENT 4
OBJECTIVES

What do we want to include in the study?

What do we want to include in the study?
Objectives help to define and limit the study scope.

1.	Go back to your problem statement and literature search.
2.	Put into words what you want to achieve.
3.	Write an overview of your aims. This reflects your problem and defines the scope of the study (**the general objective**).
4.	Breakdown your overview into specific areas addressing different aspects of your problem (**the specific objectives**). Limit to only 3-5 specific objectives. a. Phrase it clearly. b. Derive it from your problem analysis diagram. c. Cover the different aspects of the problem. d. Define them in operational terms that can be measured. e. May include recommendations for implementation of findings.
5.	Be realistic with respect to the scope of your study. Achievable with available resources?

Learning points:
Objectives clearly state what you plan to do and are a “road map” (keeps study in focus).

It helps to avoid unnecessary data collection.

THE METHOD

This section is the research design. The design contains:

- **OVERVIEW OF RESEARCH DESIGN**
- **STUDY TYPE**
- **ETHICAL CONSIDERATIONS**
- **VARIABLES**
- **SAMPLING**
- **TECHNIQUES FOR DATA COLLECTION & PRE-TESTING**
- **PLAN FOR DATA ANALYSIS & INTERPRETATION**

Although they are discussed separately here, they should be merged into one write up in the proposal with separate headings.

One of the weaknesses in writing the method is a tendency to just describe the study type without describing the research design adequately.

For this reason, we have deliberately put in a chapter on "Overview of Research Design" to encourage researchers to write a detailed framework at the beginning of the method before writing the specifics.

The research design is the heart of the proposal. It is the blueprint. We use this section to clearly spell out what will be done. A manager or research committee will read this section to see the quality of the scientific content.

WHY THIS?
So that the research team knows what is being done.
Others know what you have done and enables them to replicate it (when the study is completed).

COMPONENT 5

OVERVIEW OF RESEARCH DESIGN

What is your plan to answer the research objectives?

What is your plan to answer the research objectives?

Write in a narrative form exactly what you plan to do.

1.	Use the problem analysis chart to identify the areas to be addressed.
2.	Use the literature to help identify the best approach to answer this problem.
3.	Formulate a clear approach to answer every specific objective. This might require more than one study type for the problem.
4.	Use the secondary and tertiary bubbles to ensure all areas are covered.
5.	Cover the following areas: a. study type. b. ethical considerations. c. variables. d. sampling. e. techniques for data collection & pre-testing. f. plan for data analysis & interpretation.

Learning points:
The overview of the research design ensures that there is a clear framework of what the researchers plan to do.

WHY THIS?
To choose the most viable approach to achieve your objectives.

COMPONENT 6

STUDY TYPE

What is the best way to do it?

What is the best way to do it?

Choose the most appropriate study type to answer your objectives.
More than one study type can be used in a research project.

1.	Decide if the aim of your research project is to describe or intervene. If your research objective is to change the situation, this requires an interventional approach.
2.	If you plan to evaluate or explain/audit a problem, then use a descriptive approach. Descriptive approaches include: a. case study/case review. b. cross-sectional study. c. case control. d. cohort.
3.	If you plan to intervene (i.e. change the situation/management/procedure), then use an interventional approach. Interventional approaches include: a. community trial. b. clinical trial. (These are randomised control trials or quasi-experimental studies.)
4.	Determine the time perspective of your study (data collection). • If you are collecting data from available records, this is retrospective. • If you are collecting new data over time (same data from the same person repeatedly over time, or same data from the same community repeatedly over time), this is prospective. • If you are collecting data at one point in time (data from the same person only once, or data from the same community only once), this is cross-sectional.

Learning points:
The study type ensures that the appropriate approach is used to answer the research objectives.

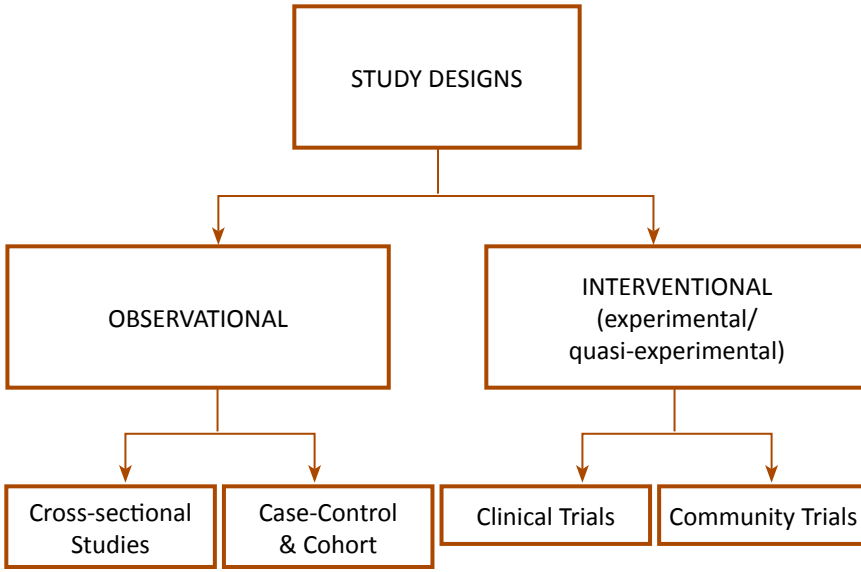

Figure 2: Schematic overview of study designs

OBSERVATIONAL

CROSS-SECTIONAL STUDIES

It is the systematic collection and presentation of data to give a clear picture of a particular situation.

Can involve populations or individuals.

Usually data is collected at a specific time (The Picture Today) and involves single or several variables.

They ask questions like:

- Who is affected (age, sex, etc.)?
- Where, When and Opinions.

They are either qualitative or quantitative (often mixed elements).

CASE-CONTROL & COHORT

These determines or tests the relationship between several variables to suggest or establish possible causes of problems. They describe the distribution of disease in human population and investigate possible aetiological factors to explain that distribution.

The investigators have no control over whom and who is not exposed to the factor under study.

CASE-CONTROL STUDIES

In case-control studies, a group of people with a particular disease (the cases) are compared with a group of people without the disease (the controls).

The purpose of the comparison is to determine whether, in the past, the cases have been exposed more (or less) often to a specific factor than the controls.

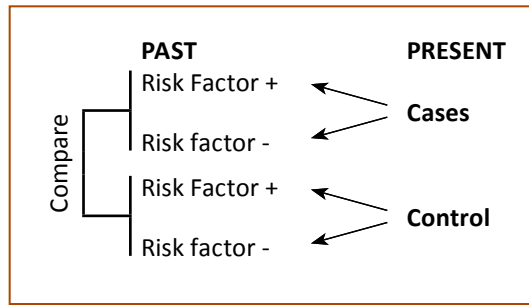

Figure 3: Case-control study

COHORT STUDIES

Cohort (or follow-up) studies are those in which people are identified and grouped with respect to whether or not they have been exposed to a specific factor.

The groups are followed-up over time to determine whether the incidence of a particular disease is any greater (or less) in the exposed group than in the non-exposed group.

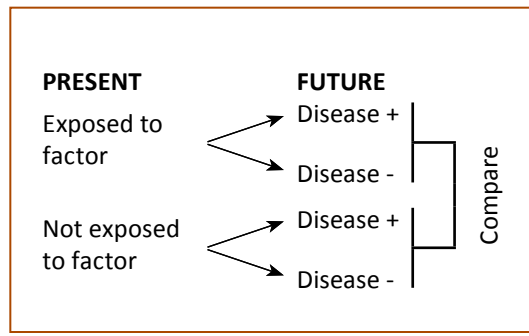

Figure 4: Cohort

INTERVENTIONAL TRIALS

Interventional studies may be experimental (randomisation, control group, interventional) or quasi-experimental (one of, or both the elements is missing – randomisation or control group).

These are studies in which the investigators do have control over who is and who is not exposed to the factor under investigation.

Interventional studies can be:

- clinical trials.
- community trials.

Clinical trials are interventional studies of the effect of a specific treatment on patients who already have a particular disease. Most clinical trials involve testing a new drug or medical device.

Community trials are interventional studies done at community or facility level. They test feasibility of new approaches at system level.

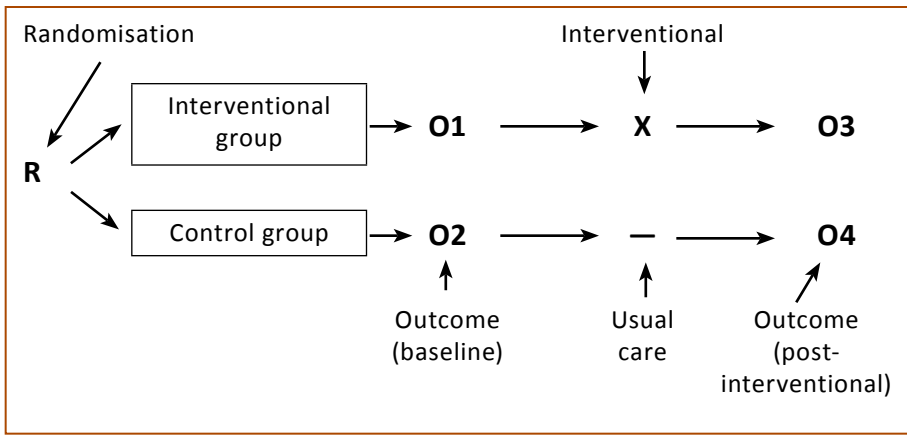

Figure 5: Randomised control trial

WHY THIS?
To ensure respect and dignity of respondents.
It is a researcher's responsibility and reflects our integrity.

COMPONENT 7

ETHICS IN RESEARCH

Any ethical considerations for:

- **Respondents?**
- **Researchers?**

ETHICAL ISSUES FOR RESPONDENTS

Any ethical considerations for respondents?

Points on ethics for respondents.

1.	Respect the confidentiality of information given by respondents.
2.	Participation must be voluntary and respondents allowed to say "No" to participation, or to stop/drop out at any time. The respondent's choice not to participate must not affect the health care provided.
3.	Inform your respondents fully about the study and possible risks, if any (informed consent).
4.	Do not harm the respondents.
5.	Respondents should not be paid for participation (apart from reimbursements for travel expenses, etc.)

ETHICAL ISSUES FOR RESEARCHERS

Any ethical considerations for researchers?

Points on ethics for researchers.

1.	Any conflict of interest between the researcher and the study being conducted must be declared.
2.	Make sure the study is scientifically and methodologically sound.
3.	Integrity in data collection, analysis/interpretation and reporting.
4.	Researchers should not be paid for conducting a study (apart from reimbursements for travel expenses, etc.)
5.	A researcher must be fully aware of the aims, methods and use of the research.
6.	Failure to act on or report adverse events of interventions.
7.	All researchers involved in clinical (experimental) trials must be GCP (Good Clinical Practice) certified.

8. Authorship credit should be based on (http://www.icmje.org/):
   a. substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
   b. drafting the article or revising it critically for important intellectual content.
   c. final approval of the version to be published.

   Authors should meet conditions 1, 2, and 3.

Learning points:
Never compromise your respondent's dignity and safety for research.
Always get research approved by an independent ethics committee.

TIPS FOR IDENTIFYING PROJECTS THAT REQUIRE ETHICAL APPROVAL

MOH guidelines states (https://www.nmrr.gov.my/):

"Research involving human subjects require prior ethics review and approval by the MOH Research and Ethics Committee (MREC)."

"A human subject (in the context of research) is 'a living individual about whom an investigator obtains either data through intervention (e.g. clinical trial) or interaction (e.g. questionnaire in health survey) with the individual, or identifiable private information'."

If your project contains any of the following, you should apply for ethical approval.

1. Any study with direct intervention (e.g. change in medication/management plan, invasive procedure).
2. Taking any samples (e.g. blood, tissue).
3. If there is any likelihood of causing physical or psychological harm (e.g. causing pain/anxiety).
4. Respondents who may not be able to give informed consent (e.g. mental impairment/disability, children).
5. Observation of people without their knowledge (e.g. hand-washing study).
6. All interviews or questionnaire administration.
7. All extraction and use of data from whatever sources (e.g. medical records, registries, etc).
8. Respondents in other agencies/institutions (e.g. schools).

NATIONAL MEDICAL RESEARCH REGISTRY (NMRR)

All medical/health research in Malaysia must be registered with the NMRR at https://www.nmrr.gov.my/. All research requires ethical review. Submission and approval is conducted online. You also require institutional approval (e.g. approval from hospital/health director from study site).

Why this?
To make sure all important aspects are measured. To be clear how to measure the areas to be studied.

COMPONENT 8

VARIABLES

What do we want to measure?
How do we measure it?

IDENTIFYING VARIABLES

What do we want to measure?

1.	A variable is a characteristic/event that has different values. It is measurable.
2.	This should be linked to your objectives.
3.	Use your secondary, tertiary and further generation bubbles to identify areas to be studied (these are your variables).
4.	Can they be measured directly or indirectly?
5.	It is important to be realistic in the number of variables you want to measure. Justify why certain areas are not going to be studied.
6.	List all variables to be studied (so that you do not miss out any).

MEASURING VARIABLES

How do we measure it?

1.	Write the definition for your variable. It must be easily understood by all and clearly measurable
2.	Determine the type of variable. Variables can be discrete (e.g. smoking status – smoker/non-smoker) or continuous (e.g. smoking status – number of cigarettes/day).
3.	Define the scale of measurement you want to use for that variable based on the type of variable

Learning points:
Identify all variables necessary. Otherwise, key variables may be missed.
Define all variables clearly to enable you to measure them accurately.

WHY DO WE NEED TO IDENTIFY VARIABLES?

Identification of variables will help the investigator to:

- specify the important items for study.
- determine what are the relationship among them that must be known.
- avoid unnecessary data collection.
- ensure that all data that are relevant to the objectives are collected.

RELATIONSHIP BETWEEN VARIABLES

Certain characteristics are associated with each other as shown in the problem analysis chart. To know the relationship between them, the variables concerned must be identified.

There are 3 main groups of variables involved in research:

a. dependent variables.
b. independent variables.
c. confounding variables.

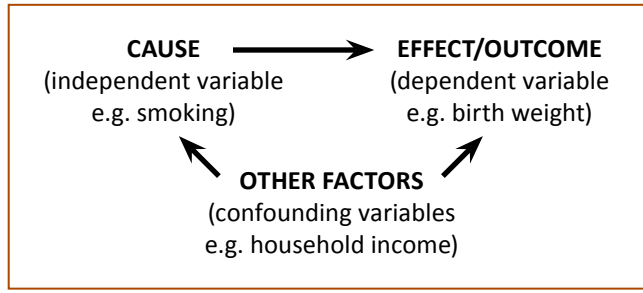

Figure 6: Relationship between groups of variables

In most "cause" and "effect" studies, we are looking at the relationship between independent and dependent variable. That is, the "effect/outcome" is the dependent variable, the "cause" is an independent variable.

A variable that is associated with both the problem and the possible cause of a problem is a potential confounding variable.

The confounding variable may either strengthen or weaken the apparent relationship between an outcome and a possible cause. Therefore, in order to give a true picture of cause and effect, the confounding variables must be considered, either at planning stage of or during data analysis.

Example: In a survey to investigate whether there is a relationship between mothers who are cigarette smokers and weight of their newborn, the dependent variable is the newborn's weight, the independent variable is the mother's smoking habit. In this example, household income would be the confounding variable. Refer figure 6.

Once the variables have been selected, each of them should be clarified. Two aspects need to be considered: define the variables and state the scale of measurement.

DEFINING VARIABLES

Two kinds of definitions are required:

a. Conceptual definition:

This is to define the variable as it is conceived.
For example; obesity is defined as excessive fatness, overweight etc.

b. Operational definition ("working" definition):

- This defines the characteristics to measure. It should be objective, observable and is sufficiently clear and explicit to avoid ambiguity.
- This is to ensure similar findings could be obtained if the study were performed by different investigator or repeated by the same investigator (i.e. repeatability, reliability).

For example: obesity is defined as: "A weight based on weighing using a bathroom scale in underclothes and without shoes, which exceeds the upper normal limit of BMI (body mass index) of the subject's sex, age and height."

SCALE OF MEASUREMENT

This refers to the type of variable.
1. Categorical (discrete) – nominal & ordinal.
2. Numerical (continuous/metric).

Specify the scale of measurement to be used.
The selection for a scale is determined by the variable itself and the methods available for measuring it.

CATEGORICAL VARIABLE

a. Nominal variable

This consists of two or more mutually exclusive categories, presented as counts. A type of data in which the variables are divided into a number of named categories. These categories however, cannot be ordered (graded) one above another.

Example:
- Race: Malays, Chinese, Indians.
- Sex: Male, Female.

b. Ordinal variable

A type of variable in which the responses are divided into a number of categories that can be ordered one above another. The categories can be ranked.
Example:
- Level of knowledge: poor, average, good;
- Opinion of individual: fully agree, agree, disagree, and totally disagree.

NUMERICAL VARIABLE

This consists of a continuum of measurements. A type of variable in which there is an unlimited number of equally spaced categories; thus a continuum of values is possible. It consists of actual measurements of individuals.

Example:
- Age (1 year, 35 years, 70 years, …)
- Haemoglobin level (12.1, 13.6, 7.2,…)
- Birth-weight (3.71 kg, 2.75 kg, 4.01 kg, …)

EXAMPLE OF A FRAMEWORK FOR DEFINING VARIABLES

Variable	Definition of variable	Scale of Measurement
Age	Child's age at admission to hospital, calculated from date of birth and date of admission.	Months and years
Patient has dengue fever	Dengue fever confirmed by serology (IgM positive or four-fold rise in IgG titre) or virology.	Yes/No/Not available
Social class	Head of household's main occupation as stated by respondent in answer to a question in a structured questionnaire.	Detailed occupation, classified into social class I - V
Haemoglobin	Haemoglobin concentration in capillary blood, measured by haemoglobinometer.	g/dl

Variable	Definition of variable	Scale of Measurement
Patient's satisfaction on counter services at clinic	Response to specific questions put to patients on counter services at clinic (response to a question during a structured interview).	☐ Very satisfied ☐ Satisfied ☐ Don't know or no answer ☐ Somewhat dissatisfied ☐ Very dissatisfied
Level of education of mother	Highest education level achieved by mother as obtained in answer to a question in a structured questionnaire (father may be interviewed if mother is not present).	☐ No education ☐ Primary school ☐ Secondary school ☐ College ☐ University
Severity of illness at birth	Requirement for resuscitation at birth as recorded in referral letter/medical records.	☐ Cardiopulmonary resuscitation ☐ IPPV with intubation ☐ PPV with bag and mask ☐ Nasal Oxygen ☐ Nil

WHY THIS?
Sampling is done so that one studies a smaller group instead of everyone. This is more cost-effective & feasible.
We may not get results that reflect the true picture if we use the wrong sampling size and method.

COMPONENT 9

SAMPLING

Who do we measure?
How many should we measure?
How do we select them?

STUDY POPULATION

Who do we measure?

The first step in sampling is to clearly define the study population and its characteristics.

1.	Determine who you need to study by referring to your problem statement. The study population should be the group with the problem or those potentially affected (at risk).
2.	Decide your inclusion and exclusion criteria. Choose the group that fulfils the inclusion criteria. Then, identify who you need to exclude. a) Inclusion criteria – determines who can be accepted into the study. b) Exclusion criteria – determines who will not be accepted into the study. These criteria are based on such factors as age, geographical location, disease severity or stage, previous treatment, presence of other medical conditions, etc.
3.	Describe your population clearly in the method. Include important demographic characteristics, the inclusion/exclusion criteria and any other factors defining them. ***Remember to report the numbers excluded and the reasons in the results.***
4.	Look at your study type to help you decide if you need a control group. Identify the control population from a group with similar characterictics but without the disease/condition being studied.

SAMPLE SIZE

How many should we measure?

The sample size must be large enough to be able to solve the research questions.

1.	The key factors determining the sample size are: a) the proportion/mean of the main variable of interest (outcome variable). Determine this from available literature and expert opinion. b) the power of the study (i.e. how reliable the sample size is to answer the objective). This is usually set at a minimum of 80%. c) the level of significance (the *p* value). This is usually set at 0.05.
2.	This needs the use of a software (e.g. EpiCalc 2000), the help of an experienced researcher/statistician or a sample size table*.
3.	Researchers should not be distressed with sample size calculation but should get help.
4.	The sample size calculated above is the minimum required. Often, you would need to increase the calculated size by 10-20% to ensure the minimum sample size is still achieved after drop-outs, non-response, missing records, etc. This then becomes the required sample size.
5.	When you have limited resources, you may need to lower the power of the study to accept a smaller sample size.

* Lwanga SK & Lemeshow S. 1991. Sample size determination in Health Studies. A Practical Manual. Geneva, World Health Organization.

SAMPLING METHOD

How do we select them?

The sample is either selected by random procedure (probability sampling) or conveniently (non-probability sampling).

1.	Look at your objectives to determine the sampling method.
2.	If your objectives require you to make inferences (apply the results to the study population), you must select a random sample. Use probability sampling methods. (See figure 7.)
3.	If your objectives need: a) a simple, fast answer, or b) you do not have a list of your study population (sampling frame), then select a convenient sample. Use non-probability sampling methods.

Learning points:

- A representative sample should possess all the important characteristics of the population from which it is drawn.
- Define clearly the inclusion/exclusion criteria, so that everyone involved in the study are consistent in selecting the sample.
- To draw conclusions about the study population, use a random sampling method so that the sample is fully representative of the population.

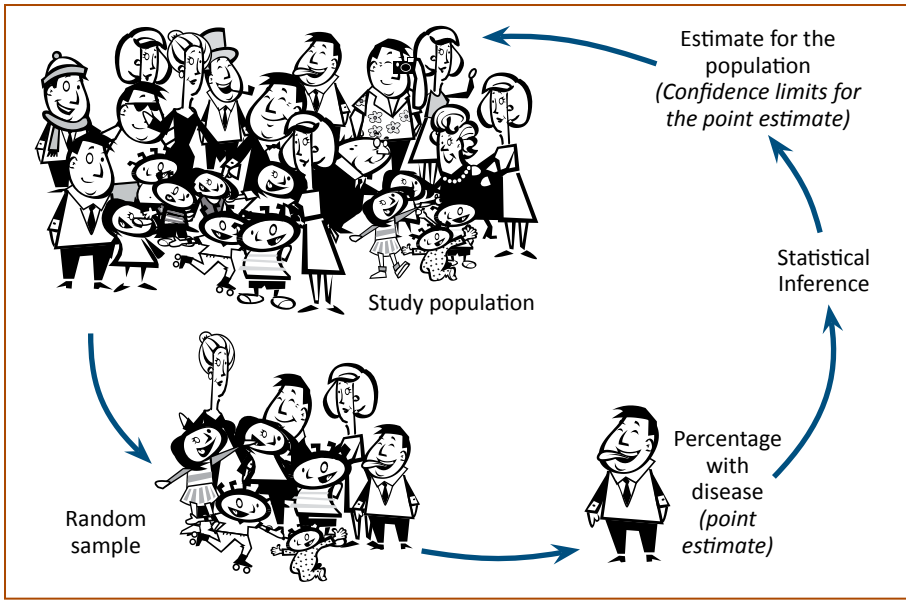

Figure 7: Sampling and statistical inference

With **random** sampling, we can make an inference about a population.

In the example above, a percentage is calculated for the **sample**. Using statistical methods, a possible range of estimates can be calculated for the population (the confidence limits).

INCLUSION AND EXCLUSION CRITERIA

Inclusion and exclusion criteria are used to ensure precision in a study. We clearly determine who can be considered as a potential sample and who cannot. These criteria are based on such factors as age, geographical location, disease severity or stage, previous treatment, presence of other medical conditions, etc.

Inclusion criteria are the criteria for including a patient in the study,
Exclusion criteria are the criteria for excluding patients from the study.

It is important that these criteria be clearly defined in an objective manner, so that everyone involved in the study are consistent in selecting the sample.

The selection criteria also determines to whom the results of the study can apply.

SAMPLING METHOD

There are various procedures that can be used to obtain a sample.

The most common ones are discussed below.

PROBABILITY SAMPLING

Probability Sampling employs **random** procedures to ensure that the sampling unit (i.e. the individuals, groups of people, objectives, villages, etc. which are the basic unit of the sample) is selected on the basis of chance.

Every member of the population should have a similar chance of being included in the sample. This method requires that a sample listing of all sampling units is available. This listing is called the sampling frame.

1. **Simple random sampling**
   The simplest form of probability sampling is simple random sampling in which each unit in the population list (sampling-frame) has an equal chance of being selected for the sample.

2. **Systematic sampling**
   Sometimes it is more convenient to choose the individuals from the list (sampling frame) by taking, say, every tenth person on the list or by investigating every fifth birth taking place. Ideally we use a random number to tell us where to start.

3. **Stratified sampling**
   The simple random sampling described above does not ensure that the proportions of individuals with certain characteristics in the sample will be the same as those in the target population.

   If it is important that the sample includes representative sub-groups of individuals (for example, urban and rural residents; or age groups), then the sampling frame must be divided into sub-groups, or strata, for these characteristics.

   Random or systematic samples of a pre-determined size will then have to be obtained from each stratum. Stratified sampling is only possible when it is known what proportion of the study population belongs to each stratum.

4. **Cluster sampling**
   A random sample of clusters is selected and all individuals in the cluster are included in the study. This is known as cluster sampling.

NON-PROBABILITY SAMPLING

1. **Convenience sampling**
   This is a sampling method in which the "sample" happened to be available at the time or period of the research and is selected for the sake of convenience.

2. **Quota sampling**
   This sampling method ensures that all known elements in the population occur in the sample (may try to ensure that these occur in the same proportions as in the population). The investigator interviews as many people in each category as he can find until he has filled his "quota". This method is only useful when it is felt that a convenience sample would not provide the desired balance of elements in the population.

HOW TO DO RANDOM SAMPLING

1. Compile a list of every person/thing in the study population.

2. Use a random number table/software (EpiCalc 2000)/calculator.

3. For simple random sampling:
   use the required sample size and the total number in the study population (after inclusion/exclusion criteria has been applied) to identify which subjects will be chosen.

4. For systematic random sampling:
   a. divide the total number in the study population (after inclusion/exclusion criteria has been applied) by the required sample size to get the interval (*Z*) for choosing samples.

   b. obtain one random start number (R). This number must be equal or less than the interval calculated.

   c. the first sample chosen is the random start number (R).

   d. subsequent samples are chosen by continually adding the interval to the random start number. (i.e. R, R+Z, R+2Z, R+3Z, R+4Z, … until the end of the sampling frame).

SAMPLE SIZE

The eventual sample size is usually a **compromise between what is desirable and what is feasible.**

However, in quantitative research it is very important to do sample size calculations before embarking on a study, because it may not be worthwhile to do a study at all if the feasible sample size is much less than the desirable sample size. Thus, the maximum sample size is determined by the availability of resources: time, manpower, transport, and equipment.

A sample size of 30 is often quoted as the minimum for any decent study. **In reality this is not true.**

Sample size calculations take into account the power of the study to "prove" findings (often set at least 80-90%) and the significance level (often set at least 0.05). Software is available for sample size calculation, provided certain simple parameters about the population to be studies are known.

In selecting the sample it is important to determine the **inclusion** and **exclusion criteria** of subjects. Subjects may be excluded because they are biased, have pre-determined conditions that affect the current study, etc. The inclusion and exclusion criteria help the researcher determine the scope of the sample.

WHY THIS?
So that we can collect information about our subject of study (people, objects, phenomena) in a systematic way.

COMPONENT 10

TECHNIQUES FOR DATA COLLECTION

What techniques will best answer the objective?
How should we train data collectors?
How can we check whether the data collection technique is the best for our study?

What techniques will best answer our objective?

In answering your study objectives, more that one technique may be required.

1. Choose your technique based on:
   a) what your objectives are trying to answer.
   b) ideas from literature review – how others have used the technique and what their experience teaches us.
   c) expert opinion of experienced researchers.
   d) whether it is feasible to implement.

How should we train data collectors?

Training of data collectors depends partly on the technique selected (see below).

How can you check whether your data collection technique is the best for your study?

It is important to choose the most appropriate technique for your study. If you follow the steps above, you should be able to identify the appropriate technique. Anticipate that changes make take place as you develop the proposal.

Learning points:
In any study, a variety of data collection techniques can be used for one study. For each technique you must have at least one tool.
Remember to collect only relevant data.

TECHNIQUES

There are 4 major data collection techniques. They are:
1. interview /self-administered questionnaire
2. recorded sources
3. observation
4. focus group discussion (FGD)

From this section on, we will discuss each technique listed above with regard to these questions:

What tools do we need?
How do we design the tools?
How do we apply it?

INTERVIEW/SELF-ADMINISTERED QUESTIONNAIRE

An **interview** is a data collection technique that involves verbal questioning of respondents.

A **written questionnaire** (also referred so as self-administered questionnaire (SAQ)) is a data collection technique where respondents write down their answers to written questions.

What tools do we need? You need to develop a list of questions (questionnaire) that will answer your research objectives.

How do we design the tools? (Content, format and validity.)

(i) Content

1.	Look at your bubble diagram and variables to determine what questions to include.
2.	If possible, use or modify a pre-existing questionnaire (ask for permission to use and remember to acknowledge the source in your write-up).
3.	The questionnaire should be structured into the following sections: a. identifiers & administrative use. b. introduction. c. socio-demographic information. d. main study questions. e. closing statement.

4.	Identifiers. a. One unique identifier is required (e.g. the Mother's national registration identity card number in a paediatrics study) to ensure no duplication of respondents. b. The researcher may decide to use a database code number to keep track of how many questionnaires are distributed and returned. c. When an interview technique is used, have a section to identify who did the interview and the date of interview. d. If it is self-administered, you may want a question on whether the person had help in answering the questionnaire.
5.	Introduction. Include an introduction that explains clearly: a. purpose, b. confidentiality, c. use of data and d. potential benefit of study.
6.	Socio-demographic information / biodata. a. Personal information (e.g. age, sex, ethnicity, education, personal income, height, etc.). b. Household and geographical information (e.g. urban/rural location; type of residence; household income).
7.	Main study questions. a. Check each question with the objectives of the study and use your list of variables as a guide for deciding how to phrase the question in relation to the data to be collected. b. Make sure all terms used are clearly explained in the questionnaire. c. Ensure that every question will be utilised. d. Resist the temptation to insert unnecessary questions.
8.	Closing statements. a. Thank your respondent for their time and effort. b. For self-administered questionnaires, include instructions for its return and deadline.
9.	Draw dummy tables of desired data based on the questionnaire to ensure that all information required can be captured. This is a critical step and must not be neglected.

(ii) Format

10.	Keep it as short as possible (nothing more than 15-20 minutes to complete).
11.	Sensitive and or threatening questions should not be asked in the beginning.

12.	Ask short, clear and specific questions.
13.	Ask only 1 question at a time. No double-barrel questions.
14.	Do not ask leading questions.
15.	Make the questionnaire "user friendly". a. Attractive format (structured). b. Decent font size. c. Link questions on similar areas (e.g. socio-demographic variables in the same place). d. Sequence of questions logical. e. Use simple language. f. Abbreviations should be explained in detail.
16.	Decide on the response format to be used. a. Use "close ended" questions (fixed response) rather than "open ended" (open response). Open ended questions are hard to analyse, but provides you with rich information. b. Close ended questions may be: i. categorical scale (Yes/No, Male/Female). ii. ordinal scale (Severe/Moderate/Mild). iii. continuous scale (Weight in kg, Age in years). iv. date fields.
17.	Do not abbreviate the responses you collect. Where possible, collect continuous data (e.g. actual age in years *vs*. age categories).
18.	Use "checked boxes" for responses, e.g. "Q14. Did this child have fits? ☐ Yes ☐ No".
19.	Where possible, every question should be designed to be answered, even if this is in a negative way, e.g. an option for "not applicable".

(iii) Reliability & Validity

20.	Check content validity with experts in the area – verify that important areas are addressed appropriately.
21.	Pre-test the questionnaire on individuals who are similar to (but not part of) your study population to ensure that: a. every question is clearly understood. b. time taken to complete it is reasonable. c. language is understood by the reader (do cognitive debriefing). Do at least 3-5 interviews per language used.

22.	Pre-test any language translations used with a person from that language group.
23.	Refine your questionnaire after pre-testing. Then you need to pre-test it again.
24.	Consider improving reliability. a. Internal consistency: This is checking to see if questions asking the same thing get similar answers from the same person. b. Test-retest reliability: This is checking if the same person will answer the same way on repeated testing on different days.

How do we apply it?

25.	You can either interview the respondent or have the respondents answer the questions themselves.
26.	Consider doing an interview if: a. respondents have poor literacy. b. interview is more likely to provide the data required than a self-administered questionnaire. c. you need to allow respondents to clarify questions. d. you want to collect data faster. e. you want a better response rate.
27.	Consider doing a self-administered questionnaire (SAQ) if: a. respondents are literate. b. geographical accessibility is an issue. c. you want to provide confidentiality and anonymity to the respondents. d. you want less bias in responses. e. you do not need to allow respondents to clarify questions. SAQ usually has poorer response rate. This can be improved by: i. asking respondents to return the questionnaire even if they are unable to complete all items. ii. providing a self-addressed paid envelope if the questionnaire is mailed to respondents. iii. waiting there for the respondent to return the questionnaire immediately, e.g. in a classroom style. iv. where anonymity is not required, repeated follow-up can be done. In addition, questionnaires can be emailed out for better response.
28.	Conduct training for all data collectors. See section on Training for Data collection for further details.

RECORDED SOURCES

A technique that involves retrieving information from recorded sources and documents e.g. census data, patient medical records, attendance records, etc.

What tools do we need?
You need to develop a checklist of all the data to be collected that will answer your research objectives.

How do we design the tools? (Content, format and validity.)

(i) Content

1.	Look at your bubble diagram and variables to determine what questions to include.
2.	If possible, use or modify a pre-existing checklist (ask for permission to use and remember to acknowledge the source in your write-up).
3.	The checklist should be structured into the following sections: a. identifiers & administrative use. b. instruction. c. socio-demographic information. d. main study areas. e. definitions.
4.	Identifiers. a. One unique identifier is required (e.g. the Mother national registration identity card number in a paediatrics) to ensure no duplication of respondents. b. have a section to identify who collected the data.
5.	Socio-demographic information / biodata. a. Personal information (e.g. age, sex, ethnicity, education, personal income, height, etc). b. Household and geographical information (e.g. urban/rural location; type of house you live in; household income).
6.	Main study areas. a. Check each item with the objectives of the study and use your list of variables as a guide for deciding on the areas of data to be collected. b. Ensure that every item collected will be used.

7.	Definitions. a. The purpose of this is to guide the data collector, to standardise terms used. b. E.g. In a waiting time study, the time measured could be defined, from patient registration to patient entering the doctor's office or exiting the consultation room, or leaving the pharmacy.
8.	Draw dummy tables of desired data based on the checklist to ensure that all information required can be captured. This is a critical step and must not be neglected.

(ii) Format

9.	Each statement should address only one item at a time.
10.	Make the checklist "user friendly". a. Attractive format (structured). b. Decent font size. c. Link items on similar areas (e.g. sociodemographic variables in the same place). d. Sequence items logically and according to the flow of the recorded source used. e. Abbreviations should be explained in detail.
11.	Decide on the response format to be used. a. Use "close ended" items (fixed response) rather than "open ended" (open response). Open ended items are hard to analyse but provide rich information. b. Close ended items may be: i. categorical scale (Yes/No, Male/Female) ii. ordinal scale (Severe/Moderate/Mild) iii. continuous scale (Weight in kg, Age in years). iv. date fields
12.	Do not abbreviate the responses you collect. Where possible, collect continuous data (e.g. actual age in years *vs*. age categories).
13.	Use "checked boxes" for responses, e.g. "Q14. Were fits documented? ☐ Yes ☐ No"
14.	Where possible, every item should be designed to be answered, even if this is in a negative way, e.g. an option for "not applicable".

(iii) Reliability & Validity

15.	Check content validity with experts in the area – verify that important areas are addressed appropriately
16.	Pre-test the checklist on recorded sources which are similar to (but not part of) the study population to ensure: a. that every item is clearly understood. b. time taken to complete it is reasonable. c. language is understood by the data collector. Do at least 5 records.
17.	Refine your checklist after pre-testing. Then you need to pre-test it again.
18.	Consider improving reliability. a. Test-retest reliability: This is checking if the same person will answer the same way on repeated testing on different days. b. Inter-rater reliablity: This is checking to see if items checked by different data collectors yield the same answers.
19.	There are limitations to the use of recorded sources. Data was collected for different reasons other than for the current study. These include: a. missing data. b. no such information documented. c. not able to validate the accuracy of the data. d. there may be differences in definitions.

How do we apply it?

20.	Usually you use one checklist per recorded source, though you may use a tabulated checklist for multiple sources.
21.	Conduct training for all data collectors. See section on Training for Data collection for further details.

OBSERVATION

Observation is a technique which involves systematically selecting, watching and recording behaviour and characteristics of living beings, objects or phenomena.

What tools do we need?

Here the **eye** is the most important research tool. Here you **observe** and **record** data, unlike in recorded sources where you extract data. Data capture can be

done directly by an observer or by pre-recording (camera/audio) followed by an **assessment**. Observation could be done in a structured and unstructured manner. For **structured observation**, you need to develop a checklist of all the data to be observed that will answer your research objectives. For **unstructured observation**, there are no instructions etc on how and what to observe.

How do we design the tools? (Content, format and validity.)
(See recorded sources.)
There may be a need to have **anonymity** when observing in some situations. Where this is required, use a "Trojan horse". This means that people being observed are not aware of being observed or not aware of what they are being observed for. You can do this by using proxy individuals, or informing the study respondents of a "false" study objective. For ethical reasons, you have to strictly maintain confidentiality of participants when you do this. Do not disclose personal particulars etc.

How do we apply it?

1.	Check that you know the contents of the checklist just before the observation commences.
2.	Bring all tools required along, e.g. checklist, stopwatch, thermometer, etc.
3.	Record information immediately as it is observed. This is to avoid forgetting to record something. Only when you use a recording device (camera/audio) can you extract data after the event.
4.	When you apply a "Trojan horse", the false study will have to be explained to the respondents later.
5.	Conduct training for all data collectors. See section on Training for Data collection for further details.

FOCUS GROUP DISCUSSION

A focused group discussion consists of a group discussing topics of relevance to the particular study.

Usually 6-10 people, of similar status, participate under the guidance of a moderator (facilitator). Duration is usually about 1 to 1½ hours and may involve multiple groups.

The informal group situation and open-ended nature of the questions are intended to encourage participants to comment on behaviour and elaborate on opinions to an extent that is more difficult in more formal individual interview situations.

What tools do we need?

You require a moderator who is able to facilitate dialog without influencing the group on his/her opinions. The moderator should have a guide on topics for discussion. You need a format to collect information on participants. There should be at least one additional observer who is the note-taker. In addition, use an audio-recording for accuracy of data collection.

How do we design the tools?

(i) Selection & role of moderator.

- Choose someone (usually part of the research team) who has the skills to bring out quiet participants and control overly expressive ones. He/she should not show support or objections to any opinion discussed, either verbally or non-verbally. Moderator manages the time to ensure all topics are covered.
- Moderator should be respected by the audience, but not intimidate them. E.g. use a doctor to moderate a group of doctors, use a lady to moderate a group of ladies etc.

(ii) Other tools

1.	FGD Guide: List all the topics to be discussed in the session.
2.	A format to capture basic socio-demographic data of participants (e.g. age, sex, ethnic) and their seating arrangements.
3.	Note-taker: a competent individual who records the discussion verbatim (in the words of the respondents). Audio-recording will supplement the written records of the note-taker. He/she does not participate in the discussion.
4.	Audio-recording device: consent has to be taken from participants before this can be used.
5.	Conducive site for discussion and adequate refreshments.

How do we apply it?

1.	Moderator introduces participants and note-taker.
2.	Moderator informs participants about the rules of the discussion. This includes confidentiality of participants and information obtained.
3.	Moderator gets consent for audio-recording.
4.	Moderator introduces the first topic for discussion and initiates dialogue.

5.	Moderator introduces subsequent topics as the discussion progresses, making sure each topic has been adequately explored. Additional questions may arise that need to be asked when exploring an area to obtain in-depth information.
6.	Moderator summarises the topics that have been discussed, closes the session and thanks participants.
7.	Analysis of a FGD is beyond the scope of this manual (see http://www.idrc.ca/en/ev-56615-201-1-DO_TOPIC.html)
8.	Conduct training for all data collectors. See section on Training for Data collection for further details.

In order to avoid confusion in the use of terms, the following table points out the distinction between techniques and tools applied in data collection.

	Data Collection Technique	Data Collection Tools
1.	Interview/self-administered questionnaire	Interview schedule/checklist; questionnaires, audio-recording device
2.	Recorded sources	Checklist
3.	Observation	Eyes, pen/paper, watch, scales, microscope, checklist, video camera etc
4.	Focus Group Discussion	FGD guide, note-taker, audio-recording device

PRE-TESTING/PILOT

Check whether the data collection techniques are **correct** before beginning a study.

Pre-test: a small scale trial of a particular study technique.

Pilot: the process of carrying out a preliminary study, or a component of the study, going through the entire procedure with a small sample.

What aspects to check?

1. Data collection tools.
2. Reaction of respondents.
3. Sampling technique.
4. Proposed work plan.

Who to conduct?

1. The researchers themselves should do so.

Analysis and evaluation

1. What are the limitations, weaknesses, time and resource requirements of the technique?
2. To repeat pretest/pilot with revised instrument/methodology if necessary.

TRAINING FOR DATA COLLECTION

Who to train?
When and how long?
What to train?
How to control quality of data?

Who to train?

1.	All data collectors and supervisors should be trained by the researchers.
2.	Who you choose to be data collectors depends on the study type and location.
3.	Choose supervisors who would ordinarily have authority over data collectors. E.g. nursing sisters supervising staff nurses.
4.	Preferably limit the number of data collectors so as to reduce error in data collection.

When and how long?

1.	Train immediately prior to data collection to avoid memory lapse and loss of data collectors from the research project.
2.	Do training for all data collectors and supervisors together. This promotes team work; different people raise different issues and they can learn from each other; it standardises training for all.
3.	Duration of training depends on the size/number of the tools and be sufficient to allow for role play and field experience.

What and how to train?

1.	Make sure that the data collectors and supervisors all have a clear understanding of the study and methods.
2.	Train everyone on the chosen technique(s) for the study. E.g. give a session on interview techniques if you are interviewing people.
3.	Everyone must know the detailed contents of the tools and the purpose behind the questions/items.
4.	The following training approaches must be covered. a) Classroom i) theory, and ii) role play. b) Supervised field work/practical session. c) Feedback on common errors.
5.	Supervisors need additional training supervision of data collectors, quality control and project management.

How to ensure quality of data?

1.	Development of a good instrument/tool for data collection.
2.	Choose appropriate data collectors and supervisors and train them meticulously.
3.	Put in checks at various stages of data collection. a) Data collectors should be trained to verify specific and important data on collection before they leave the site or respondent. b) A check by supervisors at the initial data collection stage can provide feedback of common errors made by data collectors. c) Spot or supervisory checks are also useful to determine quality of data collected by a particular data collector. This can be done by direction observation or by repeat observation/interview of same respondent and comparing with earlier data collected. d) Supervisors should check all data formats submitted for completeness. e) Checks are also required prior to data entry for completeness and further error detection.

WHY THIS?
We do this to:

1. Reduce error
2. All information needed is collected
3. Unnecessary data is not collected
4. Facilitate analyses

COMPONENT 11

PLAN FOR DATA ANALYSIS & INTERPRETATION

What will we do with the collected data?

1. **Compile, check, label and store.**
   a. Obtain all forms from data collectors/supervisors.
   b. Check for completeness and errors.
   c. Give feedback to data collectors and supervisors (if data collection is still ongoing) and request for further information if still possible.
   d. Label all data forms – unique identifiers, batch number, date etc.
   e. Store systematically (e.g. by state/batch number) until data entry.

2. **Design database.**
   a. Decide the software you want to use for data entry and for data analysis (see Pros & Cons of Database Packages).
   b. Create data entry variables and coding to be used.
   c. Create data entry screen.
      i. Customizse data entry screen to look like the data form if possible.
      ii. Design screen with valid values and labels incorporated (e.g. 1=female, 2=male). Some packages allow for drop down menu to choose the values to be keyed in.
      iii. Designate a code for missing and not applicable values.
   d. Test the database created with a few entries to detect problems/errors.
   e. Test exporting of database if a different program is required for data analysis.
   f. Modify if necessary.

3. **Enter data.**
   a. Train staff for data entry.
   b. Enter all variables into the database.
   c. Do spot checks for quality of data entered (for mistakes).
   d. Ensure that no data entry cell has not been filled.

4. **Clean.**
   a. Do this when all data has been entered.
   b. Run frequency counts and key cross-tabulations to look for
      i. completeness
      ii. abnormal/illogical values
      iii. inconsistencies (e.g. male with PAP smear)

5. **Plan for data interpretation.**
   a. Examine the objectives.
      i. To identify variable types. These determine the statistical tests that can be used.
      ii. Ensure that the data collection tool will capture the variable in the format required (e.g. if you require mean age, data for age must be collected as a continuous variable).
   b. Dummy tables.
      i. Examine the objectives to identify the important outcome variable(s).
      ii. Cross tabulate these variables with socio-demographic variables.

Learning points:
Make sure the variables needed are measured.

DUMMY TABLES

It is helpful to prepare "dummy tables" while designing the study. Dummy tables are blank tables that clearly show what data will be collected and how comparisons will be made. See examples in appendices.

Dummy tables help to:
- ensure that the data you collect will answer the question you pose.
- prepares you for the results section.

PROS & CONS OF SOME STATISTICAL PACKAGES

Data entry and analysis is possible using databases and statistical packages available nowadays which any researcher with interest can learn to use. E.g. DBase for DOS or Windows, Microsoft Access, Epi-Info, SPSS for DOS or Windows.

A brief comparison of some programs is provided below.

Software	Useful features & abilities	Disadvantages
EpiCalc 2000 v1.02	• Freeware from http://www.brixtonhealth.com/epicalc.html • Offers analysis for summarized data • Able to calculate sample size	• Does not allow raw data to be analysed
EpiInfo (EPI) Version 6 or 2000	• Free from CDC (http://www.cdc.gov/EpiInfo/) • Simple to learn & use • Can build in checks to minimize wrong data entry • Built-in nutrition anthropometric program • Able to do complex survey analysis	• Interface is not as user-friendly
SPSS for Windows	• User-friendly software for data analysis • Easy to do detailed & "higher end" data analysis (e.g. regression analysis) • Excellent graphics, can be incorporated into document	• Errors easily committed during data entry • Easy to change data without being aware of it • Expensive!
STATA	• Versatile and efficient • Relatively cheap • User-written programmes and free updates available on the web • New version has windows interface	• Need to learn programming language to make it more efficient
MS Access	• Mainly for data entry • Set-up & usage of database simple • Can build checks to minimise wrong data entry	• Detailed analysis requires exporting to another program
MS Excel	• Allows data entry but no labeling, no valid values etc.	• Needs to be imported into a statistical software for analysis

WHY THIS?
To ensure the research project:
1. covers the planned scope.
2. follows methodology.
3. runs on time.
4. within resources budgeted.

COMPONENT 12

PROJECT MANAGEMENT

Who does what & when?
What resources do we need? Where will the resources come from?

TASK ALLOCATION
Who does what & when?

1.	Decide what task to perform
2.	Decide the time frame for each task.
3.	Map the tasks and time-frame in your Gantt Chart.
4.	Decide who to do it (allocate responsibility).
5.	Have a plan to monitor progress.

RESOURCE REQUIREMENTS & APPROPRIATION
What resources do we need? Where will the resources come from?

1.	Identify the areas that need funding.
2.	Calculate the costs involved (project budget).
3.	Identify source(s) of funding and apply for funding.

Learning points:
Have a plan.
Plan it.
Stick to it.

GANTT CHART

This covers items 1-4 of **"Who does what & when"**.

A Gantt chart helps map out the research activities, by person and time-frame. It offers a plan for the entire research project. It facilitates monitoring.

Activties	Person responsible	Year: 200X											
		J	F	M	A	M	J	J	A	S	O	N	D
Discussions with stakeholders	All researchers	X											
Development of research proposal	All researchers	X	X										
Pretest & refine research tools	Researcher 1 & 2		X										
Pilot testing	Researcher 3			X									
Recruitment & training of data collectors	Researcher 2 & 3			X									
Data collection	Researcher 4				X	X	X						
Monitor progress of implementation	Researcher 4				X	X	X						
Data entry, cleaning & analysis	Researcher 1 & 2					X	X	X	X				
Report writing	All researchers								X	X	X		
Dissemination of findings	All researchers											X	X
Writing draft for publication	All researchers												X

Figure 8: Example of a Gantt chart for a research project.

MONITORING PROGRESS

This covers item 5 of **"Who does what & when"**.

1. **Progress** – This involves making sure activities happen as planned and on time.
2. **QC** – It involves checking that the correct procedures are used (this is the quality control (QC) of your data).

What to monitor, how to do this, and how often

1.	Progress of data collection – Both the sample required and the coverage (response rate).
2.	QC – check that the sampling method chosen was implemented, completeness of data collected in tools used.
3.	Periodic feedback to data collectors on problems with progress and QC.
4.	Use site visits, phone call checks, faxed returns, and/or emails to do this.
5.	Frequency of monitoring progress depends on duration of data collection and data size.

Tips on who to carry out the study

In identifying who to collect data, make sure they are culturally and socially appropriate to respondents.

This is to enhance the respondents' answers and willingness to respond.

- Don't use young data collectors to interview older persons about sexual issues.
- When doing an interview on sexual issues, it is more appropriate for a person of the same gender to interview them.

Tips on when to carry out the study

Take into account environmental and socio-cultural aspects when you choose the time to implement the data collection.

- For example, some diseases vary with different months of the year (dengue peaks at dry season).
- It is difficult to carry out a study on one disease during a major outbreak of another disease.
- Avoid community surveys during the fasting month, festive seasons or school holidays.
- People may be more defensive to surveys during elections.

Areas that require funding

This covers items 1-2 of **"What resources do we need? Where will the resources come from?"**.

Take into account the following areas that may require funding.

1.	Meetings & travel – planning, implementation (including supervision), report writing and dissemination.
2.	Hiring research assistants – for data collection and data entry.
3.	Training of data collectors/data enterers.
4.	Materials/equipment.
5.	Printing costs.

Source of funding

This covers item 3 of "How much will it cost? Where will the money come from?"

Many research projects can be conducted without formal funding (using operational funds). However, some projects will need application for funds, especially if it requires equipment and research assistants. Funds can be obtained from:

1. Ministry of Health (see below)
2. MOSTE
3. Various professional bodies
4. International sources (WHO, World Bank, UNICEF, etc.)

MOH RESEARCH FUNDING PROCEDURE

1. Go to **National Institutes of Health (NIH)** website: http://www.nih.gov.my/. This gives you the procedure and forms necessary for funding application.
2. The website gives priority areas for research for the current Malaysian Plan.
3. NIH periodically issues calls for applicants in areas that will be funded for research.
4. Researchers can also submit applications to NIH secretariat for funding of research not listed at any time of the year

Note: Only MOH staff are allowed to apply for these grants. For projects, which involves collaboration with non-MOH researchers, the principal investigator of the project must be a MOH staff.

EXAMPLES OF RESEARCH PROPOSALS

EXAMPLE #1:

TITLE

Effective implementation of a structured psychoeducation programme among caregivers of patients with schizophrenia in the community

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INTRODUCTION

Worldwide, mental health problems present as the fifth most common cause of disability with half of these figures causing marked morbidity. In Malaysia, schizophrenia presents as the main mental health problem. The burden of disease has increased over the years. The National Mental Health Registry in Schizophrenia showed a 8.07% increase in registered cases in the year 2004 with 2436 cases to the 2254 cases in 2003 (Aziz S.A., 2006).

Aside from the usual pharmacological treatment, psychoeducation has shown great promise in the management of schizophrenia. The clear aim of the treatment of such disorders is not only to control the symptoms, but it is also to prevent new symptomatic acute phases, to bring the patient to comply with the prescribed treatment plan, to restore a certain social and working functioning and to reach a better quality of life. Psychoeducational approaches have been developed to increase patients' and their carers' knowledge of, and insight into, their illness and treatment.

A review of more than 30 randomized clinical trials have shown that family psychoeducation reduces the rate of relapses, encourages recovery of patients as well as improves family dynamics among participant (McFarlane W.R. et al, 2003). Another recent study also showed significant reduction in patient rehospitalization rates and improved compliance over a period of 2 years after patients and their families attended a psychoeducational program consisting 8 sessions (Pitschel- WalZ G et al, Mar 2006). In the Asian setting, similar results were seen among families of Chinese patients in Hong Kong (Chien WT, Chan SW, 2005). Participants in the psychoeducation group families' and patients' functioning, families' burden of care and the number and length of patients' rehospitalization over the 12-month follow-up period, compared with the standard care group.

Family psychoeducation is a method of working in partnership with families to impart current information about the illness and to help them develop coping skills for handling problems posed by mental illness in one member of the family. The goal is that practitioner, consumer, and family work together to support recovery. It respects and incorporates their individual, family, and cultural realities and perspectives. It almost always fosters hope in place of desperation and demoralization.

Increasingly, mental health facilities are feeling pressure to meet the demands of service and productivity. Mental health program leaders find they need to direct services that will satisfy these demands without sacrificing the quality of care being offered. At the same time, program leaders are concerned about practitioners' level of satisfaction. According to the American Psychiatric Association (APA, 2004) and the DFPPN (German Society for Psychiatry, Psychotherapy and Neurology), psychoeducational interventions belong to a standard therapy program in acute and postacute phases of patients with Schizophrenia. In the Cochrane analysis of Pekkala et al, 2002, such interventions were accompanied by a higher level of compliance, lower rate of relapse, and improved psychopathological status.

What is the benefit of psychoeducation for practitioners? Research has shown that psychoeducation provides practitioners with an opportunity to (Implementation Resource Kit, Draft Version 2003):

- Promote improved clinical outcomes, satisfaction, & higher rates of recovery amongst their clients
- Feel more supported in their efforts to manage the effects of illness
- Build relationships with families
- Experience improved cost-benefit ratios

For consumers, the practice of family psychoeducation

- Helps building a support network for recovery
- Provides hope
- Reduces relapse and hospitalization
- Improves symptom management
- Reduces medication dosages
- Improves social skills and community participation
- Increases employment, earnings and career options
- Strengthens family ties
- Reduces family conflicts

Most family intervention studies have focused only on Caucasian populations (Pharoah FM et al, 2001, Magliano L et al, 2005). Only a few studies have been carried out with Chinese or Asian populations, in which great importance is attached to intimate interpersonal relationships and interactions with family members (Li Z. Arthur D, 2005, Chien WT et al, 2007). The application of family psychoeducation in Malaysia has been rather limited and very recent. In June 2004, the Hospital Bahagia Ulu Kinta Psychoeducation Team (HBUK-PET) was initiated to conduct courses to train facilitators who will provide education to clients and their care-givers.

The HBUK-PET programme consists of 5 modules as below:

1. Understanding your illness
2. Understanding your treatment
3. Helping yourself prevent relapses
4. Avoiding and handling crisis
5. Healthy lifestyle – diet and exercise

Following the initiation of this programme, there was encouraging results from both the client as well as their care-givers. Notably, there was an increase in the quality of life in both the client as well as their care-givers. Relapse rates were also lower as they were able to recognize the early warning signs of possible relapse (Ghaus Z., 2006).

With the success of the HBUK-PET programme, the researchers have decided to adapt the 5 modules into a community care setting. As this is a pioneering initiative, the researchers have decided to study the effectiveness of the structured psychoeducation programme among care-givers of schizophrenics in the community. However, we do foresee some possible problems with implementation of this study. (please see Figure 1).

The main aim of this study is to assess if a structured psychoeducation programme can be effectively implemented among schizophrenia patients in the community. The researchers aim to look at sustainability, will attempt to standardize the delivery of the psychoeducation programme and monitor defaulter and drop-out rates with a view to improve the health outcome for schizophrenics and their families. The researchers hope to be able to make recommendations with regards to a uniformed national psychoeducation programme for schizophrenia patients.

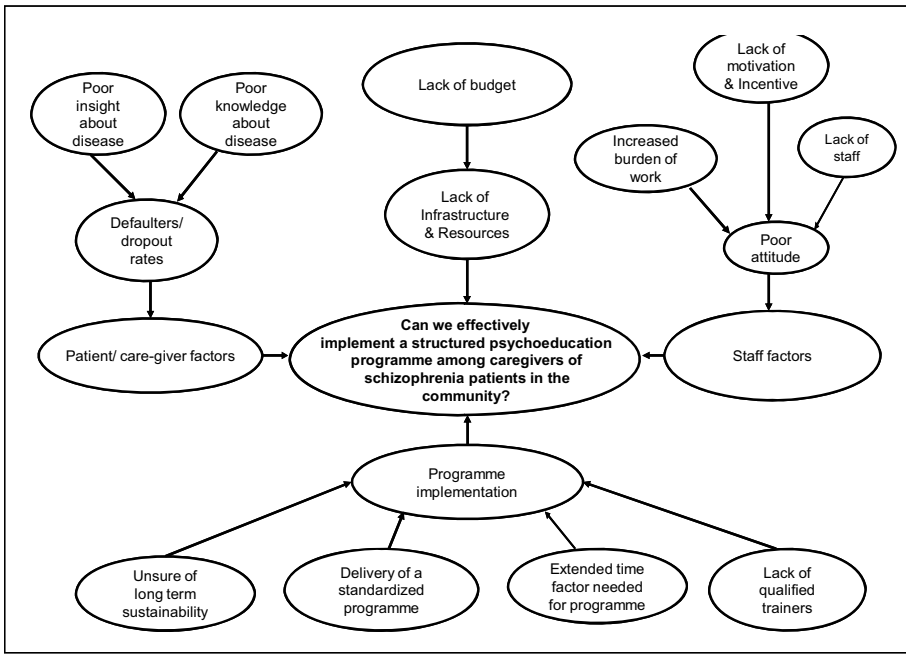

Figure 1: Problem Analysis Chart of the Study

OBJECTIVES

General Objective

To compare the effectiveness of a structured versus non structured psychoeducation program among caregivers of patients with schizophrenia in the community in the state of Perak.

Specific Objectives

1. To determine if the use of a structured psychoeducation program will significantly:
   a. improve the knowledge about schizophrenia among caregivers
   b. decrease patient readmission rates
   c. improve compliance to follow up
   d. decrease the caregivers burden
2. To determine the feasibility of the program among the staff implementing it.
3. To make recommendations regarding the implementation of a structured psychoeducation program in the community.

METHODOLOGY

Overview of Research Design

This is an interventional study with a control group involving health clinics. The intervention to be used is the introduction of a structured psycho education program. Specific health staffs in the interventional group will be trained in the structured psycho education module, after which will administer the structured psycho education to the caregivers. The control group will be those caregivers of patients who follow the standard treatment without any structured intervention. Please see Figure 2 for the diagrammatic description of the study.

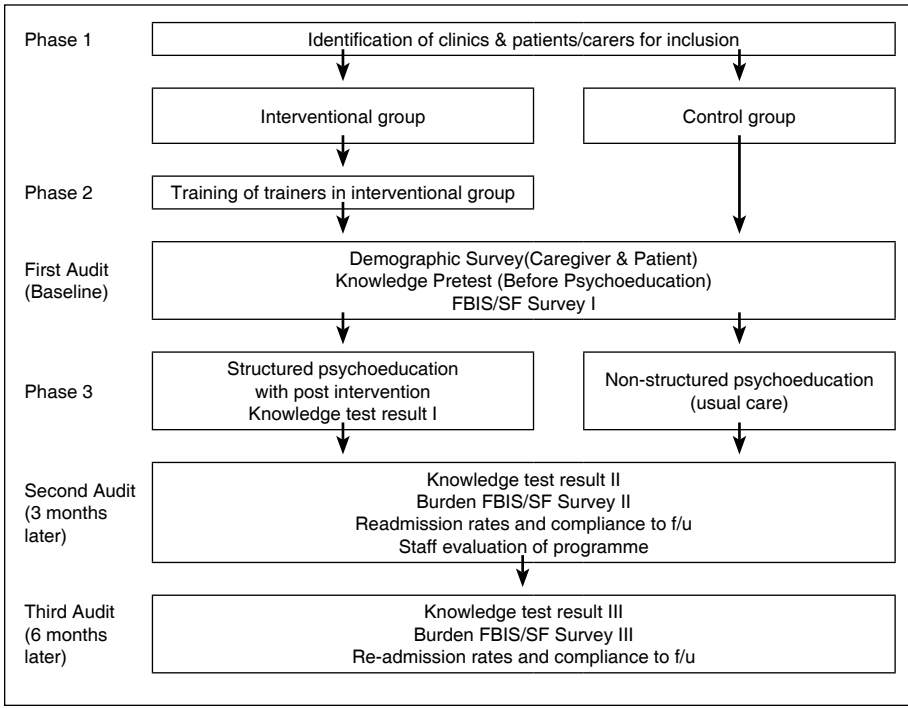

Figure 2: Methodology flowchart

Phase 1

Health clinics and patients/carers will be identified for inclusion in the study and allocated to the intervention and control groups respectively.

Phase 2

Specifically identified health staff in the interventional group, from the respective clinics will be trained in the use of the modules of the structured psychoeducation (see Appendix). All the respondents identified in both groups will be given the demographic survey, pretest questionnaire and The Family Burden Interview Schedule- Short Form (FBIS/SF) prior to intervention (see Appendix).

Phase 3

Respondents in the interventional group will be taken through the structured psychoeducational program. To ensure the modules were taught adequately and in a standard manner, all the staff involved in giving the psychoeducation program will be required to complete a checklist. The caregivers are given psychoeducation using 5 modules as used in the PET programme.

The patients in the interventional groups will be given the psychoeducation mainly in the clinics. Methods of teaching include audio visual aids e.g. LCD projectors with powerpoint presentations, charts, and also one to one teaching. Those who are unable to come to the clinic will be taught at their homes. The teaching materials that will be provided to the trainers during the training sessions will be used during the teaching. All the five modules will be completed within 2 weeks. For the interventional group the post-test questionnaire will be done immediately after the completion of the modules to assess the quality of the training.

In the post interventional phase the knowledge questionnaire and FBIS/SF will be conducted further after three months and six months for both groups. The staff will also be required to complete a survey form regarding their opinion of the whole psychoeducation program 3 months into the program.

After the completion of the six months study period, the patients' treatment card will be screened to trace follow-up default or readmission. The caregiver may be interviewed to get this information. The information gained will be recorded in the initial demographic survey form.

Study type

This is community trial using a quasi-experimental design. There is an intervention (the introduction of a structured psycho education program), an interventional and control group but no randomization as this will not be possible (contaminate subjects and available clinics limited).

Ethical considerations

The researcher will request approval from the national ethic committee prior to implementing the study (NMRR). All the information from the questionnaire will be kept confidential. Written informed consent will be taken before the respondents' involvement in the study. Caregivers will be allowed to refuse consent to participate in the study.

Variables

Variables	Operational Definition	Scale of Measurement
Age of staff	Age of staff as of completed year.	Years
Age of caregiver	Age of caregiver as of completed year.	Years
Age of patient	Age of patient as of completed year.	Years
Working experience of medical personnel	Duration of working experience of the medical personnel in the Ministry of Health	Years
Sex of caregiver	Answers provided to specific question in questionnaire	Male /Female
Sex of patient	Answers provided to specific question in questionnaire	Male /Female
Ethnicity of caregiver	Ethnic of the caregiver based on paternal side	Malay/Chinese/Indian/Others
Ethnicity of patient	Ethnic of the patient based on paternal side	Malay/Chinese/Indian/Others
Marital status of caregiver	Current marital status of the caregiver	Single/Married/Divorced/ Widow/Widower

Variables	Operational Definition	Scale of Measurement
Marital status of patient	Current marital status of the patient	Single/Married/Divorced/ Widow/Widower
Household income	Total income of all the members in the household	Ringgit Malaysia per month
Occupational status of caregiver	As obtained from caregiver in response to specific question in questionnaire	Organized by social class
Occupational status of patient	As obtained from caregiver in response to specific questionnaire	Organized by social class
Duration as Caregiver status	Number of years taking care of the patient as the primary caregiver	Years
Educational status	Formal education received by respondent	No/Education/Primary/ Secondary/Tertiary
Pretest	Standard designed test regarding knowledge about schizophrenia	Marks obtained: 0-20 marks
Post test	Standard designed test regarding knowledge about schizophrenia	Marks obtained: 0-20 marks
Family Burden Interview Schedule	A toolkit for evaluating family experiences with severe mental illness. As obtained from caregiver in response to specific question in standardized FBIS questionnaire	Marks obtained: • 7-63 in daily living assistance module • 5-45 in supervision module • 1-5 in financial expenditure module • 4-20 in impact on daily routines module • 5-35 in worry module
Readmission	Number of admissions to a psychiatric unit due to a psychiatric condition	Total number of readmission events
Default follow up	Any incidence of default in follow-up(within one month of appointment)	Total number of default in follow up

Sample size and sampling method

The minimum sample size required is in each arm (interventional & control group) is 46. This figure was arrived at by using the Epical 2000 software. Setting the significance level at 0.05 with a power of 90% and assuming a change in knowledge level from 55% to 85%. To allow for loss to follow up the researchers will sample 60 respondents in both the interventional and control arms.

A total of 6 health clinics in Perak which offer care to patients with schizophrenia will be selected (convenient sample) - 3 in the interventional group and 3 in the control group. 120 respondents will be selected randomly from these 6 clinics, with 20 from each clinic.

Inclusion criteria:

1. The caregivers' of patients with schizophrenia diagnosed according to DSM-IV
2. The caregiver should be agreeable to be involved in the psychoeducation program
3. The caregiver should be able to understand either the Malay or English language.

Exclusion criteria:

1. Those caregivers' of patients who have co-morbidity of substance abuse.
2. Those caregivers' of patients with uncontrolled or unstable medical illness requiring admission i.e. uncontrolled hypertension, ischemic heart disease, cerebrovascular accident, or uncontrolled diabetes mellitus.
3. Caregiver's who had already undergone a structured psycho education programme.

Techniques for data collection & pre-testing

1. Data on demography of caregiver, patient and staff will be recorded in the Caregivers demographic data form (Appendix A), Patient's demographic data form (Appendix B) and in the Staff demographic data (Appendix F).

2. Evaluation of the understanding of the Schizophrenia illness will be done using the Pretest and post-test questionnaire form (Appendix C) based on existing HBUK questionnaire module.

3. Data on burden of the patient on the caregiver will be scored using The Family Burden Interview Schedule- Short Form (FBIS/SF) (Appendix D) which is self administered by the caregiver with the help of the interviewer. The FBIS/SF is a toolkit for evaluating family experiences with severe mental illness prepared by Richard Tessler, Ph.D. and Gail Gamache, Ph.D., from the Department of Sociology, Social and Demographic Research Institute, University of Massachusettes- Amherst (used with permission from the author).

4. Questionnaire on the Feasibility of the Psychoeducation Program (Appendix E) will be used to assess the opinion of the staff conducting the Psychoeducation Modules.

Pretest

1. Data on pretest and post test results will be recorded using the Pre & post-test report form (Appendix G).

2. Data on Readmission rate and default on follow up will be recorded at the end of the study using the initial demography form (Appendix C), which will be filled up by the staff.

Plan for data analysis & interpretation

The raw data will be processed and entered for data analysis according to the different phases, starting as soon as the patients are recruited, until end of study. Data collected was sorted out and processed on a weekly basis. Data entry, utilizing codes was done using the SPSS programme version 12. Computer assisted analysis will be carried out at the end of the study. Chi-square and t-test statistical tests will be used in the analysis.

Table X: Demography of caregivers of patients with schizophrenia in intervention and control group

	Interventional group	Control Group	P Value
Age (mean)			
Gender Male Female			
Ethnic Distribution Malay Chinese Indian Others			
Marital Married Single Widow/widowed			
Household Income < RM500 RM 500- RM 999 RM1000- RM 1499 >RM 1500 No response			
Educational level No formal education Primary Secondary & above			
Duration as a care-giver			

Table X: Knowledge of Caregivers about Schizophrenia in intervention and control group at base line and 3 & 6 month audits

	Baseline	Immediate post test	p-value 1	Post test 3 mths	p-value 2	Post test 6 mths	p-value 3
Intervention group							
Non-intervention group		—	—				

p1 = comparison between baseline and immediate post test
p2 = comparison between immediate post test and post test at 3rd month
p3 = comparison between post test at 3rd month and post test at 6th month

Table X: Outcome of patients with Schizophrenia in intervention and control group at 6 month

	Interventional group	Non Interventional group	P Value
Readmission rate			
Default to follow-up			

Project management
Work Plan (Gantt Chart)

Activities	Responsible Personnel	Sept 2006	Oct 2006	Nov 2006	Dec 2006	Jan 2007	Feb 2007	Mar 2007	Apr 2007	May 2007	June 2007	July 2007
HSR Workshop Finalise Draft Research Proposal	Researchers	X										
Meeting of Facilitator & Identifying staff involved	Researchers		X									
Training of staff on usage of Psychoeducation modules	Trainer HBUK & Staff			X								
Recruitment of respondent	Researchers & designated staff			X	X							
Data collection (Pretest & Baseline)	Staff				X							
Psychoducation Module & Post test 1	Staff					X						
Post test 2	Staff						X					
Post test 3	Staff							X				
Data analysis	Researchers								X			
Draft report & Meeting HSR Trainer	Researchers									X		
Final report	Researchers										X	
Dissemination of findings	Researchers											X

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APPENDICES

Appendix A:
SOAL SELIDIK MENGENAI PENJAGA

Tandakan √ dalam petak berkenaan. *Please tick √ IN the appropriate box.*

A. DEMOGRAFI/*DEMOGRAPHY*

1. Unique ID :.....

2. Umur/*Age*…….....…tahun/*years*

3. Jantina/*Sex*
   - ☐ Lelaki/*Male*
   - ☐ Perempuan/*Female*

4. Bangsa/*Race*
   - ☐ Melayu/*Malay*
   - ☐ Cina/*Chinese*
   - ☐ India/*Indian*
   - ☐ Lain-lain/*Others*

     Nyatakan/*specify*……

5. Taraf Perkahwinan/*Marital status*
   - ☐ Bujang/*Single*
   - ☐ Kahwin/*Married*
   - ☐ Cerai/*Divorced*
   - ☐ Janda/Duda/*Widow*/*Widower*

6. Pekerjaan/*Occupation* (nyatakan/*specify*) ……..

7. Pendapatan keluarga/*household income*(nyatakan/*specify*) RM ……..bulan/*month*

8. Taraf pendidikan/*educational level*
   - ☐ Tidak bersekolah/*no formal education*
   - ☐ Rendah/*Primary*
   - ☐ Menengah/*Secondary*
   - ☐ Diploma/*Teknikal*
   - ☐ Universiti/*Tertiary*

9. Tempoh menjadi penjaga pesakit/*Duration as a care giver* .....tahun/*years*

Appendix B:
QUESTIONNAIRE ON THE FEASIBILITY OF THE PSYCHOEDUCATION PROGRAM

Please answer this questions below as frankly as possible. All responses will be kept strictly confidential. Your cooperation is greatly appreciated.

OCCUPATION:

DURATION IN SERVICE: Please circle the best answer that applies to you to questions below

1	2	3	4	5
Strongly disagree	Disagree	Unsure	Agree	Strongly agree

1. In your opinion, is this psychoeducation programme beneficial to the patient?

1	2	3	4	5

2. Do you find the programme a burden?

1	2	3	4	5

3. Do you find it easy to implement the module

1	2	3	4	5

4. Do you have support from the other staff in implementing this programme?

1	2	3	4	5

5. Are you satisfied in giving the psychoeducation to the patient/ caregiver?

1	2	3	4	5

6. Do you find the program too time consuming?

1	2	3	4	5

7. Any suggestion to improve this programme?

Appendix C:
THE FAMILY BURDEN INTERVIEW SCHEDULE – SHORT FORM FBIS/SF

(Only a small part of this scale is reproduced here as an example) Adapted from the Toolkit for Evaluating Family Experiences with Severe Mental Illness & Prepared for the Evaluation Center@HSRI by Richard Tessler, Gail Gamache, 1994, Department of Sociology, Social and Demographic Research Institute, Machmer Hall, University OF Massachusetts, Amherst, Ma 01003-4830. Used with permission from the authors.

SECTION A: ASSISTANCE IN DAILY LIVING MODULE

It frequently happens that persons who have a mental illness need help or need help or need to be reminded to do everyday things. The next questions are about that. All of them may not apply to (Name), but please try to answer them to the best of your knowledge.

A1a. During the past 30 days, how often did you help (Name) with, or remind (Name) to do things like grooming, bathing or dressing? Was it?

1	2	3	4	5
not at all (GO TO A2a.)	less than once a week	1 or 2 times a week	3 to 6 times a week	every day?

A1b. How much did you mind helping (Name) with or reminding about these things? Was it:

1	2	3	4
not at all	very little	some	a lot

A2a. During the past 30 days, how often did you help, remind or encourage (Name) to take (his/her) medicine? Was it:

1	2	3	4	5
not at all (GO TO A3a.)	less than once a week	1 or 2 times a week	3 to 6 times a week	every day?

A2b. How much did you mind helping, reminding or encourage (NAME) to take (his/her) medicine? Was it:

1	2	3	4
not at all	very little	some	a lot

SECTION B. SUPERVISION MODULE

Less frequently, persons with mental illness can require some assistance when certain troublesome behaviors occur. Te next questions may not apply to (NAME) but please try to answer them to the best of your knowledge.

B1a. During the past 30 days, how often did you try to prevent or stop (Name) from doing something embarrassing? Was it:

1	2	3	4	5
not at all (GO TO B2a.)	less than once a week	1 or 2 times a week	3 to 6 times a week	every day?

B1b. How much did you mind dealing with (Name)'s embarrassing behavior? Was it:

1	2	3	4
not at all	very little	some	a lot

B2a. During the past 30 days, how often did you try to prevent or stop (Name) from doing excessive demands for attention? Was it:

1	2	3	4	5
not at all (GO TO B3a.)	less than once a week	1 or 2 times a week	3 to 6 times a week	every day?

B2b. How much did you mind dealing with (Name)'s attention-seeking behavior? Was it:

1	2	3	4
not at all	very little	some	a lot

EXAMPLE #2:

TITLE
Vaccine storage in private practice: A Community Trial in Malaysia

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INTRODUCTION
The cold chain refers to a continuum of safe handling practices including materials, equipment and procedures that maintain vaccines between a specified temperature range of 2-8 °C from the time it is manufactured to the time it is administered to patients (WHO, 1998). Vaccines which are not stored in the recommended temperature range risk losing their potency (WHO, 1998; Woodyard, Woodyard & Alto, 1995; Canadian immunisation guide, 2006; Pickering *et al.,* 2006; Gazmararian *et al*, 2002). This may produce an unsatisfactory immune response, incapable of protecting the recipient from life threatening infections (Lewis, Reimer & Dixon, 2001).

Evidence shows that good vaccine storage practices are still lacking (Matthias DM, 2007) even in developed countries among the private practitioner (Grasso, Ripabelli & Sammarco *et al.*, 1999 ; Jeremijenko, Kelly, Sibthorpe *et al.*, 1996; Woodyard, Woodyard & Alto, 1995.), and there is a great need to evaluate the situation in Malaysia since at least an estimated 20-30% of the population seeks immunisation services from the private physician clinics. Poor vaccine storage could lead to an increase in the morbidity and mortality rates of the diseases preventable by vaccination.

Very little information is available about the extent to which private physician clinics in Malaysia meet quality assurance needs for vaccine storage. Faulty handling and storage may occur and maybe are more common than is generally believed. This study aims to evaluate vaccine storage practices and the effectiveness of an intervention package among private physician clinics in Malaysia.

OBJECTIVES

General Objective
To evaluate the cold chain status, with respect to vaccine storage practices, and the effectiveness of an intervention package to improve these practices among Private Health Clinics in selected states.

Specific Objectives
1. To evaluate the vaccine storage practices among private health clinics with respect to adherence to six essential criteria based on WHO vaccine storage guidelines:
    a. Appropriate refrigerator to store vaccines
    b. Availability of a dedicated refrigerator for vaccines
    c. Correct placement of the vaccine refrigerator

d. Correct placement of vaccine in the refrigerator
e. Maintenance of refrigerator temperature between 2-8 °C
f. Daily monitoring of internal refrigerator temperature

2. To develop a practical intervention package to improve vaccine storage practices among private health clinics that is sustainable. This includes:
   a. Training of private health clinic staff
   b. Periodic audits with feedback
   c. Incentives for private health clinics
   d. A self monitoring tool for private health clinics

3. To evaluate the intervention package to improve vaccine storage practices among private health clinics including:
   a. Degree of improvement
   b. Sustainability of improvement
   c. Value of intervention package to private doctors
   4. To use the finding from the study to improve vaccine storage among private health clinics in Malaysia.

METHODOLOGY

Overview of Research Design

A non-controlled community trial will be conducted in four administrative regions in Malaysia, evaluating vaccine storage practices. We plan to base this evaluation on WHO guidelines (WHO, 1998), and will focus on the six essential criteria below:

1. Appropriate refrigerator to store vaccines
2. Availability of a dedicated refrigerator for vaccines
3. Correct placement of the vaccine refrigerator
4. Correct placement of vaccine in the refrigerator
5. Maintenance of refrigerator temperature between 2-8 °C
6. Daily monitoring of internal refrigerator temperature.

Registered nurses from the public health clinics will be identified as research assistants as they are well versed with vaccine storage practices and had contacts with private clinics when they obtained monthly feedback on vaccination returns from the clinics.

The trial consisted of four audits with the implementation of the intervention package carried out concurrently with the audits. An overview of the study design is shown in Figure Y.

Phase 1: FIRST audit (baseline)

The baseline audit will be done immediately following staff training, simultaneously in all regions. Researchers target that the baseline audit is completed within a week of commencement to reduce bias (communication between the private clinics).

Consent from clinic practitioners will be obtained by research nurses. In the event there are problems in obtaining consent, research nurses will contact research team members from the respective states who will then personally contact the private practitioner by phone. If they still failed to get consent, the clinic will be excluded from the study.

Once consent is obtained, the intervention package will be handed over to the clinic staff and the audit carried out using the audit checklist (refer Appendix A). Feedback will be given simultaneously if any discrepancies were noted during audit process.

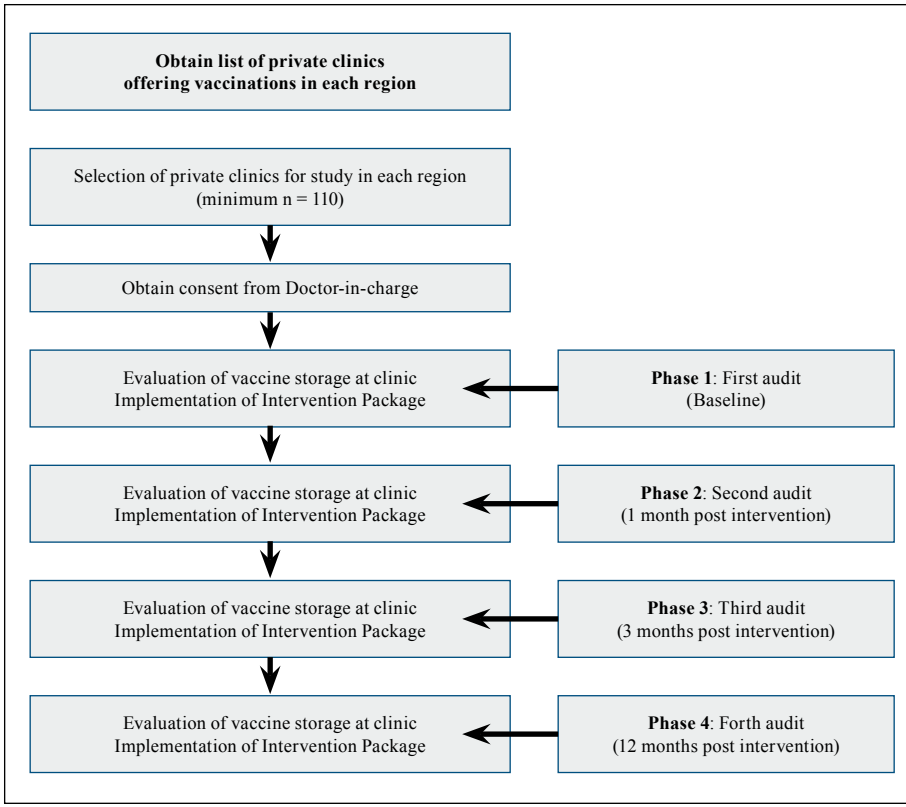

Figure Y: Flow chart of study design

Following the audit, the research nurses will answer any queries by clinic staff pertaining to good vaccine storage practice and will reinforce the six essential messages by showing the power point presentation. They will then give a copy of audit checklist to the participating clinic after it has been signed by a named personnel, thank clinic staff and remind them of subsequent visit (but not to mention any dates).

The research nurses will then submit the original of the audited checklist and relevant formats to the Supervisor for quality control (QC) checks. These include fidelity testing (refer Appendix B) and QC checks on the original copies of audit checklist before sending it centrally (to IHSR) for data entry.

Fidelity test is to monitor quality of implementation of the intervention by research nurses. It focuses on materials given to participating clinic and the audit process. A random sample of one-third of all participating clinics will be selected for the conduct of this fidelity test by supervisors.

Phase 2: Second Audit (1 Month Post intervention)

In the second audit, a tool to address the value of survey will be circulated to private practitioners (refer Appendix C). This asks questions on practicality of survey to the private practitioner to obtain feedback/ suggestions for improvement of the intervention package.
The research nurses will hand-deliver this questionnaire to the private practitioner at the end of the second audit and collect it back from the clinic staff within 2 days.

The rest of the audit process will not differ from flow of the baseline audit except the fidelity test will be conducted on every third clinic in the list of participating clinics, excluding the clinics that already had the fidelity test done in phase 1.

Phase 3 & 4: Third and Forth Audit

The schedule for all audits will be prepared in advance. The work flow for these audits will be similar to that of the second audit, except that the fidelity and value of survey tools will not be administered.

Intervention package

The research team emphasized practicality, sustainability and the provision of incentives in the development of the intervention package. The package consists of a training session, a laminated "Six Essential Messages" card, WHO manual on vaccine storage (WHO 1998), a Dial thermometer, temperature monitoring sheets and stickers. In addition, a power point presentation on a CD-ROM in two languages (English and Bahasa Malaysia) that could be used by the private practitioner for further training of staff. Additional incentives include two stickers, for the refrigerator and a certificate of vaccine storage status.

The training session on recommended vaccine storage practice for private physician clinics' staff requires research nurses to give immediate feedback to all accompanying staff during the audit process and advice on temperature charting and maintenance. To reinforce learning, research nurses will show a power point presentation on recommended vaccine storage practice followed by a question and answer session with all clinic staff.

Study type

This is a quasi-experimental study (non-controlled community trial) conducted in four administrative regions in Malaysia. There is no randomization nor a control group as researchers felt that it would not be ethical not to intervene in the event there are problems in vaccine storage.

Ethical considerations

Researchers applied for approval prior to conduct of this study. All clinics were considered "intervention" clinics (i.e. no control group) as researchers felt that it would not be ethical not to intervene in the clinics if the audit detects problems in vaccine storage.

Consent will be obtained from practitioners at the selected clinics prior to the study.

In addition, approval from the Malaysian Medical Council (MMC) was sought for the proposed incentive of providing clinics with a certificate (on vaccine storage status). This was to ensure that this proposed incentive does not contravene any ethical or medico-legal issues.

Variables

Variables	Operational Definition	Scale of Measurement
Two door/top loading refrigerator	Appropriate type of refrigerator to store vaccines	Yes/No (nominal/categorical)
Dedicated refrigerator for vaccine	Availability of a dedicated refrigerator for vaccines.	Yes/No (nominal/categorical)
Placement of refrigerator	Correct placement of the vaccine refrigerator.	Yes/No (nominal/categorical)
Placement of vaccine	Correct placement of vaccine in the refrigerator.	Yes/No (nominal/categorical)
Temperature between 2-8 °C	Maintenance of refrigerator temperature between 2-8 °C.	Yes/No (nominal/categorical)
Monitor temperature	Daily monitoring of internal refrigerator temperature.	Yes/No (nominal/categorical)
Fulfilled all 6 criteria#	This consisted of criterion # 1 to #6, as below: 1. Appropriate type of refrigerator to store vaccines 2. Availability of a dedicated refrigerator for vaccines 3. Correct placement of the vaccine refrigerator 4. Correct placement of vaccine in the refrigerator 5. Maintenance of refrigerator temperature between 2-8 °C 6. Daily monitoring of internal refrigerator temperature	Yes/No (nominal/categorical)
Fulfilled all 6 criteria & drug@	This consisted of criterion #1 to #6 and also allowed the refrigerator to also store drugs together with vaccines.	Yes/No (nominal/categorical)
Fulfilled all 4 criteria+	This consisted of criterion #2, #4, #5 & #6. The refrigerator type and placement of refrigerator was excluded from the criterion list.	Yes/No (nominal/categorical)
Fulfilled all 4 criteria & drug@	This consisted of criterion #2, #4, #5 & #6. The refrigerator type and placement of refrigerator was excluded from the criterion list. This allowed the refrigerator to also store drugs together with vaccines.	Yes/No (nominal/categorical)

Sampling

All private health clinics sending monthly vaccination feedback to MOH constituted the sampling frame. From this, a geographically convenient sample of clinics will be selected to improve response rate. In the initial implementation of the study, an impressive response rate was seen. Hence, we decided to extend the study to two other regions, using simple random sampling.

Exclusion criteria

All private hospitals, private physician clinics affiliated to hospitals or facilities that had a central pharmacy store providing and distributing vaccines.

Sample size was calculated using EpiCalc 2000 version 1.02, using sample size for two proportions, considering a difference in proportion of 10% to 30%, a power of 90% and a significance of 0.05. The minimum number of clinics required was 81, and to account for poor response rate, a minimum sample of 100 per region will be targeted.

Techniques for data collection & pre-testing

Tools used in the community trial included:

1. An introduction letter to the study for the private doctor, endorsed by the respective State Health Departments and pediatricians in the research team (Appendix D).

2. A flier on the Cold Chain Survey, which provides information on the purpose of the study, assurance of confidentially, benefits of participation in the study and number of audit visits. These two tools above will be shown by the research nurses upon first entry to the clinic as means to facilitate consent to participate in the study.

3. An audit form (checklist) that covered the six core areas for vaccine storage and other pertinent questions (refer). The checklist incorporated an assessment of problems with the current cold chain practice and recommended ideal practices. Research nurses will conduct the audit.

4. Fidelity form – This is to monitor quality of implementation of the intervention and fieldwork by research nurses. It focuses on materials given to participating clinic and the audit process. Supervisors will administer this via telephone interview.

5. Value of survey – this is a self-administered tool, to be hand delivered to the clinic practitioner and collected back by research nurses within 2 days.

6. Dial thermometer for reading of internal refrigerator temperature. Verification of thermometers used in the research will be done by comparing the reading of research nurse thermometers with the thermometers in the Ministry of Health refrigerators used in vaccine storage. Research nurses will do this before each field visit.

Pretest

The audit form (checklist) will be pre-tested in private pediatrician clinics not included in the study sample. Following the pre-test, the audit form will be revised and modified.

Plan for data analysis & interpretation

We will analyze clinic vaccine storage practice in terms of fulfilling either all six criteria, or the minimum four criteria. In addition, we plan to compare results of clinic vaccine refrigerators with and without drugs and/or reagents stored together. Also, each criterion will be analyzed singly.

Analyses will at clinic level, and applied to only all refrigerators storing vaccines. Clinic performance will be deemed adequate only if all clinic refrigerators storing vaccines passed the audit. *Dummy tables (only selected tables reproduced)*

Table X: Characteristics of staff working in clinics by state

Characteristic		Overall (n=872) (total clinics=218)		Region I (n=431) (total clinics=108)		Region II (n=441) (total clinics=110)	
		Count	%	Count	%	Count	%
Duration of working experience in clinic	< 2 yrs						
	2 to < 5 yrs						
	5 to < 9 yrs						
	10 to < 15 yrs						
	> = 15 yrs						
	Not available						
Highest Qualification	Less than Form 3						
	Form 3						
	Form 5						
	STPM/Dipl./Mat*						
	SRN						
	Degree/Bachelor						
	NA						
Personally handling vaccines in the clinic	Yes						
	No						
	NA						
Prior training on vaccine storage among all staff	Yes						
	No						
	NA						
Prior training on vaccine storage among staff handling vaccines	Yes						
	No						
	NA						

Note: * STPM/Diploma/Matriculation

Table X: Comparison of six essential criteria for baseline and first post-intervention audit (to repeat this table for each region)

	Essential Criteria	Total (n)	Overall				
			Baseline Audit (A1)		Post-Intervention Audit (A2)		P Value (using 2- dependent proportions test)
			Count	%	Count	%	
Criterion #1	Two door/top loading refrigerator						
Criterion #2	Dedicated refrigerator for vaccine						
Criterion #3	Placement of refrigerator						
Criterion #4	Placement of vaccine						
Criterion #5	Temperature between 2-8 ºC						
Criterion #6	Monitor temperature						
Criterion #2d	Vaccine & drugs@						
Compliance	Fulfilled all 6 criteria#						
	Fulfilled all 6 criteria & drug@						
	Fulfilled all 5 criteria**						
	Fulfilled all 5 criteria & drug@						
Compliance	Fulfilled all 4 criteria+						
	Fulfilled all 4 criteria & drug@						

Note: @ This allowed the refrigerator to also store drugs together with vaccines.
This consisted of criterion # 1 to #6
** The type of refrigerator was excluded from the criterion list.
+ The placement of refrigerator was excluded from the criterion list.

Project management
Proposed Work Plan

Activities	Responsible Personnel	April 2007	May 2007	June 2007	July 2007	Aug2007	Sept 2007	Oct 2007	Nov 2007	Dec 2007	July 2008	Aug2008	Sept2008	Oct 2009
Finalise Draft Research Proposal	Researchers	X	X											
Identifying personnel involved in data collection	Researchers			X										
Develop intervention package	Researchers		X	X										
Pretest & refining instruments	Researchers			X										
Recruitment of research nurses (data collectors	Researchers & designated staff			X										
Training of research nurses	Researchers				X									
Audit 1	Research nurses				X									
Audit 2	Research nurses					X								
Data analysis	Researchers						X	X	X		X	X		
Interim report –draft	Researchers						X	X	X					
Executive Summary and policy brief	Researchers							X	X					
Audit 3	Research nurses							X						
Dissemination of findings – interim report	Researchers								X	X			X	X
Audit 4	Research nurses										X			
Final report	Researchers											X	X	
Executive Summary and policy brief	Researchers											X	X	
Dissemination of findings	Researchers												X	X

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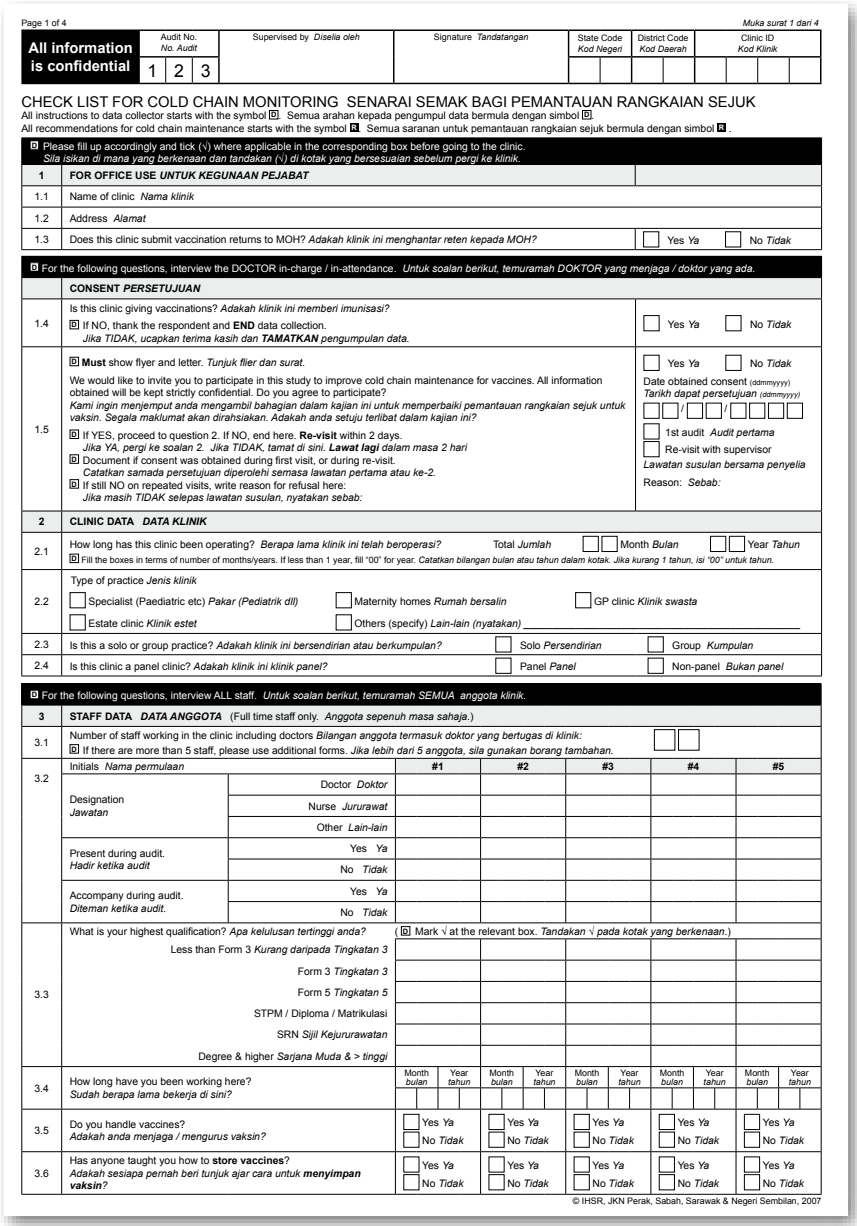
APPENDICES

APPENDIX A: This shows the final revised checklist (post preliminary data analysis after the second audit). *Only the first page reproduced.*



Page 1 of 4 — *Muka surat 1 dari 4*

All information is confidential	Audit No. *No. Audit*	Supervised by *Diselia oleh*	Signature *Tandatangan*	State Code *Kod Negeri*	District Code *Kod Daerah*	Clinic ID *Kod Klinik*
	1 2 3					

CHECK LIST FOR COLD CHAIN MONITORING SENARAI SEMAK BAGI PEMANTAUAN RANGKAIAN SEJUK

All instructions to data collector starts with the symbol D. Semua arahan kepada pengumpul data bermula dengan simbol D.
All recommendations for cold chain maintenance starts with the symbol R. Semua saranan untuk pemantauan rangkaian sejuk bermula dengan simbol R.

D Please fill up accordingly and tick (√) where applicable in the corresponding box before going to the clinic.
Sila isikan di mana yang berkenaan dan tandakan (√) di kotak yang bersesuaian sebelum pergi ke klinik.

1	**FOR OFFICE USE *UNTUK KEGUNAAN PEJABAT***	
1.1	Name of clinic *Nama klinik*	
1.2	Address *Alamat*	
1.3	Does this clinic submit vaccination returns to MOH? *Adakah klinik ini menghantar reten kepada MOH?*	☐ Yes *Ya* ☐ No *Tidak*

D For the following questions, interview the DOCTOR in-charge / in-attendance. *Untuk soalan berikut, temuramah DOKTOR yang menjaga / doktor yang ada.*

	CONSENT *PERSETUJUAN*	
1.4	Is this clinic giving vaccinations? *Adakah klinik ini memberi imunisasi?* D If NO, thank the respondent and **END** data collection. *Jika TIDAK, ucapkan terima kasih dan **TAMATKAN** pengumpulan data.*	☐ Yes *Ya* ☐ No *Tidak*
1.5	D **Must** show flyer and letter. *Tunjuk flier dan surat.* We would like to invite you to participate in this study to improve cold chain maintenance for vaccines. All information obtained will be kept strictly confidential. Do you agree to participate? *Kami ingin menjemput anda mengambil bahagian dalam kajian ini untuk memperbaiki pemantauan rangkaian sejuk untuk vaksin. Segala maklumat akan dirahsiakan. Adakah anda setuju terlibat dalam kajian ini?* D If YES, proceed to question 2. If NO, end here. **Re-visit** within 2 days. *Jika YA, pergi ke soalan 2. Jika TIDAK, tamat di sini. **Lawat lagi** dalam masa 2 hari* D Document if consent was obtained during first visit, or during re-visit. *Catatkan samada persetujuan diperolehi semasa lawatan pertama atau ke-2.* D If still NO on repeated visits, write reason for refusal here: *Jika masih TIDAK selepas lawatan susulan, nyatakan sebab:*	☐ Yes *Ya* ☐ No *Tidak* Date obtained consent (ddmmyyyy) *Tarikh dapat persetujuan (ddmmyyyy)* ☐☐/☐☐/☐☐☐☐ ☐ 1st audit *Audit pertama* ☐ Re-visit with supervisor *Lawatan susulan bersama penyelia* Reason: *Sebab:*
2	**CLINIC DATA *DATA KLINIK***	
2.1	How long has this clinic been operating? *Berapa lama klinik ini telah beroperasi?* Total *Jumlah* ☐☐ Month *Bulan* ☐☐ Year *Tahun* D Fill the boxes in terms of number of months/years. If less than 1 year, fill "00" for year. *Catatkan bilangan bulan atau tahun dalam kotak. Jika kurang 1 tahun, isi "00" untuk tahun.*	
2.2	Type of practice *Jenis klinik* ☐ Specialist (Paediatric etc) *Pakar (Pediatrik dll)* ☐ Maternity homes *Rumah bersalin* ☐ GP clinic *Klinik swasta* ☐ Estate clinic *Klinik estet* ☐ Others (specify) *Lain-lain (nyatakan)* _____	
2.3	Is this a solo or group practice? *Adakah klinik ini bersendirian atau berkumpulan?*	☐ Solo *Persendirian* ☐ Group *Kumpulan*
2.4	Is this clinic a panel clinic? *Adakah klinik ini klinik panel?*	☐ Panel *Panel* ☐ Non-panel *Bukan panel*

D For the following questions, interview ALL staff. *Untuk soalan berikut, temuramah SEMUA anggota klinik.*

3	**STAFF DATA *DATA ANGGOTA*** (Full time staff only. *Anggota sepenuh masa sahaja.*)						
3.1	Number of staff working in the clinic including doctors *Bilangan anggota termasuk doktor yang bertugas di klinik:* ☐☐ D If there are more than 5 staff, please use additional forms. *Jika lebih dari 5 anggota, sila gunakan borang tambahan.*						
3.2	Initials *Nama permulaan*		#1	#2	#3	#4	#5
	Designation *Jawatan*	Doctor *Doktor*					
		Nurse *Jururawat*					
		Other *Lain-lain*					
	Present during audit. *Hadir ketika audit*	Yes *Ya*					
		No *Tidak*					
	Accompany during audit. *Diteman ketika audit.*	Yes *Ya*					
		No *Tidak*					
3.3	What is your highest qualification? *Apa kelulusan tertinggi anda?*		(D Mark √ at the relevant box. *Tandakan √ pada kotak yang berkenaan.*)				
		Less than Form 3 *Kurang daripada Tingkatan 3*					
		Form 3 *Tingkatan 3*					
		Form 5 *Tingkatan 5*					
		STPM / Diploma / Matrikulasi					
		SRN *Sijil Kejururawatan*					
		Degree & higher *Sarjana Muda & > tinggi*					
3.4	How long have you been working here? *Sudah berapa lama bekerja di sini?*		Month *bulan* / Year *tahun*	Month *bulan* / Year *tahun*	Month *bulan* / Year *tahun*	Month *bulan* / Year *tahun*	Month *bulan* / Year *tahun*
3.5	Do you handle vaccines? *Adakah anda menjaga / mengurus vaksin?*		☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*
3.6	Has anyone taught you how to **store vaccines**? *Adakah sesiapa pernah beri tunjuk ajar cara untuk **menyimpan vaksin**?*		☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*	☐ Yes *Ya* ☐ No *Tidak*

Summarized version of proposal: **Vaccine Storage in Private Practice.** *Only selected and/or a small part of appendices are reproduced. Used with permission from authors.*

APPENDIX B: Fidelity Test Form

COLD CHAIN SURVEY 2007-2008 – FIDELITY OF INTERVENTION

(To be administered by supervisors via telephone calls to every third clinic [#3, #9, #12, etc…] that consented to be audited)

State Code		District Code		Clinic ID			

Research Nurse	
Supervisor	

1.1	Name of clinic:
1.2	Address:
1.3	Initials of Staff accompanying the audit:

Standard Phone Introduction

(Ask for nurse or doctor who was interviewed by the KKM staff in study. Make sure you interview the person accompanying the audit. See initials in Q1.3. Please ask for hand phone of staff accompanying, if the person is not there when you called)

I am calling regarding he Cold Chain Survey that my nurse conducted in your clinic yesterday. I would like to ask you some questions that will help me determine the quality of her work. This will only take 3-5 minutes.

Section A: Delivery of Intervention Package

(Focus on the items given and not the content/knowledge of staff)

What did my nurse give you? *

No.	Items	Yes	No
1.	Cold Chain Survey Flier		
2.	Sticker (Open me only when necessary)		
3.	6 Essential Messages (laminated card for Refrigerator)		
4.	Temperature Monitoring Chart		
5.	WHO Booklet on Safe Vaccine Handling		
6.	PowerPoint Presentation CD-ROM (English Version)		
7.	PowerPoint Presentation CD-ROM (Malay Version)		
8.	Dial thermometer		

(Once they have completed their listing, then ask about the remainder items above)*

Section B: Delivery Verification of Audit

I would now like to ask you about the audit process.

No.	Items	Yes	No
1.	Did my nurse give you a copy of the audit results? (blue copy)		
2.	Did she show you how to use a temperature-monitoring chart?		
3.	Did she measure how far your refrigerator was from the **side**?		
4.	Did she measure how far your refrigerator was from the **top**?		
5.	Did she tell you what you should and should not keep in your vaccine refrigerator?		
6.	Did she tell you at what temperature vaccines should be stored?		
7.	Did my nurse give feedback to your doctor about the audit?		

Thank you for your time. We appreciate all your help in this study.

DIFFERENT TERMS USED IN RESEARCH

- Research is a quest for information through scientific investigation/ experimentation.
- It often aims to solve problems or discover new information.
- Research method is a systematic way to carry out investigation or experimentation. All different forms of research use the same basic research method.
- Research can be divided into basic and applied research.
    - Basic research involves a search for new information, usually laboratory in nature. Often theoretical and does not seek to solve problems.
    - Applied research aims to provide a solution(s) for an existing health problem.
- The following are common terms used to describe various forms of research:
    - systematic reviews (including meta analysis).
    - experimental research (including clinical trials).
    - health systems/services research.
    - clinical audits.
    - quality assurance studies.
- All these forms use basic research methodology. They all formulate a research question and attempt to find a solution to health problems.
- The difference between them could be in terms of scope and focus. For example,
    - systematic review uses completed studies to reach an evidence-based opinion.
    - experimental research attempts to show the value of interventions.
    - health systems research emphasises on a systems approach.
    - clinical audits evaluate services provided with a view for improvement.
    - QA has a cycle which encourages re-evaluation.

UNIFORM REQUIREMENTS

This was extracted in part from "Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication" at http://www.nlm.nih.gov/bsd/uniform_requirements.html.

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9. The National Medical Research Registry (NMRR) at https://www.nmrr.gov.my/

10. The TREND statement: Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) group is a 22-item checklist specifically developed to improve the reporting standards of nonrandomized evaluations of behavioral and public health interventions. Useful to use this to plan research studies. http://www.trend-statement.org/asp/documents/statements/AJPH_Mar2004_Trendstatement.pdf

11. The CONSORT statement: Consolidated Standards Of Reporting Trials (CONSORT) statement developed for randomized controlled trials. Useful to use this to plan research studies. http://www.consort-statement.org/index.aspx?o=1011

12. The STARD statement: Standards for Reporting of Diagnostic Accuracy to improve the reporting the quality of reporting of studies of diagnostic accuracy. The statement consists of a checklist of 25 items and flow diagram that authors can use to ensure that all relevant information is present. http://www.clinchem.org/cgi/content/full/49/1/7.

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