NATIONAL CAPACITY BUILDING WORKSHOP ON OPERATIONAL RESEARCH IN HIV/AIDS

28 – 30, March 2019
Negombo – Sri Lanka

RESOURCE BOOK

Jointly organized by

National STD/AIDS Control Programme (NSACP), Sri Lanka

&

The Voluntary Health Services (VHS), India

Supported by **Centers for Disease Control and Prevention (CDC/DGHT-India)**

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

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on
Operational Research in HIV/AIDS

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VHS-CDC Project

The Voluntary Health Services (VHS), India
Supported by Centers for Disease Control and Prevention (CDC/DGHT-India)
T.T.T.I. Post, Rajiv Gandhi Salai,
Taramani, Chennai – 600 113, Tamil Nadu, INDIA.
Ph.: +91-44-22541965 | Email: vhs.cdcproject@gmail.com

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Book Title	:	**Resource Book on National Capacity Building Workshop on Operational Research in HIV/AIDS.**
No. of pages	:	**195 pages including wrapper pages**
Year of Publication	:	**March 2019**
Technical Guidance & Mentoring team	:	**Dr Joseph D Williams, Director Projects, VHS** **Dr Ariyaratne Manathunge, Consultant-Venereologist, SIMU, NSACP**
Team of Authors	:	**Dr T Ilanchezhian, Senior Technical Advisor, VHS-CDC Project** **Dr Yujwal Raj, Technical Advisor (SI), VHS-CDC Project**
Compiled & designed by	:	**Ms T Sudha, Senior Programme Associate, VHS-CDC Project**
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Contents

Foreword

Dr Joseph D Williams,
Director Projects,
The Voluntary Health Services (VHS),
Chennai/INDIA.

VHS-CDC project with the support of CDC/DGHT-India and in partnership with NSACP, Govt. of Sri Lanka providing Technical Assistance to NSACP on Strategic Information through a technical partnership initiative on the following areas:

1. Enhance SIM Unit capacity to utilize electronic and manual program data for decision making
2. Improve capacity of SIM Unit to carryout management, analysis, documentation, and dissemination of summary program data reports
3. Improve capacity of SIM Unit to conduct and disseminate results of operational research
4. Consultation with stakeholders on monitoring and documentation of accomplishments and sustainability plans

As a part of this technical cooperation initiatives, VHS-CDC project is in the process of providing capacity building initiatives, system strengthening, documentation and dissemination, etc. In accordance with the capacity building initiatives, the project is planning to organize series of training programs. The project with the partnership of NSACP is organizing a *'National Capacity Building Workshop on Operational Research in HIV/AIDS'* with the objective to enhance the capacity of the NSACP SI teams in Operational Research methods to support and strengthen programmatic decision making. To support this training, the project has developed resource materials including hand-outs, tools, formats and reference materials. To complement, the project is pleased to bring out this Resource Book titled *'National Capacity Building Workshop on Operational Research in HIV/AIDS'*. This Resource Book will be useful for participants to use as a reference material, obtain additional information beyond the training programs and complement the information presented as a part of the training program. These resource materials are collected and consolidated for immediate reference.

We thank Dr. Rasanjalee Hettiarachchi, Director-NSACP for her leadership and supportive guidance in this technical cooperation initiatives and in conducting this training program.

Our special thanks to Dr. G. Weerasinghe, Consultant – Venereologist, NSACP for his support and guidance extended for this training program.

We wish to acknowledge and thank Dr. Ariyaratne Manathunge, Consultant-Venereologist and Coordinator-SIMU, NSACP for his strenuous support, strategic guidance and cooperation being extended in evolving and executing this technical cooperation initiatives. Acknowledge the support extended by SIMU team, senior consultants in NSACP, SI team in peripheral STD clinics and key stakeholders.

We sincerely thank and acknowledge the technical guidance and support being extended by Dr. Timothy Holtz, Director, Mr. Lokesh Upadhyaya, Associate Director for Management and Operations, Ms. Srilatha Sivalenka, Public Health Specialist, CDC-DGHT/INDIA and CDC team.

We would like to thank Dr. T. Ilanchezhian, Senior Technical Advisor - VHS and Dr. Yujwal Raj, Technical Advisor (SI) – VHS-CDC project for their systematic support and inputs in developing & bringing out this Resource Book and contribution for conducting this training program.

We wish to acknowledge Dr Niranjan Saggurti, Director, Population Council and Dr Madhusudana Battala, Senior Program Officer, Population Council, Consultants, VHS-CDC project for contributing and extending support in conducting training sessions.

We thank Ms. T. Sudha, Senior Programme Associate – VHS for her support in documentation and in the preparation and designing of this document. And also we thank Mr. Sathyaraju, Associate Manager - Finance and admin team for their support in this initiative.

We greatly appreciate the fullest cooperation extended by NSACP and SIMU team in this technical cooperation initiatives and in conducting this training program.

Dr Joseph D Williams,
Director Projects,
The Voluntary Health Services (VHS),
Chennai.

Acronyms

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral Treatment
CDC	Centers for Disease Control and Prevention
EPI Unit	Epidemiology Unit
FGD	Focus Group Discussion
FSW	Female Sex Worker
HIV	Human Immunodeficiency Virus
IDI	In-Depth Interviews
M&E	Monitoring and Evaluation
MSM	Men who have Sex with Men
NSACP	National STD/AIDS Control Programme
OR	Operational Research
PEPFAR	President's Emergency Plan for AIDS Relief
PHI	Public Health Inspector
PHLT	Public Health Laboratory Technician
PHNS	Public Health Nursing Sister
PLHIV	People Living with Human Immunodeficiency Virus
STD	Sexually Transmitted Diseases
STI	Sexually Transmitted Infections
SI	Strategic Information
SIMU	Strategic Information Management Unit
TA	Technical Assistance
VHS	Voluntary Health Services

NATIONAL CAPACITY BUILDING WORKSHOP ON OPERATIONAL RESEARCH IN HIV/AIDS

Organized by
National STD/AIDS Control Programme (NSACP), Sri Lanka
&
The Voluntary Health Services (VHS), India
Supported by **Centers for Disease Control and Prevention (CDC/DGHT-India)**
(VHS-CDC Project)

AGENDA

OBJECTIVES:

To enhance the capacity of the NSACP SI teams in Operational Research methods to support and strengthen programmatic decision making.

OUTCOMES:

1. Built the knowledge & skills of NSACP programme managers in designing, planning & execution of Operational Research in identified priority area.
2. Identified the Operational Research titles for undertaking research studies for strengthening programmatic decisions.
3. Developed draft research protocols on the identified priority areas for Operational Research.
4. Evolved research plan for follow up and implementation of OR studies, after the workshop (supported with mentorship plan).
5. Established network of trained personnel on Operational Research for exchanging experiences.

FACILITATORS:

Core Facilitators – VHS-CDC Project Consultants	**Facilitators**
• Dr Niranjan Saggurti, Director, Population Council, New Delhi • Dr Yujwal Raj, Epidemiologist & Public Health Management Specialist-Technical Advisor (SI), VHS-CDC Project • Dr Madhusudana Battala, Senior Program Officer, Population Council, New Delhi	• Dr Ariyaratne Manathunge, Consultant-Venereologist, NSACP • Ms. Srilatha Sivalenka, Public Health Specialist, CDC • Dr Joseph D Williams, Director Projects, VHS • Dr T Ilanchezhian, Senior Technical Advisor, VHS-CDC Project • Mr Suneel Kumar Chevvu, M&E Officer, VHS-CDC Project

Time	Session	Session Type	Details	Facilitator
	DAY 1 – 28/03/2019 (Thursday)			
0830 – 0900	Registration			
0900 – 0945	Inauguration		Welcome address Inaugural address Introduction of participants Objectives of the workshop Methodologies Expected outcomes Activities during and post workshop	Dr Ariyaratne Manathunge Dr Joseph D Williams Dr T Ilanchezhian
0945 – 1030	Setting the Ground	Presentation Interaction	• Need and importance of Operational Research • Need for OR in NSACP - Summary of feedback from previous reviews & prog feedback • Expectations of participants, finalization of the agenda and developing ground rules for conducting the workshop • Using the workshop learnings for programmatic purposes	Dr Joseph D Williams Dr Ariyaratne Manathunge Dr T Ilanchezhian Participants
1030 – 1130	Understanding the research problem	Facilitated Discussion	A brief unstructured talk by the teams on the identified programmatic issues	Team Leaders/Participants
1130 – 1145	Break			
1145 – 1300	Framing the research questions & objectives	Presentation Exercise	Exercise on writing research questions	Dr Yujwal Raj
1300 – 1400	Lunch			
1400 – 1500	Types of Research - Identifying appropriate approach to answer the research questions	Presentation Facilitated Discussion	Introduction to various types of research; Primary vs Secondary; Quantitative & Qualitative; Epidemiological, Behavioural & Operational research, etc. and their application; Steps involved in undertaking research;	Dr Yujwal Raj
1500 – 1530	Elements of Research Protocol	Presentation & Discussion	Structure of Research Protocol	Dr Madhusudana Battala

Time	Session	Session Type	Details	Facilitator
1530 – 1730	Group Work 1 – Protocol Writing Part 1	Group Work	Writing background, research problem, questions & objectives	All Facilitators
	DAY 2 – 29/03/2019 (Friday)			
0900 – 0930	Recap of Day 1			Dr Ariyaratne Manathunge Dr T Ilanchezhian Dr Yujwal Raj
0930 – 1000	What is Operational Research?	Presentation	Overview & Approaches	Dr Yujwal Raj
1000 – 1130	Quantitative Research Methods & Sampling Designs	Presentation & Interaction	Study designs, data collection methods, sample size & sampling plan	Dr Niranjan Saggurti
1130 – 1145	Break			
1145 – 1315	Qualitative Research Methods & Sampling Designs	Presentation & Interaction	Study designs, data collection methods, sample size & sampling plan	Dr Madhusudana Battala
1315 – 1415	Lunch			
1415 – 1530	Study Tools – Principles of design	Review of tools	Types of tools, design considerations	Dr Yujwal Raj Mr Suneel Kumar
1530 – 1730	Group Work 2 – Protocol Writing Part 2	Group Work	Writing the methodology & overview of tools	All Facilitators
	DAY 3 – 30/03/2019 (Saturday)			
0900 – 0930	Recap of Day 2			Dr Ariyaratne Manathunge Dr T Ilanchezhian Dr Yujwal Raj Mr. Suneel Kumar
0930 – 1030	Data Management & Analysis Plan	Presentation	Indicators & Tabulation plan, Data recording, entry, cleaning, adjustments, analysis, weights, presentation	Dr Niranjan Saggurti
1030 – 1130	Research Project Management	Presentation & Interaction	Field planning, HR planning, Logistics, Monitoring & Supervision, Timelines, Budget planning	Dr Yujwal Raj
1130 – 1145	Break			
1145 – 1230	Ethics in HIV/AIDS Research	Presentation	Principles of Ethics, Vulnerable Groups, Informed Consent, Data Confidentiality, Respondent protection, reporting	Dr Madhusudana Battala

Time	Session	Session Type	Details	Facilitator
1230 – 1300	Scientific Writing	Review of various formats	Preparation of Study reports, scientific papers, abstracts & publications	Dr Niranjan Saggurti Dr Yujwal Raj
1300 – 1345	Lunch			
1345 – 1500	Group Work 3 – Protocol Writing Part 3	Group Work	Writing the data management plan, PM plan & ethical considerations	All Facilitators
1530 – 1700	Team Presentations of OR Study Protocol			
1700 – 1730	Next Steps		Role of various stakeholders; Mentors & Mentoring Plan; Timelines; Abstract development;	Dr Yujwal Raj
1730-1800	Valedictory Function		Certificate Distribution; Post-training Assessment	

Coordination and Logistics Support (VHS-CDC Project) Team:

Documentation	Ms. T. Sudha, Senior Programme Associate, VHS-CDC Project
Logistics Support & Finance	Mr. S. Sathyaraju, Associate Manager – Finance, VHS-CDC Project

REFERENCE MATERIALS

National Capacity Building Workshop on Operational Research in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Objective

To enhance the capacity of the NSACP SI teams in Operational Research methods to support and strengthen programmatic decision making.

Outcomes

- Built the knowledge & skills of the NSACP programme managers in designing, planning & execution of Operational Research in identified priority area
- Identified the Operational Research titles for undertaking research studies for strengthening programmatic decisions
- Developed draft research protocols on the identified priority areas for Operational Research
- Evolved research plan for follow up and implementation of OR studies, after the workshop (supported with mentorship plan)
- Established network of trained personnel on Operational Research for exchanging experiences

Facilitators

- Dr Niranjan Saggurti, Director, Population Council and Consultant, VHS-CDC Project.
- Dr Yujwal Raj, Epidemiologist & Public Health Management Specialist and Technical Advisor (SI) – VHS-CDC Project.
- Dr Madhusudana Battala, Senior Programme Officer, Population Council and Consultant, VHS-CDC Project.

Workshop Approach

- Three days of active learning
- Learning by doing approach
- Presentations, Discussions, Interactive Sessions, Group Works & Presentations by the Participants
- Identification of priority topics relevant to the current HIV/AIDS programme in Sri Lanka
- Real time development of research protocols on identified topics, during the workshop
- Experienced Facilitators to guide and hand hold the participants
- Residential programme, to ensure complete focus

Feedback from TNA

Programmatic areas that need improvements

- HIV testing among drug users
- STI prevention and sexual and reproductive health education among school children
- Health education and HIV testing among school leavers out of school students
- Programmes directed at children & youth
- Epidemic tracking using programme data
- Effective ways of analysing & presenting data, incl. infographics
- Easier & efficient ways of finding data errors – DQA
- Ability to frame goals & objectives to develop a comprehensive annual, mid term & long-term action plans for programme
- Database management, cross-sectional & longitudinal analysis

Feedback from TNA

Specific areas of learning/ Expectations from the Workshop

- Data analysis using softwares – SPSS, etc.
- Sample size calculation & sampling
- Research proposal and paper writing
- Informative ways of presenting data
- Research designs
- Questionnaire or tool preparation
- Research planning & practical issues when engaging in research
- Qualitative data analysis
- Publications
- Supports available for research
- GIS

Sessions Overview – Day 1

- Operational Research – Need & Importance
- Discussing the priority issues under NSACP
- Framing research questions
- Types of Research
- Steps involved in undertaking research
- Structure of research protocol

Exercises / Group Works

- Framing research questions for the identified topics
- Group Work 1 – Protocol Writing Part 1 - Writing background, research problem, questions & objectives

Sessions Overview – Day 2

- Operational Research - overview and approaches
- Quantitative Research Methods & Sampling Designs
- Qualitative Research Methods & Sampling Designs
- Study Tools – Principles of design

Exercises/Group Works

- Group Work 2 – Protocol Writing Part 2 - Writing the methodology & overview of tools

Sessions Overview – Day 3

- Data Management & Analysis Plan
- Research Project Management
- Ethics in HIV/AIDS Research
- Scientific Writing
- Next Steps
- Team Presentations of OR Study Protocols

Exercises/Group Works

- Group Work 3 – Protocol Writing Part 3 - Writing the data management plan, project management plan & ethical considerations, timelines & budgets

Ground Rules for the Workshop

- Timely reporting
- Active Participation in the sessions
- Mobile on the silent mode
- Contribute productively to the team works
- Feel free to seek clarifications
- Avoid arguments & side talks
- Respect others' point of views
- Handover the group work papers to the facilitators
- Consistent effort to develop the draft protocol by the end of the workshop
- Interact with the facilitators informally during the breaks
- Any Other???

Guidance for forming groups

- Will identify and narrow down on six priority topics for OR, that are of immediate need under NSACP
- Participants may select one topic out of the six, on which they have some experience and interest to take it up further
- However, if there is uneven distribution of participants, the decision of facilitators may be respected
- Based on this, the participants will be divided into 6 groups of 4-5 members each
- Each group selects its team leader
- Group starts gathering information, material, data etc. related to their selected topic for the group works
- Teams can give feedback & inputs to other groups as well during the group works & discussions

Guidance for identifying priority topics for OR

- Carry out a free listing of topics/ issues as identified & reported by participants
- Categorise them by programme areas – STI, Testing, Treatment, Care & Support to PLHIV, KP Prevention, PMTCT, Lab, IEC, SI, Admin & Finance
- Review the topics – Eliminate overlaps – Merge wherever apt – Break where the topic is heavy or complex
- Narrow down on a short list of topics under each prog area
- Apply prioritisation technique to identify the most important one in each area
- Then, reapply prioritisation at overall level to come out with six key OR topics

Things we expect with you

- Notepads & pens
- Laptops
- Sample data of one or a few months from your centres or on the topic of interest
- Full attention
- Critical thinking
- Active participation
- Timely completion of group works

Role of Mentors/ Facilitators

- Adhere to the schedule in facilitating the sessions
- Create & sustain interest of participants
- Make the sessions interactive & participatory
- Maintain a pace that is appropriate for the participants
- Provide opportunity to ask questions and seek clarifications
- Give adequate time, either in group or in person, to clarify the questions asked
- Guide the teams in group works & hands-on sessions
- Review the content developed by the groups & give feedback
- Facilitate coordination b/w different groups
- Focus on achieving productive outputs by the end of workshop

Need & Importance of Operational Research in HIV/AIDS

Dr Joseph D Williams,
Director Projects,
VHS, Chennai.

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Research & Service Provision

Research and service provision feed each other!

Need for OR

- To explore what needs to be done to address an issue
- To understand the facilitators and barriers for a service or system or issue; factors that matter for the problem & solution
- To test an approach or intervention, whether it works or not
- To study how a planned intervention or strategy is working
- To assess the reasons for success/ failure of an approach or intervention, in one place vs other, etc.
- To identify the mid-course corrections needed
- To gather the beneficiary & stakeholder perspectives, acceptance, engagement, empowerment, etc. due to an intervention

Case Scenario

- A health care worker 'P' works in a community health clinic. As part of her job, she conducts counseling sessions to women about a free screening test offered by the clinic that is proven to detect a specific disease. She gives information about the test, its importance and benefits. She encourages women to get the screening test.
- Another health care worker 'R' recruits women from the same community into a research to study the willingness to take the specific screening test. She recruits from those who attended the counseling session of 'P' as well as from those who didn't attend. She compares their preference & willingness for the taking the test.
- What are 'P' & 'R' doing? How do they complement each other?

Basic vs Applied Research

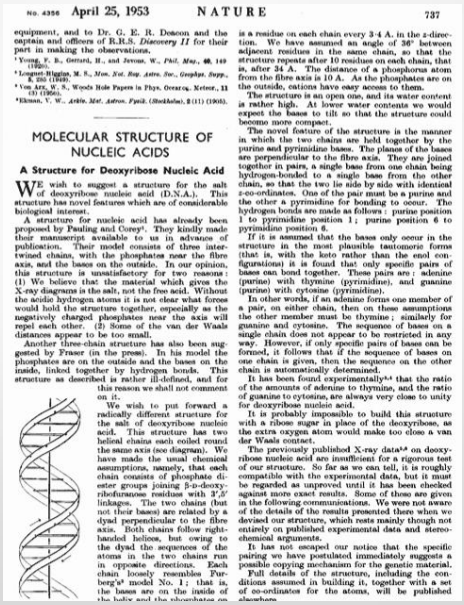
- Basic research is motivated by curiosity about the way the world works; interested in knowing the How & Why of the nature
- Applied research is motivated by desire to solve practical problems; interested in knowing the How & Why of the real life problems and the How & Why of solving them

Basic Research that changed the world

"We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological importance"

Watson JD, Crick FHC.

A structure for deoxyribose nucleic acid. Nature 1953; 171: 737-8



No. 4356 April 25, 1953 NATURE 737

equipment, and to Dr. G. E. R. Deacon and the captain and officers of R.R.S. *Discovery II* for their part in making the observations.

MOLECULAR STRUCTURE OF NUCLEIC ACIDS

A Structure for Deoxyribose Nucleic Acid

WE wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological interest.

A structure for nucleic acid has already been proposed by Pauling and Corey[1]. They kindly made their manuscript available to us in advance of publication. Their model consists of three intertwined chains, with the phosphates near the fibre axis, and the bases on the outside. In our opinion, this structure is unsatisfactory for two reasons: (1) We believe that the material which gives the X-ray diagrams is the salt, not the free acid. Without the acidic hydrogen atoms it is not clear what forces would hold the structure together, especially as the negatively charged phosphates near the axis will repel each other. (2) Some of the van der Waals distances appear to be too small.

Another three-chain structure has also been suggested by Fraser (in the press). In his model the phosphates are on the outside and the bases on the inside, linked together by hydrogen bonds. This structure as described is rather ill-defined, and for this reason we shall not comment on it.

We wish to put forward a radically different structure for the salt of deoxyribose nucleic acid. This structure has two helical chains each coiled round the same axis (see diagram). We have made the usual chemical assumptions, namely, that each chain consists of phosphate diester groups joining β-D-deoxyribofuranose residues with 3',5' linkages. The two chains (but not their bases) are related by a dyad perpendicular to the fibre axis. Both chains follow right-handed helices, but owing to the dyad the sequences of the atoms in the two chains run in opposite directions. Each chain loosely resembles Furberg's[2] model No. 1; that is, the bases are on the inside of the helix and the phosphates on is a residue on each chain every 3·4 A. in the z-direction. We have assumed an angle of 36° between adjacent residues in the same chain, so that the structure repeats after 10 residues on each chain, that is, after 34 A. The distance of a phosphorus atom from the fibre axis is 10 A. As the phosphates are on the outside, cations have easy access to them.

The structure is an open one, and its water content is rather high. At lower water contents we would expect the bases to tilt so that the structure could become more compact.

The novel feature of the structure is the manner in which the two chains are held together by the purine and pyrimidine bases. The planes of the bases are perpendicular to the fibre axis. They are joined together in pairs, a single base from one chain being hydrogen-bonded to a single base from the other chain, so that the two lie side by side with identical z-co-ordinates. One of the pair must be a purine and the other a pyrimidine for bonding to occur. The hydrogen bonds are made as follows: purine position 1 to pyrimidine position 1; purine position 6 to pyrimidine position 6.

If it is assumed that the bases only occur in the structure in the most plausible tautomeric forms (that is, with the keto rather than the enol configurations) it is found that only specific pairs of bases can bond together. These pairs are: adenine (purine) with thymine (pyrimidine), and guanine (purine) with cytosine (pyrimidine).

In other words, if an adenine forms one member of a pair, on either chain, then on these assumptions the other member must be thymine; similarly for guanine and cytosine. The sequence of bases on a single chain does not appear to be restricted in any way. However, if only specific pairs of bases can be formed, it follows that if the sequence of bases on one chain is given, then the sequence on the other chain is automatically determined.

It has been found experimentally[3,4] that the ratio of the amounts of adenine to thymine, and the ratio of guanine to cytosine, are always very close to unity for deoxyribose nucleic acid.

It is probably impossible to build this structure with a ribose sugar in place of the deoxyribose, as the extra oxygen atom would make too close a van der Waals contact.

The previously published X-ray data[5,6] on deoxyribose nucleic acid are insufficient for a rigorous test of our structure. So far as we can tell, it is roughly compatible with the experimental data, but it must be regarded as unproved until it has been checked against more exact results. Some of these are given in the following communications. We were not aware of the details of the results presented there when we devised our structure, which rests mainly through not entirely on published experimental data and stereochemical arguments.

It has not escaped our notice that the specific pairing we have postulated immediately suggests a possible copying mechanism for the genetic material.

Full details of the structure, including the conditions assumed in building it, together with a set of co-ordinates for the atoms, will be published elsewhere.

Operational Research that saved lives

- Think about the set of interventions we follow to reduce mother to child transmission of HIV.
- Think about the prevention messaging that we do to protect sexual partners from HIV transmission.
- Think about the service delivery models we have to reach out to the most vulnerable groups.

- What research must have taken place before these interventions were developed?

Operational Research in Health

- Application of scientific methods to decision making in complex real world problems which are concerned with coordination and execution of the operations within an organization
- Purpose is to generate knowledge to:
  - Improve health
  - Reduce disease
  - Prevent death
- Gives a scientific basis for making decisions about health services

Importance of Operational Research in HIV/AIDS Programming

- Diversity in the spread, patterns, drivers and factors of epidemic in various parts of the country
- Dealing with vulnerable & marginalised communities
- High levels of stigma & discrimination
- Not so confident knowledge about what works & what not
- Need to check intermittently, are we doing the right thing
- Constant need to innovate and improve the services
- Need to have dynamic programming for changing patterns
- National & Global commitments demand highly effective and efficient programming

Need for Operational Research in National STD/AIDS control programme

Dr Ariyaratne, K A Manathunge

Operational Research

- **"The use of systematic research techniques for program decision making to achieve a specific outcome." WHO**
- **Operational Research is the scientific study of operations for the purpose of making better decisions.**
- **As formal discipline operational Research originated by the efforts of military planner during World War II .**

"Any research producing practically usable knowledge (evidence , finding , information) which can improve program implementation (effectiveness , efficiency , quality , access , scale-up, sustainability) regardless the type of research (design, method, approach) falls within the boundaries of Operational Research."

Process of Operational Research

1. **Identification of program problem.**
2. **Identification of possible reasons and solutions .**
3. **Testing of potential solution.**
4. **Results utilization.**
5. **Results dissemination.**

What are the objectives of NSACP

1. **Prevention and control of new STI/HIV infections, ending AIDS by 2025**
2. **Provision of treatment care and services to people infected and affected by STIs and HIV**

What are the possible program problems which will affect the objective of our programme

- **Unless problem is clearly defined it is impossible to develop good solutions.**
- **“Right solution” can not be obtained from the “wrong problem.**
- **The first and most important stage of the work is defining the problem well.**

Need to brainstorm to identify good problems

- Examples
  - Underutilization of some STD clinics by key populations
  - Difficulty in initiating new approaches. E.g. PrEP,
  - Delay in getting some reports on time

Suggestion:

- **Write 1-2 problems by each participant**
- **Prioritize problems and proceed with developing 5-7 research proposals during these 3 days by group work**
- **Any other suggestions????**

Framing Objectives & Research Questions

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

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The Approach

Generic to Specific

Broad to Narrow

- Write Background & Context of the Issue under consideration
- Narrow down to the research area
- Specify the research problem
- Articulate the objectives of research
- Frame the research questions and/or hypotheses

Framing a good research title

- Not too long; Not too short
- Convey the subject area and the key question
- Consider a split title (e.g. "Treatment adherence among KP – Issues, Factors & Opportunities")
- Use catchy and highlighting words (Reaching the KP – A long way to go; STD/HIV Care in Sri Lanka – Unfinished agenda)
- My consider including a word on methodological aspect, if there is uniqueness or special value in the methods used (e.g. KAP relating to HIV/AIDS among youth in Sri Lanka – A multi-site cross-sectional study)
- Don't use less familiar words, confusing words, casual words & offending words or expressions

Writing the Background & Context

- Brief introduction to the subject (HIV/AIDS epidemic, prog response, intervention, etc)
- Narrow down to the research area
- Past & Current position of the issue – quote evidences from authentic publications (Papers, reports, articles, etc)
- Context for the study
- Rationale/ Justification of need for the study; How does the study contribute to the existing body of knowledge & to the ongoing efforts – Importance, Relevance, Usefulness
- Previous similar studies & their outcomes; Uniqueness of this study
- Referencing
- Brief & to the point; Not too elaborate;

Example

- Background & Context: HIV/AIDS in Sri Lanka; Rising HIV cases among MSM; Current interventions for MSM
- Research Area: Strategies to reach out to MSM with HIV prevention services; to understand what is working and what is not; outcomes, reasons for sub-optimal coverage, community perspective & mid-course corrections needed
- MSM Outreach Interventions to be studied, including the Drop-in-centre based approach
- Data on HIV among MSM from HSS/IBBS; Behavioural data among MSM; Prog data showing more cases among MSM; with references
- Rationale for the study – importance, relevance & usefulness

Specify the Research Problem

- No generics
- Specify the geographic area
- Specify the time period under consideration
- Specify the intervention or health service under study
- Specify the community/ beneficiaries/ clients that will be involved
- Specify the core area of study in 2-3 lines
- Crisp; Clear; Concise;
- Support with data wherever possible
- No theories; No assumptions; No vagueness;

Example Contd…

Research Problem

- The outreach interventions through the drop-in-centre and outreach workers could not reach out to a large number of MSM. Even among those who are reached, the uptake of prevention services such as condoms, HIV testing, STI care, etc. is not up to the mark. Overall coverage is low.
- Supporting evidence to show the above fact
- The reasons for the same to be studied in Colombo over the last one year.

Articulate the Objectives

- What you exactly want to achieve through the study? Where? In whom? When?
- If comparing, what/ who is compared to what/ whom?
- Simple short sentences
- Only one idea or enquiry per objective
- Not more than three objectives, in the order of priority
- May consider adding not more than two secondary objectives, that may or may not be achieved, depending on feasibility and primary outcomes

SMART Objectives

- Simple
- Measurable
- Actionable
- Relevant
- Timely

Problems with Objectives

- Too ambitious, too much work proposed
- Unfocused aims, unclear goals
- Limited aims and uncertain future directions

Questions to ask yourself about each Objective

- Is it too ambitious? Be realistic!
- Is it focused?
- Is it clear?
- Are there alternative approaches?
- Can the reader understand it?
- Are the statistical analyses appropriate?

Example Contd…

- Badly worded objectives:
  - To study the MSM interventions
  - To study the MSM interventions and their impact in Colombo
  - To understand the community perspectives
  - To identify the mid-course corrections
- Well framed objectives
  - To identify the factors responsible for low coverage of MSM outreach interventions in Colombo
  - To understand the MSM community perspectives towards outreach interventions
  - To identify mid-course corrections to improve the MSM outreach interventions

Other examples…

- Bad obj: To study treatment adherence among PLHIV
- Good obj: To determine the rate of adherence to ART among PLHIV at 12, 24 & 36 months of treatment initiation, at XX hospital, Colombo
- To identify the factors for adherence & non-adherence to ART among PLHIV
- Bad obj: To study the effect of alcohol on TB
- Good obj: To compare the TB conversion rates among those who take alcohol & those who don't
- Bad obj: To study the impact of STI services on HIV
- Good obj: To assess the impact of STI service uptake among key population on HIV prevalence among them, over the last five years in Colombo

Frame Research Questions

- To make the objective more specific in the form of a question
- May split one objective into one or two questions
- Most narrow and specific part of the research protocol
- No vagueness; No ambiguity; No detailing
- **Short – Simple – Specific – Focussed – Direct**

A Precise Research Question

GOOD	BAD
• Crystal clear	• Broad, Vague
• Razor sharp focus	• Descriptive
• Crisp language	• Poetic; Dragging;
• Limited word count	• >1 hypothesis
• Possible to answer with data	• Too ambitious to answer

Example Contd…

- To identify the factors responsible for low coverage of MSM outreach interventions in Colombo
  - What are the intervention-side factors responsible for low coverage of MSM outreach interventions in Colombo?
  - What are the community factors for the low uptake of prevention services among MSM in Colombo?
- To understand the MSM community perspectives towards outreach interventions
  - Do MSM in Colombo have awareness about the outreach interventions?
  - Do MSM value the outreach interventions for HIV prevention in Colombo?
- To identify mid-course corrections to improve the MSM outreach interventions
  - What specific mid-course corrections should be initiated to enhance the uptake of HIV prevention services by MSM in Colombo?

Hypothesis

- Statement of Fact that you intend to prove or disprove
- Research Questions or Hypothesis – one is preferred
- Research Questions mostly used in studies where you are exploring new knowledge
- Hypothesis mostly used in studies where you prove something

Exercise on Framing Objectives & Research Questions

- Each team is given one research problem, based on the topics identified for the workshop
- Discuss among the team members and narrow down the research area and the research problem
- Discuss and specify three objectives for the study
- Define the geographic area, time period, population groups, etc. for the objectives
- Write one or two research questions for each objective, to further break it down and give more clarity
- Use simple, short sentences with direct, explicit meaning
- Review, Revise & Refine them till you are satisfied
- Include them in the protocol in the evening group work

Introduction to Research & Types of Research Designs

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sr Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Participants: share with facilitator

- What are some words, images and concepts that come to your mind when you hear the word 'research'?
- Have you have ever conducted, or been part of research study?

Research defined

Common definition: a detailed study of a subject, especially in order to discover (new) information or reach a (new) understanding. (Cambridge Dictionary, 2003)

Technical definition: A systematic process of discovering new knowledge, involving application of the scientific method to make generalizable statements based upon specific inquiries

The Scientific Method

Scientific Method

Problem/Question

Observation

Formulate a Hypothesis

Experiment

Collect and Analyze Results

Conclusion

Communicate the Results

Research study design

- Like a recipe for a meal
  - Ingredients and instructions
- Spelled out in the protocol
- Must be followed precisely

Research study design

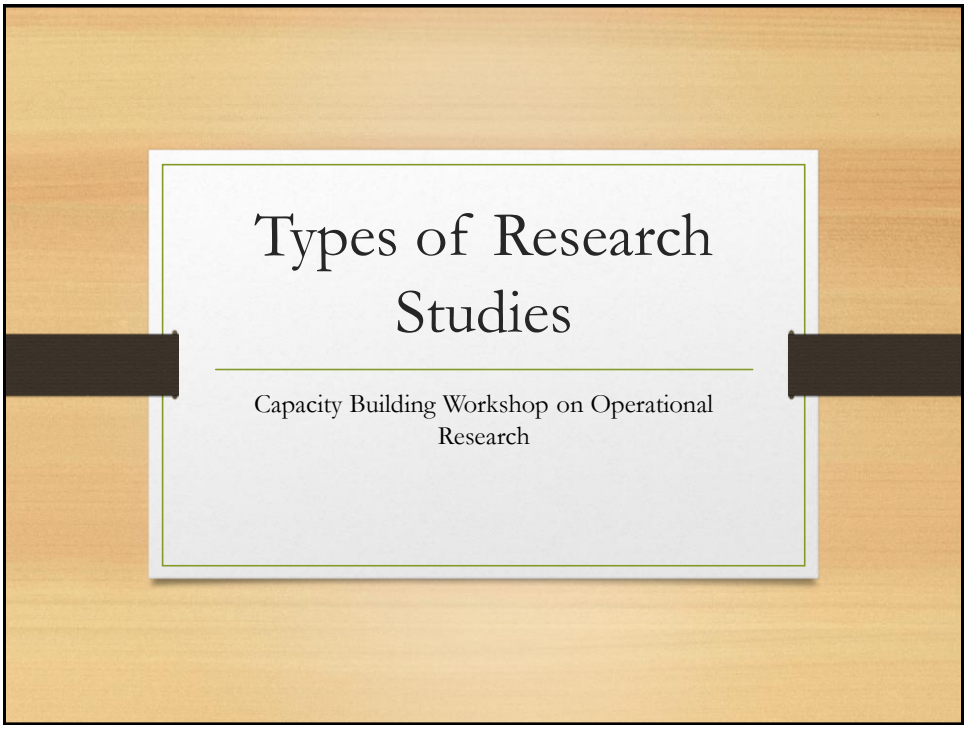
- Mostly depends on the study questions:

Does X cause Y?

How do I describe X and Y?

What is the relationship between X and Y?

- Also depends on:
  - Time and money available
  - Ease/difficulty in finding study participants



Criteria for Classification

- By nature of measurement – Quantitative, Qualitative, Semi-, Mixed
- By broad purpose & design – Exploratory/ Formative, Descriptive, Analytical, Experimental
- By specific purpose of programmes – Policy, Operational, Systems, Evaluation
- By subject area – Basic, Epidemiological, Social, Behavioural, Clinical, Genetic, Economic, etc.
- By site for data collection – Community-based, Facility-based
- By nature of data collection – Desk Research, Field Research

By Broad Purpose & Design

- Exploratory/ Formative – When nothing/ a little is known about the subject
- Observational – No intervention; Natural experiment
  - Descriptive – Generate hypothesis
  - Analytical – Test hypothesis
- Experimental – With intervention
  - RCT
  - Quasi-experimental

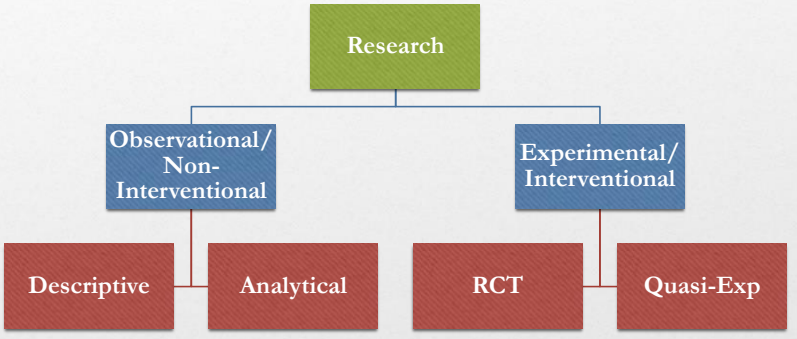
Quantitative vs Qualitative

Quantitative	Qualitative
General framework	**General framework**
• Seek to confirm hypotheses about phenomena • Instruments use more rigid style of eliciting and categorizing responses to questions • Use highly structured methods such as questionnaires and surveys	• Seek to explore phenomena • Instruments use more flexible, iterative style of eliciting and categorizing responses to questions • Use semi-structured methods such as in-depth interviews, focus groups, and participant observation
Analytical objectives	**Analytical objectives**
• To quantify variation • To predict causal relationships • To describe characteristics of a population	• To describe variation • To describe and explain relationships • To describe individual experiences • To describe group norms

Quantitative vs Qualitative

Quantitative	Qualitative
Question format	**Question format**
Closed-ended	Open-ended
Data format	**Data format**
• Numerical (obtained by assigning numerical values to responses)	• Textual (obtained from audiotapes, videotapes, and field notes)
Flexibility in study design	**Flexibility in study design**
• Study design is stable from beginning to end • Participant responses do not influence or determine how and which questions researchers ask next	• Some aspects of the study are flexible (for example, the addition, exclusion, or wording of particular interview questions) • Participant responses affect how and which questions researchers ask next
Software used: SPSS, STATA, SAS	**Software used:** Atlas-Ti, N-Vivo

By Broad Purpose & Design



By Broad Purpose & Design

- **Observational:** studies that do not involve any intervention or experiment
  - **Exploratory:** used when the state of knowledge about the phenomenon is poor. Examples: case-reports, case-series, ecological studies
  - **Descriptive:** used to formulate a certain hypothesis. Examples: cross-sectional studies
  - **Analytical:** used to test hypotheses. Examples: case-control, cohort, ecological
- **Experimental:** studies that entail **manipulation** of the study factor (exposure) and **randomization** of subjects to treatment (exposure) groups.

Observational vs Experimental

Observation (Natural Experiment)	Experiment
Nature affects the outcome	Researcher intervenes to affect the outcome.
Investigator measures only	Investigator intervenes & measures
Demonstrates association; may or may not imply causation	May prove causation
Ethical problem: Less. e.g. health hazards of Tsunami victims	Ethical problem: more e.g. Drug trial
Chance of Bias – more	Less – extraneous variables are relatively tightly controlled

Descriptive vs Analytical

Descriptive	Analytical
Describes the disease occurrence with general information	Explains the disease occurrence
Distribution of disease	Determinants of disease
More diffuse & superficial.	Narrow down to answer specific questions
No attempt to analyze the link between exposure and outcome	Exposure and outcome relationship is analyzed
Usually no hypothesis testing	Hypothesis testing usually done
Case reports, Case series	Cross-sectional, Case-control, Cohort

Case Reports and Series

- Case report: describes an observation in a single patient.
  - "I had a patient with a cold who drank lots of orange juice and got better. Therefore, orange juice may cure colds."
- Case series: same thing as a case report, only with more people in it.
  - "I had 10 patients with a cold who drank orange juice…."
- May generate a hypothesis: "maybe orange juice cures colds…."
- Weakness: cannot test the hypothesis
  - no control group
  - often too few people to make generalizations

Cross-sectional (Prevalence) Studies

- **Characteristics:** Snap-shot of a definite population at a particular point/period of time; Exposure and disease outcome are determined simultaneously for each subject. Example IBBA survey
- **Merits:** Feasible; quick; economic; allows study of several diseases/exposures; useful for estimation of the population burden, health planning and priority setting of health problems
- **Limitations:** Temporal ambiguity (cannot determine whether the exposure preceded outcome); not suitable for rare conditions
- **Effect measure:** Point prevalence, Association

Advantages and Disadvantages of Cross-Sectional Study

Advantages

- Quick, inexpensive.
- Can study several exposures & outcomes at one time.
- Provides prevalence information.
- May provide clues to hypothesis generation.

Disadvantages

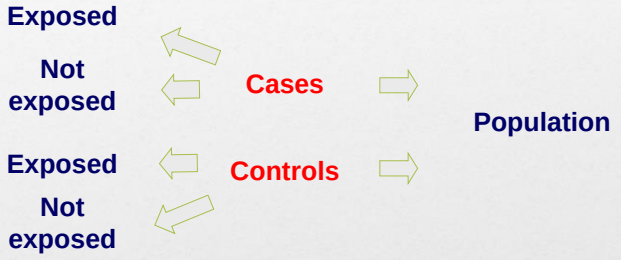
- Can't infer causality
- Prone to bias
- Not good for rare disease
- Not good for disease with short duration & high fatality

Case Control Studies

- Cases identified
- Controls selected – unmatched / matched
- Exposure history of Cases and Controls ascertained
- Frequency of exposure among Case's & Control's compared

Case-Control Studies (Retrospective studies)

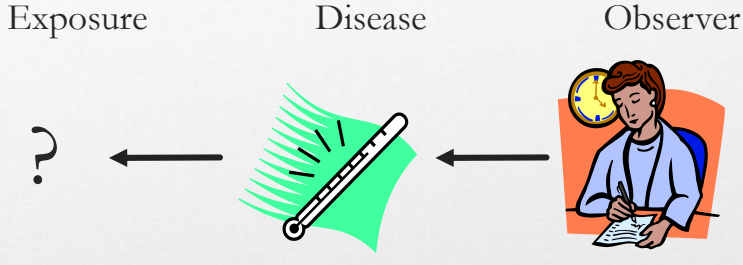
- **Characteristics**: retrospective studies; assumption that non-cases are representative of the source population of cases.



- **Effect measure:** Odds Ratio

E.g. A case–control study of HIV sero-conversion among health care workers after percutaneous exposure

Case Control Study



Choose groups with and without disease, look back at what different exposures they may have had

Advantages and Disadvantages of Case Control Study

Advantages:

- Quick, inexpensive, small sample size needed.
- Good for disease with long latent period.
- Can estimate multiple risk factors for a disease.

Disadvantages:

- Prone to recall bias.
- Can't measure incidence rate.
- Not good for rare exposure

Association Measure of CC Study : Odds Ratio (OR)

	Disease	No disease
Exposed	a	b
Unexposed	c	d

$$OR = \frac{a/b}{c/d} = \frac{ad}{bc}$$

Cohort Studies

- Cohort assembled (Prospectively / Retrospectively)
- Exposure ascertained
- Exposed and unexposed groups identified
- Cohort followed up for outcome of interest
- Frequency of outcome among exposed and unexposed compared
- Cohort is a group of individuals
  - sharing same experience
  - followed up for specified period of time
- Examples
  - birth cohort
  - occupational cohort

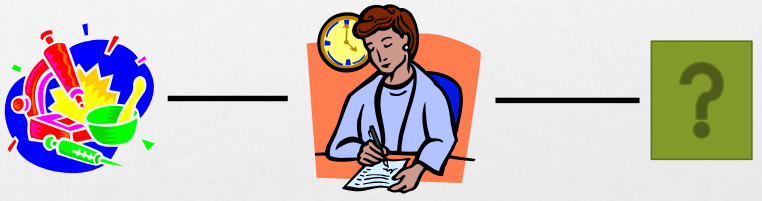
Cohort Studies

- **Characteristics**: follow-up study (prospective; retrospective)

- **Effect measure:** Risk Ratio (Relative Risk)
- E.g. Study of natural history of HIV, HIV incidence, ART adherence rate

Cohort study design (Prospective)

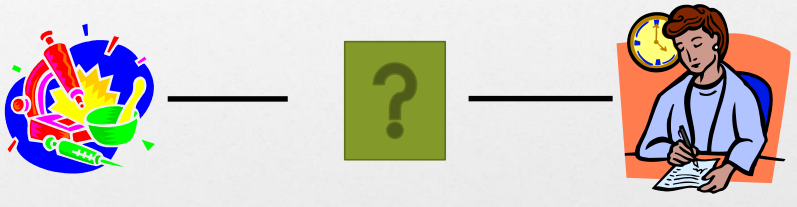
Exposure Observer Disease



Start with two groups of people who are exposed and unexposed, follow them to see who gets disease.

Cohort study design (Retrospective)

Exposure Disease Observer



Start with two groups of people who are exposed and unexposed, find out who got the disease.

Advantages and disadvantages of cohort study

Advantages:

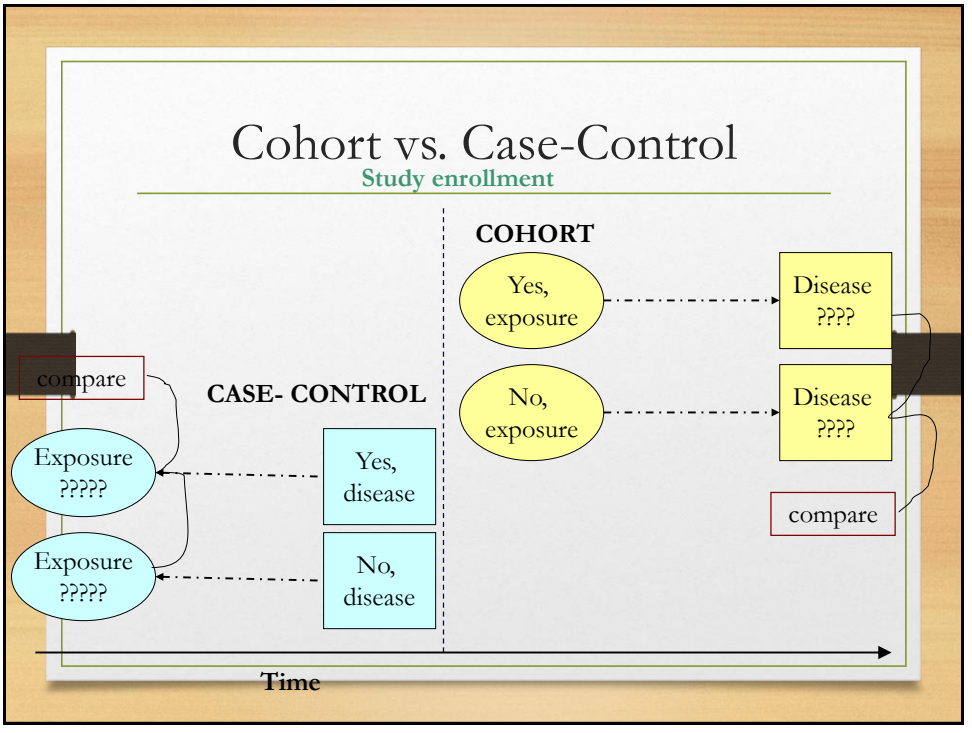
- Can estimate multiple outcomes of an exposure
- Less prone to recall bias
- Temporality clear
- Good for rare exposure
- Measures incidence

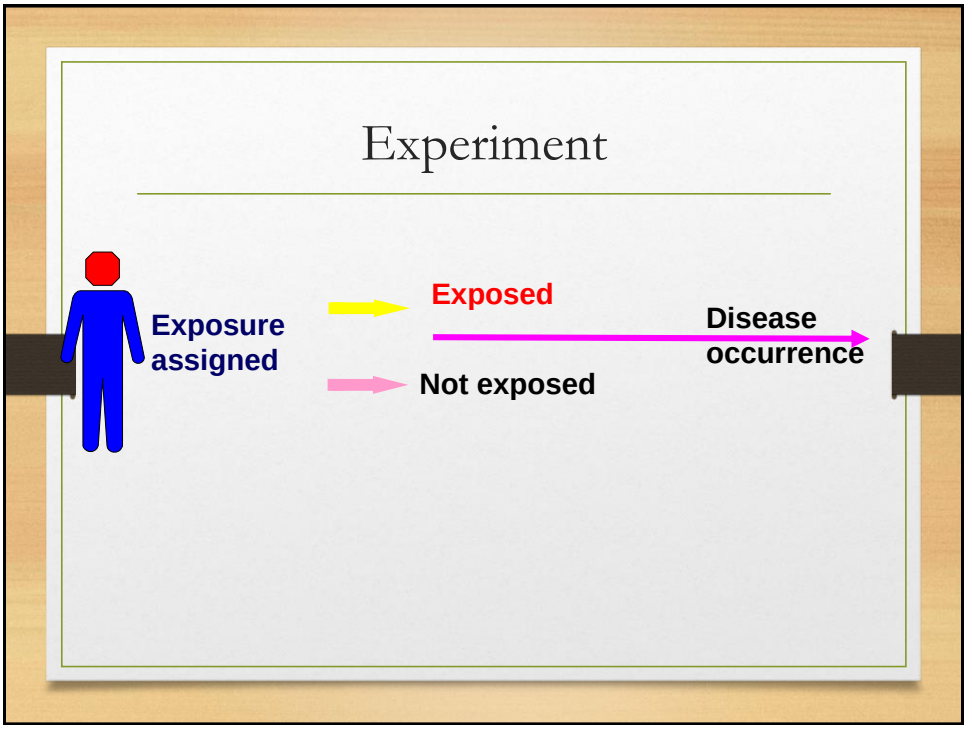
Disadvantages:

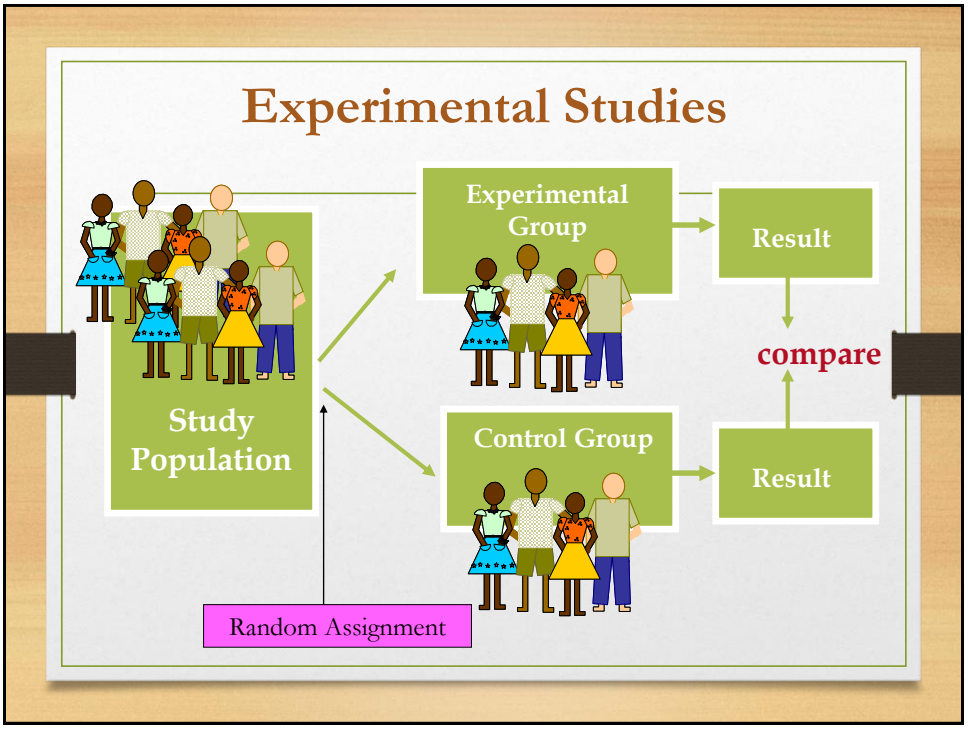
- Costly, large sample, time consuming
- Not good for rare disease
- Loss to follow up - common

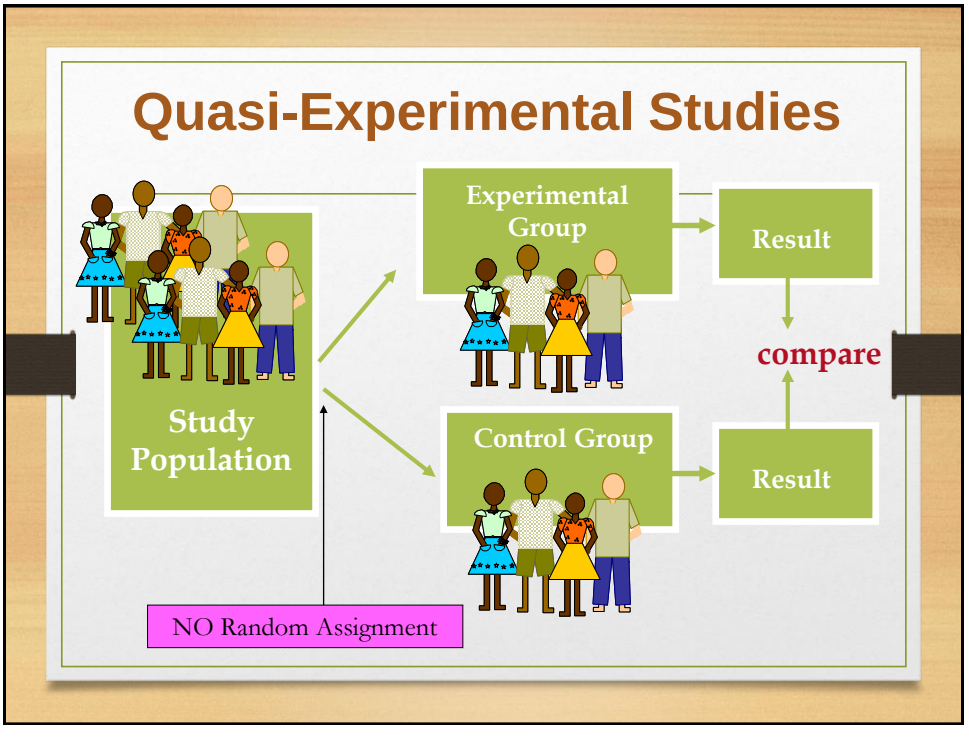
Association Measure of Cohort Study

- Risk Ratio / Relative Risk (RR)
  = Incidence in Exposed / Incidence in Not Exposed
- RR= $\frac{a/(a+b)}{c/(c+d)}$
- Risk Difference / Attributable Risk (AR)
  = Incidence in Exposed – Incidence in Not Exposed
- Population Attributable Risk (PAR)
  = Prevalance x AR


Cohort vs. Case-Control
Study enrollment
COHORT
Yes, exposure
No, exposure
Disease ????
Disease ????
compare
CASE- CONTROL
Exposure ?????
Exposure ?????
Yes, disease
No, disease
compare
Time


Experiment
Exposure assigned
Exposed
Not exposed
Disease occurrence


Experimental Studies
Experimental Group
Result
compare
Study Population
Control Group
Result
Random Assignment


Quasi-Experimental Studies
Experimental Group
Result
compare
Study Population
Control Group
Result
NO Random Assignment

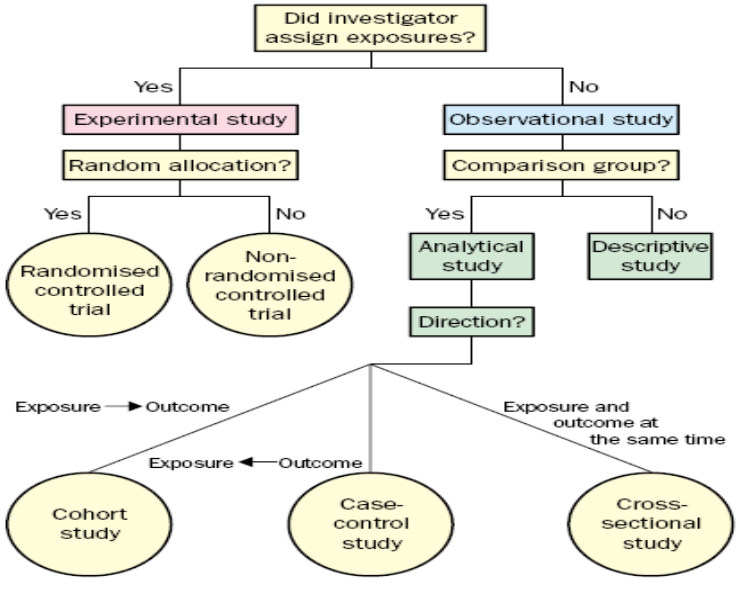
Advantages and Disadvantages of Randomized Controlled Trial

Advantages

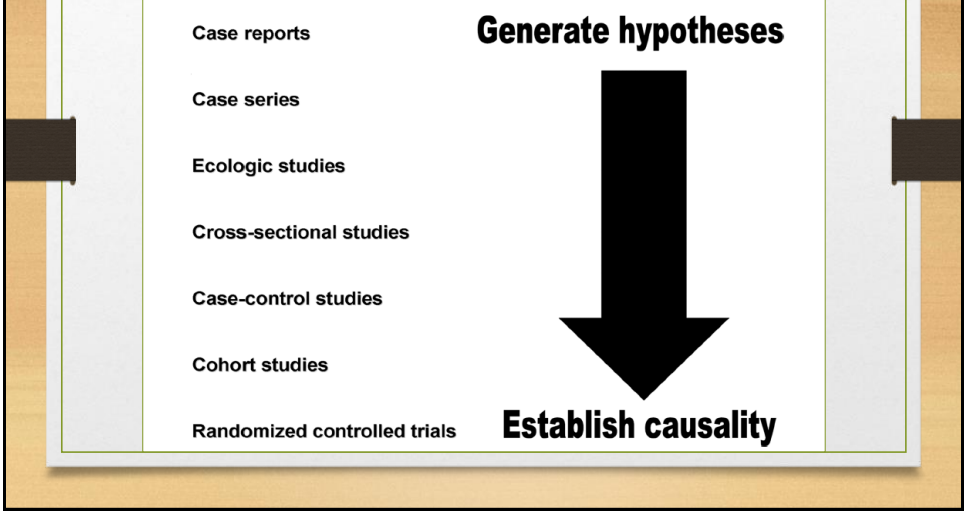
- Reliable & valid – Prospective
- Ensures temporality
- Clear Causality
- Can control confounders – by randomization

Disadvantages

- Ethical problem
- May be expensive, often need more time & large sample
- Non-representative ness of sample
- Non-compliance
- Attrition – Loss to follow up



Hierarchy of Epidemiologic Study Design



Qualitative methods

- Focus group discussions (FG)
- In-depth interview (IDI)
- Key informant interviews
- Observation
- Case studies

Focus Group Discussio

- One-on-many conversation
- To understand group norm on a particular topic. E.g. Opinion about an IEC campaign
- Not suitable for eliciting information on personal experience on sensitive topics
- Group dynamics may enhance or hinder information collected
- Ideally Six to eight participants-should be homogeneous
- Saturation: when stop hearing new info

Focus group facilitation

- Two people: facilitator and note-taker
- Using a recorder is recommended-it should not intervene research ethics or value free discussion
- Introduce group members and yourself
- Show interest and respect
- Actively listen; follow leads but stay "on topic"
- Encourage between-participant discussion; avoid group interview dynamic
- Varity of opinion is what aimed for but should not instigate conflict.
- Eye contact tip

Conducting in-depth interview

- One-on-one method
- Preferred tool for exploring more sensitive issues
- Like a conversation-in a structured way
- Individuals talk about their **own** personal feelings, opinions, and experiences
- Active listener, moderating the narration skilfully, body language is important, balancing time through out the discussion, more probing skill is required
- Privacy is must
- Guide line has broad domains and lead questions , standard probes for most of the lead questions

Take home message-1

- Qualitative designs are complementary to quantitative designs, are important in exploring and describing health problems/issues
- Descriptive studies generate hypothesis, while analytical studies used to test hypothesis
- In cross-sectional the primary output is prevalence data, though association between risk factors and disease can be generated
- In case-control studies, we know the outcome, looking for the exposure
- In cohort studies, we know the exposure, following up looking for the outcome in question

Take home message-2

- In probability sampling you can generalize findings beyond sample, which is not possible in non-probability sampling.
- Facilitation skills are key to qualitative methods of data collection.

By specific purpose of programmes

- Policy: Review of policy & strategy; Policy options, solutions, outcomes
- Operational: Objective to bring out or improve solutions; implementational
- Systems: Providers, beneficiaries, stakeholders, processes, time lags, system characteristics, infrastructure, resources
- Evaluation: Input, process, output, outcome, impact, cost-effectiveness

By subject area

- Basic: Biological, Molecular, Lab-based
- Epidemiological: Study of distribution and determinants of disease or health-related events
- Social: Social issues, factors, community dynamics, macro factors
- Behavioural: Human behaviours
- Clinical: Symptoms, Signs, Diagnoses, clinical outcomes
- Genetic, Economic, etc.

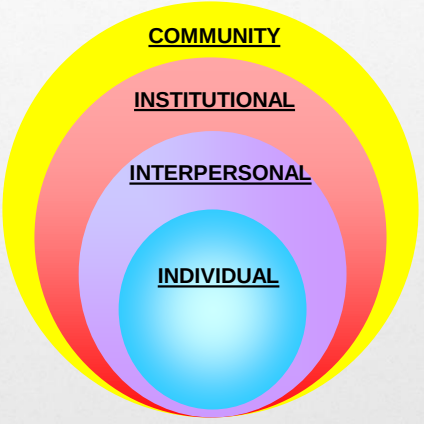
Behavioral research

- Purpose is to examine what motivates people to act as they do
  - Study behavioral or social processes that predict or influence health outcomes
- Goal to use results to help convince people to adopt healthy lifestyles
- Seeks to understand behavioral or social processes that predict or influence health outcomes or risk factors
- Examines how individuals are connected to the larger community context and considers how social factors influence health behaviors

Behavioral research at various levels of influence

Conceptual Framework

Based on the Social Ecological Framework (McLeroy et al 1988)



Clinical research

- Also known as clinical trials or clinical studies
- Medical research that involves people who volunteer to participate
- Carefully conducted investigations that to uncover better ways to treat, prevent, diagnose and understand human disease.
- A clinical trial begins with a research question
  - "Does this new treatment work against that disease?"

By site for data collection

- Community-based: Household surveys
- Facility-based: Surveillance

By nature of data collection

- Desk Research
  - Desk Review
  - Systematic Review: comprehensive survey of a topic in which all of the primary studies of the highest level of evidence have been systematically identified, appraised and then summarized according to an explicit and reproducible methodology
  - Meta-analysis: survey in which all the studies are similar enough statistically that the results are combined and analyzed as one study
- Field Research

Steps in Undertaking Research

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Basic Steps of Research - Technical

- Identification and definition of the problem
  - Introduction of needs or issues; Context
  - Review of literature
  - Describe the research problem
  - Statement of objectives & research questions
  - Rationale/ Justification

Basic Steps of Research - Technical

- Planning the Research
  - Choosing research design
  - Selection of study population and subjects
  - Finalising method of data collection
  - Plan data processing and analysis

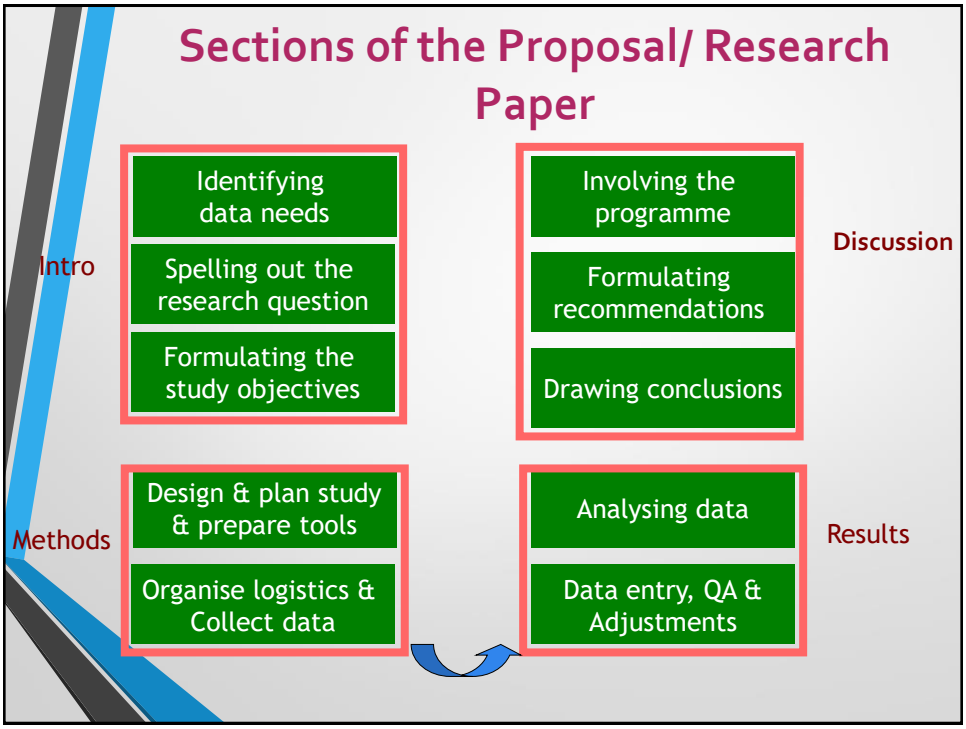
Basic Steps of Research - Technical

- Implementation of Plan
  - Data collection
  - Data processing
  - Data analysis
- Interpretation and conclusion
- Reporting of the study results

Basic Steps of Research - Administrative

- General preparations
  - Plan budget & secure resources for implementation
  - Identify necessary approvals, intimations, permissions, clearances; process for the same
  - Hiring and training of personnel
  - Scheduling of activities - Timelines
  - Procurement of logistics
  - Preparation of study area
- Feasibility study
  - Pre-survey assessments
  - Pre-testing of questionnaires
  - Piloting methodologies
- Termination of study

Sections of the Proposal/ Research Paper



Population Council

Elements of a Research Protocol

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VHS

Structure of a Research Proposal

- Introduction & Problem Statement
  - Background & Context
  - Research Problem
  - Rationale
  - Objectives
  - Research Questions/ Hypotheses
- Methods
  - Research design
  - Study sites & study population
  - Sample size & sampling design
  - Data collection methods & tools
  - Interventions & Controls
  - Data analysis plan

Structure of a Research Proposal

- Ethical considerations
- Operational plan
  - Human resources – recruitment & training
  - Logistics
  - Field work plan
  - Data management plan
  - Quality control
  - Dissemination plan
  - Stakeholder coordination - Meetings
- Study team
  - Investigators – Principal; Co-
  - Collaborations & partnerships
- Milestones & Timelines
- Budget

Problem identification and rationale

Problem statement

A well defined statement leads to research objectives, hypotheses, definition of key variables, selection of methodology for measuring outcomes.

Problem identification	Rationale
• Problem situation • Collect evidence: literature review other work/studies service statistics key informants' views geographical areas characteristics of populations affected • Probable reasons for the problem	• Is the problem current? How widespread is it? • Does the problem • affect key populations? • Does it relate to the ongoing program? • Does it relate to social, economic, health issues? • Are authorities concerned?

Problem statement

Example

- New PMTCT regimens are being implemented – ART initiated at 14 weeks gestation.
- Past experience with the PMTCT cascade shows that there is drop out at each level: ANC visits, delivery, PNC visits, EID at 6 wks, HIV testing for the infant at 9-12 months, and confirmatory test at 18 months.
- We have no information on how women will take the new treatment with 3 drugs – adherence
- Limited evidence / no longitudinal studies.

Main issues

- Early initiation, retention in the program and adherence to treatment regimen.

Problem statement

PMTCT programs routinely face high drop out rates along the cascade; many HIV-positive women attend ANC late in pregnancy, do not complete all ANC visits, do not have an institutional delivery and do not bring back the infant for EID. Given the recent global shift towards provision of highly active antiretroviral therapy (HAART) to PMTCT mothers in order to maximize viral suppression both for prevention of MTCT and for the well being of the HIV positive mother there is a need for new strategies to enhance early initiation of, retention in and adherence to HAART for HIV-positive pregnant women in Kenya.

Setting Objectives

- **Goal or global objective**: larger objective of the research study.
- **Primary objective**:
  - Main research question and main outcome
  - Should be stated clearly in behavioural terms
  - Should specify who will do, how much of what, to whom, when, where, and for what purpose.
- **Secondary objective**:
  - Additional research questions nested in the main study.

Example: Research Objective from a PMTCT study (Kenya)

- The goal of the proposed study is to increase uptake of HAART among newly diagnosed HIV-positive pregnant mothers and the continuation of HAART among women who become pregnant on treatment, improve retention in care, and promote adherence to treatment to achieve favorable outcomes for the mother child dyad.

Specific objectives (Primary):

- Evaluate the effectiveness of a XXXX intervention to promote early initiation of and adherence to ARV prophylaxis/treatment and retention for HIV-positive pregnant women compared to standard care
  - can specify time frame / direction / extent of effect

Specific aims (Secondary)

- Assess the acceptability, feasibility and additional cost of implementing a XXXX strategy in a rural community

Hypotheses

- A statement about an expected relationship between two or more variables that permits empirical testing.
- Serves to direct and guide the research by indicating the major independent and dependent variables of interest.

Study Methods

- Research design
  - Cross sectional / longitudinal cohort / randomized controlled trial
- Study population
  - Men / women / children
  - Eligibility criteria
  - Exclusion criteria
  - Where you will find them?
  - Recruitment procedures -How will you recruit them?
  - Any special concerns – vulnerable populations

Methods (contd.)

Sample size calculation

- Based on published evidence, programmatic data, expected effect size, direction of effect (one or two tailed)

Study sites

- Describe the sites, services offered
- Why these sites are suitable for this particular study
- If two groups – any distinctions - are they matched – have they been randomly assigned

Methods (contd.)

Intervention

- Describe the intervention
- Describe the delivery process
- Specific details on duration, intervals
- Content of the intervention - any manuals, SOPs
- Fidelity of the intervention – monitoring

Control or Standard of Care

- Describe the standard of care or control group

Methods (contd.)

Research activities

- Research activities – include preparatory work
- Data collection
  - Data to be collected
  - Tools to be used – type and number
  - Frequency of data collection
  - Who will collect data
- Data safety and storage
  - Where will data be entered, stored
  - Who will have access to this data
  - How will it be transferred
  - Where will the data be analysed – by whom

Methods (contd.)

Data analysis plan

- Describe for each main objective
- Statistical procedures you plan to use
- Expected outcomes

Ethical considerations

- Ethical approvals
  - Where will the protocol be submitted
- Recruitment procedures in the context of ethical guidelines
- Confidentiality, right to refuse, potential risks
- Informed consent procedures
- Care and support available in the case of unexpected events
- Person responsible

Organizations and partnerships

How will the study be implemented in the field

- Organization with overall responsibility
- Partner Organization
- Mention key staff and effort/time they will dedicate
- Mention their suitability, expertise

Monitoring

- Person responsible
- How it will be implemented – frequency, items or activities to be monitoring, reporting system, actions to be taken in case of events
- Travel to sites

Timeline

Activity	1	2	3	4	5	6	7	8	9
Hiring staff Ethical approvals									
Tool development									
Pretesting of tools									
Adaptation of intervention manual									
Baseline Data collection									
Intervention roll out									
Endline data collection									
Data entry									
Qualitative interviews									
Data analysis									
Final report									
Dissemination meeting									

Others

- **Dissemination** plan
- Utilization of study findings
- **Training** for research teams – days, topics, ethics
- Inclusion of **special groups**
- **Annexures**: sample data collection instruments, validated tools that you may adapt, draft consent forms
- **Meetings**: stakeholders, district authorities

Budget

- Excel program
- Think of every activity and enough time
- Clear headings with subtotals
  - Salaries
  - Research activities
  - Travel / Monitoring
  - Facilities costs
  - Dissemination
- Budget justification

Template

Cost element	Rate/ unit	Duration	Year 1 (July 1- Dec 31 2012)		Year 2 (Jan 1- Dec 31 2013)		Total	
			Units	cost	Units	cost	Units	cost
Salaries								
Sub-total								
Research								
Sub-total								
Travel								
Sub-total								
Office costs								
Sub-total								
Meetings/training								
Sub-total								
Overheads x%								
Grand total								

Operational Research – Overview, Types, Steps, Case Studies

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Session Outline

- What is OR?
- Goal and Objectives of OR
- Steps involved in OR
- Categories of OR
- Selected Topic Areas for OR

Introduction of OR / What is OR?

- The term OR was coined during World War-II, when British Military management called upon a group of scientist together to apply scientific approach in the study of military operations to win the battle.
- Operations research, also known as operational research, is an interdisciplinary branch of applied mathematics and formal science.
- OR is a process, a way to identifying and solving program problems.

Definition of OR

- Winston: "a scientific approach to decision making, which seeks to determine how best to design and operate a system, usually under conditions requiring the allocation of scarce resources."
- attempts to solve complex problems by developing mathematical models to analyse the many variables
- the application of systematic research and evaluation techniques to improve programs and service delivery

What is OPERATIONS RESEARCH?

- Any research producing **practically usable knowledge** (evidence, findings, information, etc.) which can **improve program implementation** (e.g. effectiveness, efficiency, quality, access, scale up, sustainability) regardless of the type of research (design, methodology, approach) falls within the boundaries of operations research

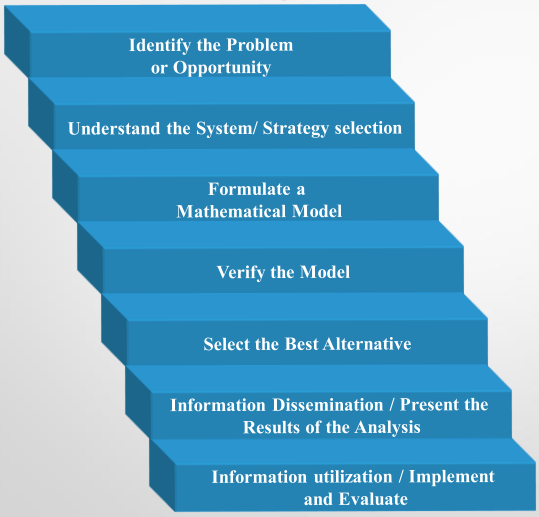
Goal and Objectives

- The Goal of OR is to to increase the efficiency, effectiveness, and quality of services delivered by providers,
- and the availability, accessibility, and acceptability of services desired by users
- An important objective of OR is to provide managers, administrators, and policymakers with the information they need to improve or scale up existing delivery activities and to plan future ones
- It diagnoses and evaluates the problems that programs have and compares one service delivery approach against another in terms of impact, cost effectiveness, quality, and acceptability to clients

Steps involved in OR

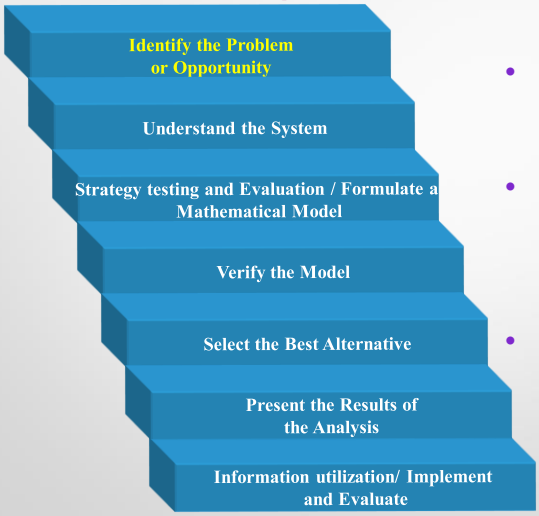
- 5 basic steps :
  - Problem Identification and diagnosis
  - Strategy selection
  - Strategy testing and Evaluation
  - Information dissemination
  - Information Utilization

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



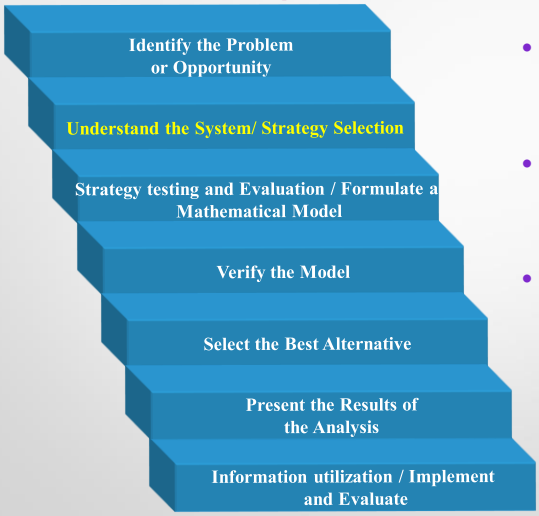
- Adapted from Winston, Wayne L., *Operations Research: Applications and Algorithms*, 3rd Edition, Duxbury Press, 1994, p. 2.

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



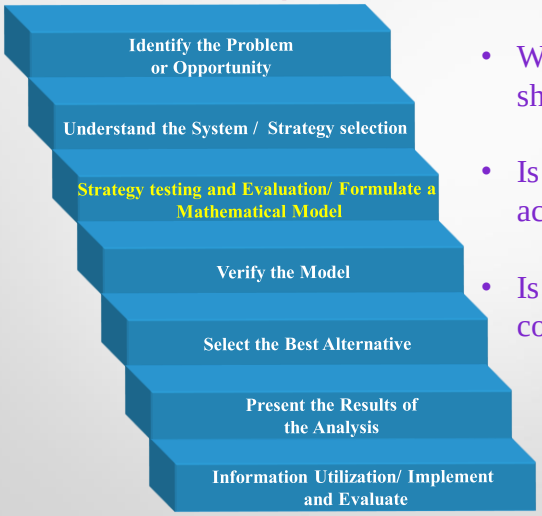
- What are the objectives?
- Is the proposed problem too narrow?
- Is it too broad?

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



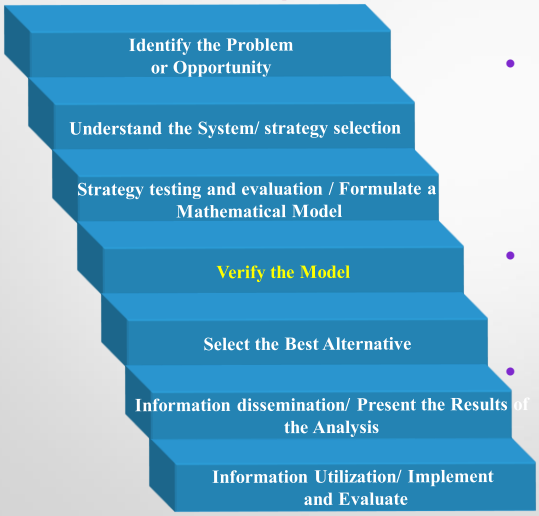
- What data should be collected?
- How will data be collected?
- How do different components of the system interact with each other?

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



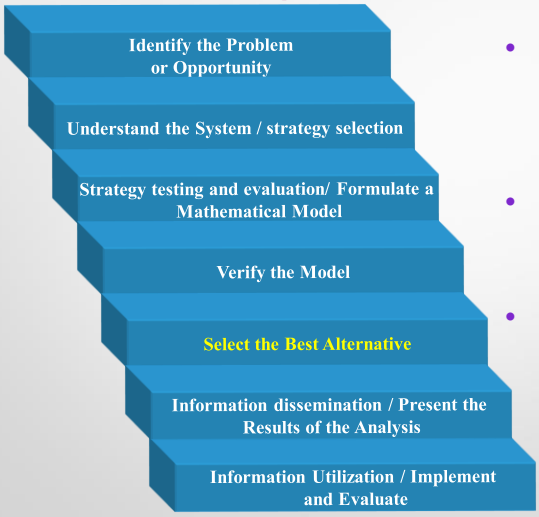
- What kind of model should be used?
- Is the model accurate?
- Is the model too complex?

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



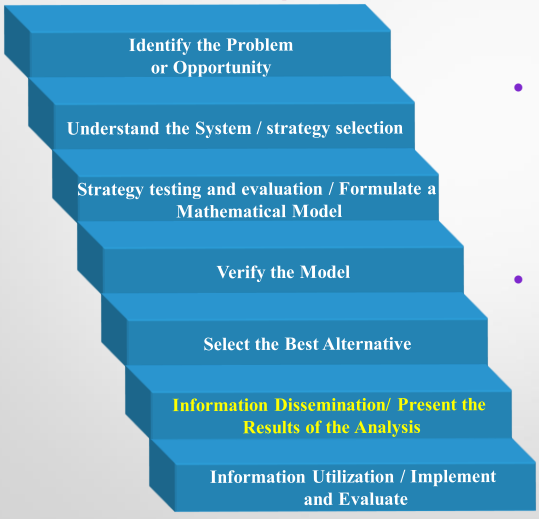
- Do outputs match current observations for current inputs?
- Are outputs reasonable?
- Could the model be erroneous?

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



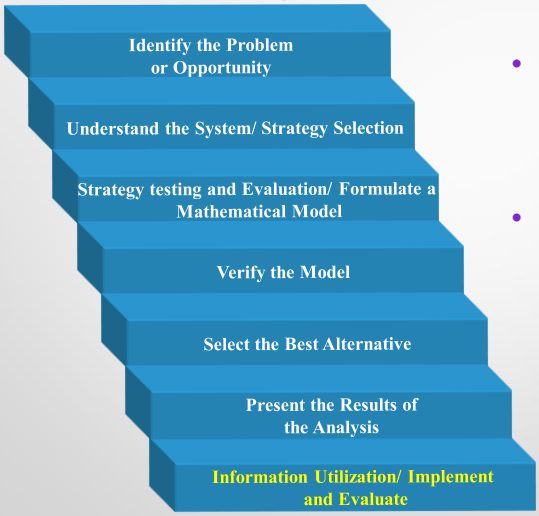
- What if there are conflicting objectives?
- Inherently the most difficult step.
- This is where software tools will help us!

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



- Must communicate results in layman's terms.
- System must be user friendly!

Methodology of Operations Research*
The Seven Steps to a Good OR Analysis



- Users must be trained on the new system.
- System must be observed over time to ensure it works properly.

Study Designs & Operations Research

- No single set of designs unique to OR
- The focus / objective of the research distinguishes OR from other research
- In broadest terms – the objective of OR is *to 'improve the delivery of services'*
- OR is for better understanding of program '*operations*' in order to make needed program '*improvements*'

Study Designs & Operations Research

- Unique feature of OR is its multi dimensional and multi disciplinary framework
- It combines concepts and tools from epidemiology with economic, sociological, anthropological, management and other disciplines as needed
- Collaboration with experts from various disciplines is hence critical for OR

OR – broad classification

1. Exploratory / diagnostic studies
   - *When the problem is not known*
2. Field intervention studies
   - *When the program approach is not known*
3. Evaluative studies
   - *When the impact is not known*
4. Cost-effectiveness studies
   - *When the cost & effectiveness is not known*

OR – broad classification

- The four categories are not mutually exclusive - they could each be done consecutively in different phases of a program
- The context, content & conduct of the program determine the OR framework
- The 'systems' configuration and approach is very critical for OR
- Findings of OR may be most useful for the specific program but may not be generalizable to other programs.

Categories of Operations Research Studies

- **Exploratory/Diagnostic Studies: Problem Not Known**
  - This type of study is most often undertaken before a program is implemented
  - Whenever there is a perceived problem but the nature of the problem and the correct program responses are not known

Field Intervention Studies: Program Approach Not Known

- These studies are experimental basis
- New approaches and solutions to overcoming a program problem
- These studies are always perspective and longitudinal and usually employ either an experimental or quasi experimental design

Evaluative Studies: Impact Not Known

- Evaluative studies can be a valuable operations research approach for examining retrospectively or cross- sectionally the effect of program activities
- It is on going process, can be conducted periodically, or over the life f the program
- Evaluation is periodically or over the life of the program

Cost-effectiveness Studies: Cost and Effectiveness Not Known

- In many cases, the overall impact of a program in terms of increasing knowledge about HIV, changing unsafe sex practices, or reducing HIV transmission may be known, but the cost and particularly the cost-effectiveness of the program are unknown
- It is part of intervention or evaluation studies

Who should do Operations Research in HIV/AIDS?

- Service providers
  - Midwives/nurses
  - Counsellors
  - Lab technicians
  - Doctors
- Program managers/coordinators
- Social scientists
- National coordinator, etc

How to Conduct OR?

- Properly recording, analyzing, sharing and utilizing our day-to-day observations
- Planned research
  - Research proposal
  - Solicit for funds
  - Ethical clearance
  - Implementation - data collection
  - Data analysis and dissemination: service
- providers, participants, scientific readings, journals
- Apply findings to change practices, policy and improve health

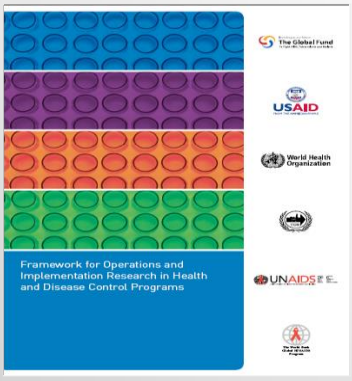
Some Research Questions- Discussion

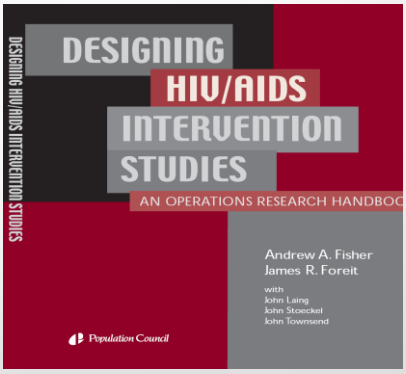
- Generate some PMTCT OR research
- questions to answered through research in your districts / regions in the areas of
  - ANC and VCT
  - Labor, delivery & immediate postnatal care
  - Postnatal follow up
  - Community and male involvement
  - Infant feeding
  - Integrating PMTCT services

Contd….

- KAP on
  - Replacement feeding
  - Wet nursing
  - Heat treated breast milk
  - Men's involvement in PMTCT
  - Condom use during preg. & B/F
  - IV status disclosure

Doing Operations Research





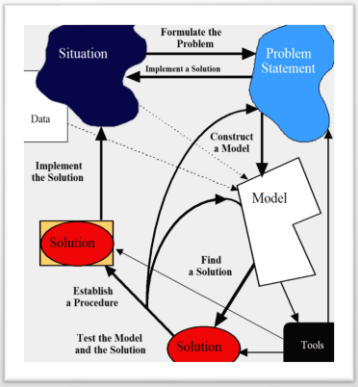
http://www.popcouncil.org/uploads/pdfs/horizons/orhivaidshndbk.pdf

The OR Process

- Problem identification (including definition and justification)
- Objectives and hypotheses
- Solution generation (intervention design, model building)
- Solution testing (sampling, implementation, data collection, analysis)
- Results dissemination and utilization

Two approaches

- Secondary data analysis
  - Review of program data, representative survey data, mathematical modeling
- Primary level research studies
  - Four type of primary OR studies
    - Exploratory/diagnostic (Problem Not Known)
    - Field intervention (Program Approach Not Known)
    - Evaluative (Impact Not Known)
    - Cost-effectiveness (Cost and Effectiveness Not Known)



Three Phases to OR studies

1. Planning
2. Implementation
3. Follow Through

Determine the research questions (and objectives)

- Be clear, be specific
- Research question—What do you want to know?
  - Observation
    - "Tuberculosis seems to be common problem among alcohol using HIV-positive men"
  - Research question
    - "What is the rate of conversion from latent to active TB among HIV-positive men, with and without alcohol use?"
- Objective
  - Not: To study adherence
  - But: To determine rates of adherence among HIV-positive individuals at the XX hospital and reasons for adherence and nonadherence

Develop a research proposal / protocol — "standard parts"

- Research objectives and questions
- Background
  - Literature review
  - Local context
- Research team
- Methods (study design, study population, sampling details, how data will be collected, data management, quality assurance)
- Data collection instruments
- Plans for use of data
- Budget

What all is involved in OR

- Action Research
- Involves policy makers, users and providers in design
- Requires collaboration between managers and researchers
- Uses standard qualitative and quantitative methods
- Non-experimental design to true experimental design

When OR is successful?

- Evidence generated leading to change in practice and policy
- Publications in scientific journals
- Capacity development among all involved stakeholders

RESEARCH DATA MANAGEMENT: ASPECTS & PRACTICES

Capacity Building Workshop on Operations Research

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Data – Information - Knowledge

DATA: *Facts concerning people, objects, events or other entities. Databases store data.*

INFORMATION: *Data presented in a form suitable for interpretation.*

Data is converted into information by programs. Data may be stored in files or in databases. Neither one stores information.

KNOWLEDGE: *Insights into appropriate actions based on interpreted data.*

Metadata

Metadata

"Data about data"

- Description of fields
- Display and format instructions
- Structure of files and tables
- Security and access rules
- Triggers and operational rules
- Data collection details

Data Collection

- Tools for collection
- Training of data collectors
- Recording responses
- Coding & categorising responses
- Verification by interviewer
- Verification by field supervisor before sending to main office

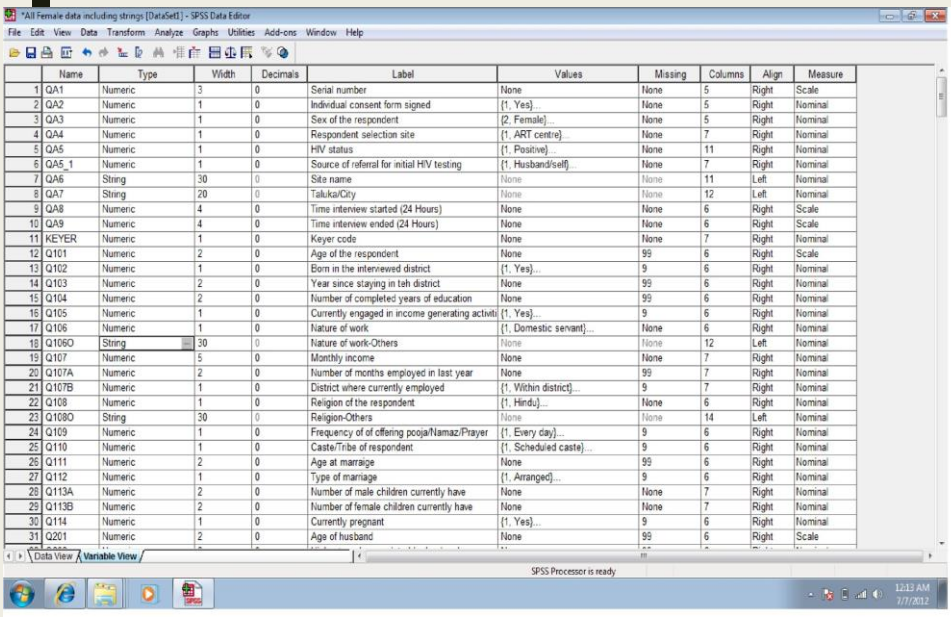
Data Entry & Management

- Transmission of paper forms
- Translation & Transcription
- Software & Personnel
- Real time entry/ Double entry
- Verification during and after data entry
- Data Management
  - *Datafiles, Directory, Metadata, Access Engine, Utility Programmes*
- Backup protocol
- Security protocol

Coding & Data Dictionary

- The person who designs the coding for data entry is not necessarily the one who does data analysis.
- Hence we need a dictionary of all codes for all variables and questions, explaining what code means what, and relates to what question, what variable…
- A data dictionary is a descriptive list of names, definitions, and attributes of data elements collected in an information system or database
- Why Data dictionary
  - *Standardization of terms used in the data base for common understanding of different users*
  - *Enhances inter operability across systems*

Illustration of DD



	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure
1	QA1	Numeric	3	0	Serial number	None	None	5	Right	Scale
2	QA2	Numeric	1	0	Individual consent form signed	{1, Yes}...	None	5	Right	Nominal
3	QA3	Numeric	1	0	Sex of the respondent	{2, Female}...	None	5	Right	Nominal
4	QA4	Numeric	1	0	Respondent selection site	{1, ART centre}...	None	7	Right	Nominal
5	QA5	Numeric	1	0	HIV status	{1, Positive}...	None	11	Right	Nominal
6	QA5_1	Numeric	1	0	Source of referral for initial HIV testing	{1, Husband/self}...	None	7	Right	Nominal
7	QA6	String	30	0	Site name	None	None	11	Left	Nominal
8	QA7	String	20	0	Taluka/City	None	None	12	Left	Nominal
9	QA8	Numeric	4	0	Time interview started (24 Hours)	None	None	6	Right	Scale
10	QA9	Numeric	4	0	Time interview ended (24 Hours)	None	None	6	Right	Scale
11	KEYER	Numeric	1	0	Keyer code	None	None	7	Right	Nominal
12	Q101	Numeric	2	0	Age of the respondent	None	99	6	Right	Scale
13	Q102	Numeric	1	0	Born in the interviewed district	{1, Yes}...	9	6	Right	Nominal
14	Q103	Numeric	2	0	Year since staying in teh district	None	99	6	Right	Nominal
15	Q104	Numeric	2	0	Number of completed years of education	None	99	6	Right	Nominal
16	Q105	Numeric	1	0	Currently engaged in income generating activiti	{1, Yes}...	9	6	Right	Nominal
17	Q106	Numeric	1	0	Nature of work	{1, Domestic servant}...	None	6	Right	Nominal
18	Q106O	String	30	0	Nature of work-Others	None	None	12	Left	Nominal
19	Q107	Numeric	5	0	Monthly income	None	None	7	Right	Nominal
20	Q107A	Numeric	2	0	Number of months employed in last year	None	99	7	Right	Nominal
21	Q107B	Numeric	1	0	District where currently employed	{1, Within district}...	9	7	Right	Nominal
22	Q108	Numeric	1	0	Religion of the respondent	{1, Hindu}...	None	6	Right	Nominal
23	Q108O	String	30	0	Religion-Others	None	None	14	Left	Nominal
24	Q109	Numeric	1	0	Frequency of of offering pooja/Namaz/Prayer	{1, Every day}...	9	6	Right	Nominal
25	Q110	Numeric	1	0	Caste/Tribe of respondent	{1, Scheduled caste}...	9	6	Right	Nominal
26	Q111	Numeric	2	0	Age at marraige	None	99	6	Right	Nominal
27	Q112	Numeric	1	0	Type of marriage	{1, Arranged}...	9	6	Right	Nominal
28	Q113A	Numeric	2	0	Number of male children currently have	None	None	7	Right	Nominal
29	Q113B	Numeric	2	0	Number of female children currently have	None	None	7	Right	Nominal
30	Q114	Numeric	1	0	Currently pregnant	{1, Yes}...	9	6	Right	Nominal
31	Q201	Numeric	2	0	Age of husband	None	99	6	Right	Scale

Data Analysis

Before you start to do any statistics:

- look at data
- save original data

Choice of statistical technique depends on

- type of data
- information required

Type of data

- discrete - finite number of values
- continuous - any value

Statistical methods by types of data

Statistical methods start with	Nominal scale (or discrete data)	Ordinal Scale	Continuous /Interval Scale
Descriptive statistics	Proportions (or) percentages	Either cont. or discrete	Mean, Median, mode, s.d., range, m.d., skewness, etc.
Corresponding inferential statistics	Z-test		T-test
Bivariate statistics	Test of attributes, odds ratio, risk ratio, sensitivity, specificity, etc..		Correlation, simple regression
Corresponding inferential statistics	Chi-sq. test		ANOVA
Multivariate statistics (all regression based)	Logistic regression technique (if dep.var-Y has only two cateogries)	Reliability analysis	Multiple regression
	Multinomial Logistic regression technique (if dep.var-Y has three or more cateogries)	Factor analysis	
Corresponding inferential statistics	Chi-Sq. test, Wald's test		ANOVA

Presenting Data

Overview

Ways to Present Data

- Text
- Tables
- Figures and illustrative graphs

Overview - Text

- Do not present data in table or figure if able to present in text
- Use text whenever there are small amounts of data to be summarized
- Do not repeat data presented in table or figure in text

Overview - Tables

Tables are arrangements of numbers or words in columns and rows that display data or relationships

- Allow presentation of exact values
- Present large amounts of data in a small space

Tables - Titles

- Precise
- Eliminate unnecessary words
- Avoid repetition of headings of columns and rows

Tables - Columns and Rows

- Arrange columns and rows in logical sequence (e.g., place cases of most interest first)
- Round to one decimal point
- Include summary statistics for making comparisons

Figures and Charts

Figures and charts give visual descriptions of relationships between groups or numbers

- Emphasize one point
- Easily understood
- Preferred for presentations

Chart Types and Uses

- **Bar chart:** Values of a single item over multiple units (e.g., dependent variable over time periods)
- **Pie chart:** Importance (in %) of categories as part of whole (100%)
- **Stacked bar chart** = Vertical Pie chart

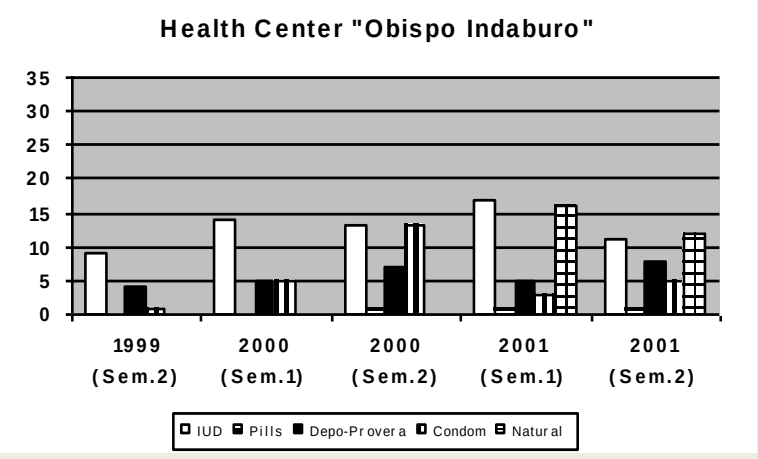
Chart Types and Uses (cont.)

- **Line graph:** Shows a variable over time (e.g., trend line)
- **Scatter plots/X-Y plots:** Show association between two or more variables (e.g., correlations)
- **Two-axis graphs:**

Common Problems in Charts

- Too many pie slices, bars, or segments
- Ambiguous labels
- Lack of contrasts between bars
- Axes of unequal length

Exercise 1: What is graph supposed to convey? Where did study take place? What conclusions should the reader draw? Is design attractive?



Principles of Designing Questionnaires

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Steps in developing effective questionnaires

- Decide what information you need
- Determine sample – respondents
- Develop accurate, user-friendly questionnaire
- Develop plan for distribution, return, and follow-up
- Provide clear instructions and an informed consent
- Pilot test

Questionnaire design–Considerations

- Kind of information: What do you want to know?
- Wording of questions and responses (Open /Closed-ended)
- Sequence of questions
- Formatting the questionnaire
- Pre-testing

Things to avoid in questionnaires

- Complexity: use simple, direct, conversational language
- Leading questions: that suggest or imply certain answers
  - Tell me about your relationship with your partners/ Do you have problems with your partners?
  - How would you rate your satisfaction with the clinic services?/ Are you very satisfied with the clinic services?
- Loaded questions: suggest social desirability, or are emotionally charged or has a controversial/ unjustified assumption.
  - Have you stopped beating your wife? How many sexual partners did you change in the last 12 months?

Things to avoid in questionnaires

- Ambiguity and vagueness: Words such as "often", "occasionally", "usually", "regularly", "frequently", "many", should be used with caution. If these words have to be used, their meaning should be explained properly.
- Double-barreled questions.
  - Are you satisfied with the services & drugs?
  - How often & how much time you spend in each visit to hospital?
- Burdensome or embarrassing sensitive questions.

Planning the measurements

Measurement variables

Continuous variables: quantified intervals of infinite arithmetic scale of values – body weight, hemoglobin, blood urea etc.
Discrete variables: finite number of quantified intervals – no. of cigarettes per day, no. of diarrhea episodes per year

Categorical variables

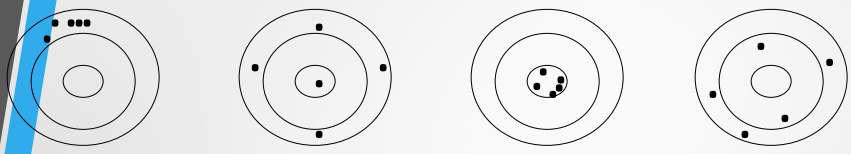
Dichotomous variables: having only two options – circumcised/ uncircumcised
Multi-categorical variable: having multiple options – education, occupation
Ordinal variables: not having ordered positions and not numerical in nature – pain [mild, moderate, severe], condom use [never, rare, frequent, always]

Prefer measurements that produce continuous numerical values: more information can be obtained and more analytical options are available

Time spent on classification and measurements can increase objectivity of information and reduce bias

Planning the measurements

[Precision and accuracy]



Good precision
Poor accuracy

Poor precision
Good accuracy

Good precision
Good accuracy

Poor precision
Poor accuracy

Precision
Measurement has the same value each time it is measured.
Assessed by comparing repeated observations.

Ensure precision by
Standardize methods
Training of observers
Automation
Repeat estimations

Accuracy
Degree to which a measurement is closer to the truth or actual.
Assessed by comparing with reference Standard.

Enhance accuracy by
Unobtrusive measurements
Blinding
Calibrating & re-calibrating instrument

Questionnaire: Ways how the information can be completed

- Face-to-face interview
- Telephone survey
- Self-administered survey (i.e. mail survey)
- Web-based

Planning the measurements: Questionnaires

Questionnaires:
Self-administered, staff time reduced
Biases due to variation in administration or instruction reduced
Privacy provided encourages honest and correct response

Interviews:
Administered verbally by researchers
Good for illiterates
Ambiguous/ unclear responses can be clarified
More complex and detailed information
There are no missing values
The order of questions can be controlled

When to use a questionnaire?

When resources and money are limited.

When it is necessary to protect the privacy of the participants.

When corroborating other findings.

Questionnaire

Definition

A questionnaire is a formalized set of questions for obtaining information from respondents.

A questionnaire is a tool that records people's expressions, feelings, perceptions, behaviors, and experiences, both past & present.

Navigating through the questionnaire

- Use headings, spacing and similarities to show groupings
- Introduction or preamble should be given before various sections and also before sensitive questions
- Instructions should be placed right where they are needed
- Matrices are confusing: it is best to order questions from top to bottom, and left to right
- Use larger and bolder font to attract attention
- Use color shading to attract attention or show groupings

Layout of questionnaire

- Self-explanatory
- Visually clear and uncluttered
- Appropriately grouped questions
- Consistent and clear response options
- Consider question placement
- Skip patterns kept to a minimum (if needed, use arrows and boxes)
- Beware of problems of using double-sided pages
- **There is strength and beauty in simplicity!**

The information obtained from each question will be specific to the information required for the analysis. Hence, all questions must be pertinent and none redundant.

1. **Understand the research questions and objectives**
2. **Think of the potential analysis plan**
3. **Group the questions under distinct heads**
4. **Introduce questions that can verify and counter-check some information, have logical check questions**
5. **Order the questions appropriately**
   - from the least sensitive to the most sensitive
   - from the more general to the more specific
   - from questions about facts to questions about opinions

Issues to consider regarding content of questionnaire

- Is every question necessary or useful?
- Are several questions needed?
- Do respondents have the needed information to answer the questions?
- Does the question need to be more specific?
- Is the question biased or loaded?
- Is the question asking about sensitive information?

Language of questions

Do the following..

- Use simple and unambiguous wording
- Be brief
- Be specific
- Use questions of appropriate length

Don't ...

- Be vague, confusing or ambiguous
- Be condescending or talk down to respondent
- Use abbreviations or scientific jargon
- Use objectionable questions
- Use in-sensitive language

Question order

- Questions should be ordered so as to seem logical to the respondent
- First questions should be relevant and easy
- Questions are effectively ordered from most salient to least salient
- Demographic questions should not be covered at the beginning
- Potentially objectionable questions are placed near the end

Question Formats

- Structured
  - Fill-in the blank
  - Rating
  - Likert Scale
  - Check all that apply
- Unstructured
  - Open ended question

Advantages of a questionnaire

- Cost effective compared to face-to-face interviews, especially if sample size is large and study population is scattered over large geographic areas.
- Questionnaires are easy to analyze. Data entry and tabulation possible with many computer software packages.
- Questionnaires are familiar to most people. Questionnaires reduce bias. There is uniform question presentation and no interviewer's bias. There are no verbal or visual clues to influence the respondent.
- Questionnaires are less intrusive than telephone or face-to-face surveys.
- Can be completed at convenience and the respondent is not interrupted by the research instrument.

Disadvantages of a questionnaire

- One major disadvantage of written questionnaires is the possibility of low response rates. They affect statistical analysis and inference.
- Another disadvantage of questionnaires is the inability to probe responses. Respondents often want to qualify their answers, which is not possible in case of a questionnaire. [Researchers can allow frequent space for comments, the researcher can partially overcome this disadvantage.
- A questionnaire probing sensitive issues or attitudes may be severely affected.
- When returned questionnaires arrive in the mail, it's natural to assume that the respondent is the same person you sent the questionnaire to. It is not possible to confirm this.
- Finally, questionnaires are simply not suited for some people, for example, a written survey to a group of poorly educated people.

Types of Questions	Examples
Dichotomous Questions	Sex: Male/ female Have you done HIV test before: Yes/ No
Nominal Questions	Which of the following symptoms you had in the last seven days after starting study medications? 1. Drowsiness, 2. Gastro-intestinal upset, 3. Skin rash, 4. Dark colored urine, 5. Giddiness
Ordinal Questions	How would you grade your fever? 1. Mild [below 99°F], 2. Moderate [99 to 101°F], 3. Severe [Above 100°F]
Interval/Ratio Questions	Since starting drug x, how much relief have you got? 1. Nil, 2. <25%, 3. 25-50%, 4. 51-99%, 5. Total or 100%

Types of Questions	Examples
Rate or rank questions	Please rank the following HIV prevention options from 1 to 5, putting 1 next to that which is most important to 5 which is the least important. ___ Blood safety ___ Early diagnosis of STDs and treatment ___ Creating awareness among young people ___ Using condoms during each sex act ___ Late initiation of sex
Number questions	"How many times did you visit the doctor during the past year?" ____ times

Principles of Designing Questions

I. Scale response categories

a. Scale should allow for maximum variability
b. Be careful about responses of 'neutral' or 'no opinion' versus 'don't know'
c. Scale should be balanced and should have anlysable value

Nature of response	Advantages	Disadvantages
Yes/ No	Easy, no confusion; good value for quantitative information	Limited value for qualitative analysis
Mild/ moderate/ severe	Manageable, less confusion	
Nil/ little/ average/ more than average/ profuse	Useful for qualitative data and analysis, gives flexibility	Can be confusing for the respondents

Principles of Designing Questions...

Questions should collect only 1 piece of information at a time, hence avoid:

- Asking two questions at once
- Asking questions that contain assumptions
- Questions that can prompt socially desirable response

Examples of wrong and right questions

	Inappropriate question/s	Appropriate question/s
Asking more than one question at a time	Do you think that your experience of vaccine trial participation and the trial team was good	1. How would you rate your experience of participation in the vaccine trial? 2. How would you rate the performance of the trial team?
Asking question that contains assumptions	Which fortified foods do you consume in your daily diet?	1. Do you know what are fortified foods? 2. Which of these do you consume? 3. Will you please specify frequency of their consumption? 4. Will you also specify the quantity consumed per day?
Questions prompting a socially desirable response	Have you beaten your wife in the last 3 months?	Have there been any circumstances when you lost the peace of your mind leading to domestic violence at home in the last 3 months?

Reword every question to be neutral

Bad and Good questions

- Bad questions: How frequently do you use condoms while having sex with sex workers?
  - Very Often
  - Often
  - Sometimes
  - Rarely
  - Never
- Good question: It is better to quantify the choices, such as:
  - At each sexual intercourse
  - 3 out of 4 times
  - 2 out of 4 times
  - 1 out of 4 times
  - Never

Bad and Good questions

Leading question	How was your experience of personnel working at the ART center? 1. Excellent, 2. Very good, 3. Good, 4. Satisfactory
Some improvement	Did you like the approach of the ART center staff towards patients like you? 1. Yes, 2. No
More improvement	Do you feel that there is some possibility of improvement in the approach of the ART center staff towards visitors? 1. Completely disagree, 2. Agree, 3. Does not matter, 4. Disagree, 5. Completely disagree
Another improvement	What level of improvement is necessary in the approach of ART center staff? Please mark in the following scale :

Completely disagree	1	2	3	4	5	Completely agree

Care while designing questions…

It is important to avoid:

- **Asking for secondhand information:**

  [Question to wife about her husband]

  Can you tell how many sexual partners your husband must have had in the past 5 years?
- **Asking hypothetical questions:**

  Will you undergo sterilization operation after 2 children?
- **Asking for solutions to complex issues:**

  [To the sex worker]

  If you are under the influence of alcohol and you are not certain if your client used condom or his condom slipped or tore during sex, which of the following will you do?

  a. Look for torn condoms in the dust bin

  b. Ask the same client when he returns next time

  c. Will go to ICTC and seek advice

  d. Ensure that the client uses condom properly

Questionnaire design problems

- Some possible challenges to accuracy:
  - Questions not understood as intended
  - Don't adequately capture respondent's experience or views
- Problems may not be visible in the actual survey data: Issues in data analysis
- Can these be predicted before data collection?

Field Pre-test

- Small-scale study in which all the conditions of the full scale-survey are simulated
- Survey modes
- Interviewer oral debriefing and written reports

Field Pre-test

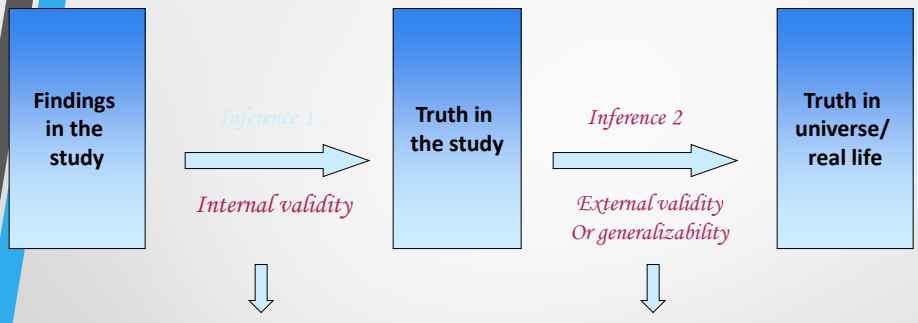
Warning signs:

- Variation (Skewed distributions)
- Response rate
- "No opinion" and "Don't know" rates
- Variable response patterns
- Problems faced by the interviewer with flow of the questionnaire

Questionnaires: Estimating reliability

- Reliability has to do with the quality of measurement. Practically speaking, reliability is the "consistency" or "repeatability" of your measures.
- Internal Consistency is one type of reliability measure. Cronbach's alpha measures internal consistency by how well a set of items (or variables) measures a single uni-dimensional latent construct.

Internal and external validity



Degree to which the investigator's conclusions correctly describe what actually happened in the study

Degree to which the investigator's conclusions are appropriate when applied to the universe

Overall goal is to maximize the validity and generalizability of inferences and this can be best achieved be employing proper study design

Preparing a questionnaire: Summary

- Target the vocabulary and grammar to the population be surveyed.
- Avoid ambiguity, confusion, and vagueness.
- Avoid emotional language and leading questions.
- Avoid double-barrelled questions.
- Avoid asking questions beyond a respondent's capabilities.
- Avoid false promises.
- Avoid asking about future intentions (if you can).
- Avoid negatives and especially double negatives.

Useful links and references

- http://www.statpac.com/surveys/surveys.pdf
- http://www.mathsisfun.com/data/survey-questionnaire.html
- http://www.scribd.com/doc/19038838/questionnaire-and-form-design
- http://www.cc.gatech.edu/classes/cs6751_97_winter/Topics/quest-design/
- http://sites.nationalacademies.org/PGA/Resdoc/PGA_044477
- http://www.iiep.unesco.org/fileadmin/user_upload/Cap_Dev_Training/Training_Materials/Quality/Qu_Mod8.pdf
- Ian Brace. Questionnaire design: How to plan, structure and write survey material for effective market research. Second edition. Published by Kogan Page, 2005.
- http://www.fao.org/docrep/w3241e/w3241e05.htm
- http://www.analytictech.com/mb313/principl.htm

Quantitative Research Methods & Sampling Designs

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Outline of presentation

- Data collection: strategies
- Data collection tools (Secondary data, Surveys etc.)
- Questionnaires: Design and steps
- Sampling designs

Data collection strategies

No one best way: decision depends on:

- What you need to know: number or stories
- Where the data reside: *environment, records, people*
- Resources and time available
- Complexity of the data to be collected
- Frequency of data collection
- Intended forms of data analysis

Which Data?

If you:	*Then Use:*
- want to conduct statistical analysis - want to be precise - know what you want to measure - want to cover a large group	Quantitative
- want narrative or in-depth information - are not sure what you are able to measure - do not need to quantify the results	Qualitative

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Quantitative Data Collection – Methods/Tools

- Records and Secondary Data
- Diaries, Self-reported Checklists
- Surveys and Interviews
  - Face to Face Interviews
  - Mail Surveys
  - Telephone/Internet Surveys
  - Computer Assisted Personal Interviewing (CAPI)
  - Diaries, Self-reported Checklists

Tool 1: Records and Secondary Data

Examples of Sources:

- ART registers (or) medical records
- Computer data bases
- Mapping data
- Census data and household survey data
- Documents (budgets, monitoring reports)

Advantages and challenges: Secondary Data

Advantages	• Often less expensive and faster than collecting the original data again
Challenges	• There may be coding errors or other problems. • Data may not be exactly what is needed. • You may have difficulty getting access. • You have to verify validity and reliability of data.

Tool 2: Field Based Surveys

- A structured way to collect information using questionnaires
- Surveys are advisable:
  - To collect standardized information from large numbers of individuals
  - When independent opinions and responses are needed
- Excellent for asking people about:
  - perceptions, opinions, ideas, and practices

Two are two common survey types

Structured	• harder to develop • easier to complete • easier to analyze • more efficient when working with large numbers
Semi-structured	• easier to develop: open ended questions • more difficult to complete: burdensome for people to complete as a self-administrated questionnaire • harder to analyze but provide a richer source of data, interpretation of open-ended responses subject to bias

Advantages and challenges: Surveys

Advantages	• Best when you want to know what people think, believe, or perceive, only they can tell you that
Challenges	• People may not accurately recall their behavior or may be reluctant to reveal their behavior if it is illegal or stigmatized. *What people think they do or say 'they do' is not always the same as 'what they actually do'.* • Response rates can be a concern • Sample size

Modes of survey administration

- Administered questionnaires (Face-to-face interviews) - Very common in the developmental context
- Self-administered questionnaires distributed by mail, e-mail, or websites
- Telephone surveys
- Computer Assisted Personal Interviewing (CAPI)

Tool 2.1: Face-to-Face interviews

- Helps in talking and listening to people
  - Verbally asking participants, the program evaluation questions and hearing the participant's point of view in his or her own words
- Can explore complex issues in-depth
- Can provide an intuitive sense of the situation
- Have a distinct advantage of enabling the researcher to establish rapport with potential participants and therefore gain their cooperation
- Yield highest response rates in survey research

Advantages and Disadvantages of Interviews

Advantages	• Flexible, adaptable • Glimpse into respondent's tone, gestures • Ability to probe, follow-up
Disadvantages	• Costly in time and personnel • Requires skill • Possible biases: interviewer, respondent, situation • Selective hearing on the part of the interviewer may miss information that does not conform to pre-existing beliefs

Tool 2.2: Mail surveys

- One of the oldest methods – e.g., Cancer surveillance
- Respondents complete questionnaires on paper and return them via the mail
- Questionnaires are typically short, simple, and contain predominantly closed-ended questions
- Suitable with highly educated respondents
- Accessibility is a challenge though
  - reliability of postal service
  - turn-around time
- Bias consideration
  - Due to very low response rates
- It needs to be structured questionnaire; open ended questions yield low response

Tool 2.3: Telephone / Internet surveys

- Less time consuming and less expensive
- Researcher can reach to anyone on the planet who has a telephone/access to internet
- Anonymity of respondents results in more honest answers to sensitive topics
- Response rate is not as high as the face-to- face interview but considerably higher than the mailed questionnaire
- Literacy issues
- Sample may be biased to the extent that people without phones/internet are part of the population about whom the researcher wants to draw inferences

Tool 2.4: Computer assisted personal interviewing (CAPI)

- A form of personal interviewing
  - Instead of completing a paper-based questionnaire, the interviewer brings along a laptop or hand-held computer device to enter the information directly into the database
- Saves time involved in processing the data, as well as saving the interviewer from carrying around hundreds of questionnaires
- Data collection can be expensive to set up and requires that interviewers have computer and typing skills
- Other method: **ACASI (Audio Computer Assisted Self Interview)**

Tool 2.5: Diaries and self-reported checklists

- Use when you want to capture information about events in people's daily lives (e.g., pill diaries)
- Participants capture experiences in real-time not later in a questionnaire
- Used to supplement other data collection

Guidelines for diaries

Step	Process
1	Recruit people face-to-face • participation, appeal to unselfishness, assure confidentiality, provide incentive
2	Provide a booklet to each participant • cover page with clear instructions, definitions, example • short memory-joggers, explain terms, comments on last page, calendar
3	Consider the time-period for collecting data • if too long, may become burdensome or tedious • if too short, may miss the behavior or event

Self-reported checklists

- Cross between a questionnaire and a diary
- The evaluator specifies a list of behaviors or events and asks the respondents to complete the checklist
- Done over a period of time to capture the event or behavior
- More quantitative approach than diary

Advantages and challenges: diaries and self-reported checklists

Advantages	• Can capture in-depth, detailed data that might be otherwise forgotten • Can collect data on how people use their time • Can collect sensitive information • Supplements interviews • Provide richer data
Challenges	• Requires some literacy • May change behavior • Require commitment and self-discipline • Data may be incomplete or inaccurate • Poor handwriting, difficult to understand phrases

Outline of presentation

- Data collection: strategies
- Data collection tools (Secondary data, Surveys etc.)
- Questionnaires: Design and steps
- Sampling designs

Steps in developing effective questionnaires

- Decide what information you need
- Determine sample – respondents
- Develop accurate, user-friendly questionnaire
- Develop plan for distribution, return, and follow-up
- Provide clear instructions and an informed consent
- Pilot test

Questionnaire design–Considerations

- Kind of information: What do you want to know?
- Wording of questions and responses (Open /Closed-ended)
- Sequence of questions
- Formatting the questionnaire
- Pre-testing

Things to avoid in questionnaires

- Complexity: use simple, direct, conversational language
- Leading questions: that suggest or imply certain answers
- Loaded questions: suggest social desirability, or are emotionally charged.
- Ambiguity and vagueness: Words such as "often", "occasionally", "usually", "regularly", "frequently", "many", should be used with caution. If these words have to be used, their meaning should be explained properly.
- Double-barreled questions.
- Burdensome or embarrassing sensitive questions.

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Sampling

Choice between Census and SAMPLE

Key sampling concepts

Who do you want to generalize to?

The Theoretical Population

What population can you get access to?

The Study Population

How can we get access to them?

The sampling frame

Who is in your study?

The sample = participants who completed study + drop-outs+ non-responders

Sampling Frame

The list defining the POPULATION (from which the sample will be drawn.)

- Examples:

– Line listing of brothels

– Transport establishments

– Household lists

Types of samples

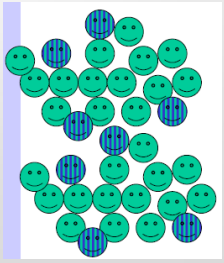
- **Probability Samples:** each member of the population has a known non-zero probability of being selected
  - Methods include random sampling, systematic sampling, and stratified sampling.
- **Nonprobability Samples:** members are selected from the population in some nonrandom manner
  - Methods include convenience sampling, judgment sampling, quota sampling, and snowball sampling

Types of Probability Samples

1. Simple random
2. Systematic random
3. Stratified random
4. Random Cluster
5. Stratified Cluster
6. Complex Multi-stage random

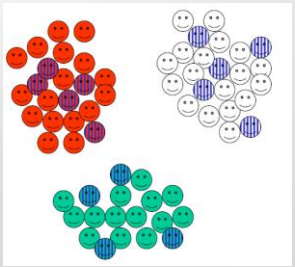
Simple Random Sampling

- Each element in the population has an equal probability of selection AND each combination of elements has an equal probability of selection
- Random numbers to select elements from an ordered list
- Random number table
- Time and cost intensive



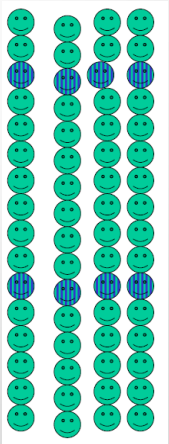
Stratified Random Sampling

- Divide population into groups that differ in important ways.
- E.g. Urban/Rural, A,B,C category of districts, brothel/home based sex workers
- Basis for grouping must be known before sampling
- Select random sample from within each group



Systematic Random Sampling

- Each element has an equal probability of selection, but combinations of elements have different probabilities
- Population size N, desired sample size n, sampling interval k=N/n
- Randomly select a number j between 1 and k, sample element j and then every kth element thereafter, j+k, j+2k, etc.
- Fairly easy to do



Random Cluster Sampling

Cluster sampling is used when:

- One do not have a complete list of everyone in the population of interest but have a list of the clusters in which they occur

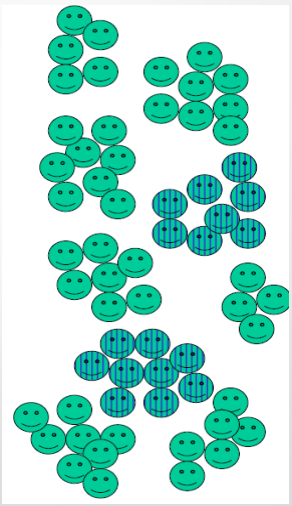
or

- One has a complete list of everyone, but they are so widely distributed that it would be too time consuming and expensive to send data collectors out to a simple random sample

Stratified Cluster Sampling

Population divided into groups, usually geographic or organizational. e.g., brothels as cluster, village

- Some of the groups (Primary Sampling Unit) are selected by using simple random sampling, systematic sampling or by Probability Proportional to Size
- In pure cluster sampling, whole cluster is sampled
- In simple multistage cluster, there is random sampling (Secondary Sampling Unit) within each randomly chosen cluster



Nonprobability sampling

1. Convenience sampling - Subjects selected because it is easy to access them. E.g. TV reporter interviewing people on street regarding opinion about corruption
2. Purposive sampling - Subjects selected for a good reason tied to purposes of research. E.g. Hard-to-reach populations
3. Quota sampling - Pre-plan number of subjects in specified categories. E.g. 100 men, 100 women
4. Snowball sampling - Identifying someone who meets the inclusion criteria, then ask them to recommend others who they may know who also meet the criteria.

Nonprobability sampling means you cannot generalize beyond the sample

Discussion

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Quantitative vs. Qualitative

Thought of as Objective	Thought of as Subjective
Research Questions include "How many" and "Strength of association"	Research Questions include "What," "How" and "Why"
Tests a Theory	Develops a Theory
Measurable	Interpretive
Strives for generalization – leads to prediction	Strives for uniqueness – leads to understanding
Basic element of analysis is numbers	Basic element of analysis is words/ideas
Context free	Context dependent

Elements of the Research Process

Deductive thinking (Quantitative)

THEORY

HYPOTHESIS

OBSERVATION

CONFIRMATION

Elements of the Research Process (Cont.)

Inductive thinking (Qualitative)

OBSERVATION

PATTERNS

HYPOTHESIS

THEORY

Definition

Qualitative Research is collecting, analyzing, and interpreting data by observing what people do and say.

Qualitative research refers to the meanings, concepts, definitions, characteristics, metaphors, symbols, and descriptions of things.

The "toolbox" of qualitative research

- PERSON
  - Self (the investigator)
  - Data Collectors
- LANGUAGE
  - Describing settings/cultures in their own terms
  - Challenge of working in a language you think you know
- EQUIPMENT
  - Digital Recorder, notebook, camera, laptop/iPad
- DATA COLLECTION TECHNIQUES

Sampling in Qualitative Research

- Purposive sampling,
- Quota sampling,
- Snowball sampling,
- Random sampling

Operational Issues

- Interference
- Generalizability
- Selection bias
- Note Taking
- Recording
- Training
- Quality control

Qualitative Research Techniques

- Focus Groups
- In-depth Interviews
- Participant observation (Participatory Methods)
- Case Studies
- Action Methods
- Document and Record Reviews Including Media Analysis

Focus Group Discussions

- Group discussions with a sample of carefully selected people who are brought together to provide their opinions on specific topics.
- Small FGDs : 4-8 members
- Large FGDs: 10-12 Members
- Homogeneous groups in at least one dimension

Focus Group Discussions

- One-on-many conversation
- To understand group norm on a particular topic. E.g. Opinion about an IEC campaign
- Not suitable for eliciting information on personal experience on sensitive topics
- Group dynamics may enhance or hinder information collected
- Ideally Six to eight participants-should be homogeneous
- Saturation: when stop hearing new info

Focus group facilitation

- Two people: facilitator and note-taker
- Using a recorder is recommended-it should not intervene research ethics or value free discussion
- Introduce group members and yourself
- Show interest and respect
- Actively listen; follow leads but stay "on topic"
- Encourage between-participant discussion; avoid group interview dynamic
- Varity of opinion is what aimed for but should not instigate conflict.
- Eye contact tip

Instruments

- **Discussion guide:** A list of questions and topics to be addressed.
  - *structured*
  - *Unstructured*
- Moderator -coordinates the discussion
- Note taker : takes notes and fills out an observation check list.
- Often the conversation is recorded and later transcribed for coding.

When to use - FGDs

- To collect qualitative and quantitative information from multiple people with similar characteristics.
- To gather feedback on perceptions of a program or an idea from a particular audience (i.e., clients of clinic, adolescent girls, program beneficiaries).
- To identify what socially accepted norms, values, beliefs are about specific topics or issues
- To test language and/or concepts that you think are relevant to a certain group and/or the program
- To provide feedback on things like public service announcements or awareness-raising posters.

Pros and Cons of FGDs

- **Pros:**
  - Quick way to get information (focus groups last 1 - 2 hours)
  - Gathers rich, descriptive data
  - High response rate, if it fits into participant's schedule
- **Cons:**
  - Logistics of organizing group interviews are time-consuming (i.e. need to schedule around their time, not yours. May need to provide childcare or snacks, etc.)
  - Mixed sex groups may inhibit women from talking.
  - Transcription might be necessary which can be time consuming to listen to and record

Field notes

- Note down conversations you overhear or has implications in your note book, when you hear it or as soon as possible
- Write details on place, persons, date etc.

Using Tape Recorder

- Don't rely on your memory, use tape recorder
- Informants will be conscious at first but will forget about the machine after discussion continues for a while
- Use good tapes. Transcribing involves listening, stopping, rewinding many times
- Test your tape recorder before every interview. Data lost is lost forever
- Check the battery indicator. Change battery and use long running batteries. Informant can not hold on to their thoughts while you change battery

Building rapport with respondents of FGD

- Welcome the respondent
- Greet the respondent with a smile
- Offer a seat to the respondent
- Introduce yourself and your team members (name and the organization you represent)
- Offer a glass of water to the respondent
- A small talk is good (light and casual conversation)– e.g., "*You had any difficulties in arriving at the venue?*"
- Offer tea/snacks to the respondent after completing the interview
- Inform that the Recorder is used only to captures the data
- Inform that the respondent will not be photographed. In case photographs are necessary, please inform in advance and get their consent. A separate consent form to be used for photography

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In-depth Interviews (IDIs)

- IDI is a detailed and personalized discussion between the interviewer and the interviewee.
- IDIs allow the interviewer to understand the interviewee's perceptions, attitudes and thoughts on a number of topics.
- On average, IDIs last from one to two hours.

Conducting in-depth interviews

- One-on-one method
- Preferred tool for exploring more sensitive issues
- Like a conversation-in a structured way
- Individuals talk about their **own** personal feelings, opinions, and experiences
- Active listener, moderating the narration skilfully, body language is important, balancing time through out the discussion, more probing skill is required
- Privacy is must
- Guide line has broad domains and lead questions , standard probes for most of the lead questions

Instruments - IDIs

- The interviewer uses an **interview guide or protocol**: a list of questions and topics to be addressed.
- *Structured* Interview: more standardized and specifically worded list of questions to be discussed
- *Unstructured interview:* follows an outline, or topic guide, and allows for more variation in conversational topic and flow.

When to Use - IDIs

- To get detailed information around topics that are not conducive to group interviews (i.e., sensitive issues and personal history)
- When you are exploring unfamiliar topics and need to use open-ended questions
- To explore a wide range of topics in which the respondent provides her or his opinions, attitudes, perceptions and reports on the occurrence of certain behaviors or events

Pros and Cons of IDIs

- Pros:
  - Allows for in-depth, detailed, "insider" information
  - A good interviewer can elicit excellent information and provide support or refer to services if and when needed
- Cons:
  - Interviewer's own opinions may be communicated in subtle ways and thereby influence the responses given
  - Get opinions from few individuals for relatively high cost
  - Requires high level of skill to avoid biasing responses

Some Operational Issues in Preparation of In–depth Interviews

DO NOT.....

- Go to any interview without interview guide
- Go to any interview without recording materials even if you are not sure to use it.
- Take more than an hour for a one-on-one interview

DO...

- Make a general list of questions to keep in your mind even if the interview is completely exploratory
- Develop a list of questions for your semi-structured interview

Interviewing process

DO NOT …

- Act in a judgmental way.
- Act surprised or disgusted even if you are.
- Show approval if you don't mean it.
- Strongly agree or disagree with things

DO…

- Accept hospitality including food
- Be sure the interviewee is comfortable with the location of the interview

Recording interviews

DO NOT …

- Take notes with a tape recorder without asking permission reveal confidences
- Share privileged information with other respondents in the field.

DO…

- Take notes – don't rely on your memory
- Write up notes right after the event or day is complete, otherwise you will forget
- Leave space between interviews to write up or jot notes down.

Six steps to good listening during the In-depth Interview process

i. Pay attention to the person.
ii. Signal that you are listening
iii. Do not be judgmental.
iv. Confirm what the person is saying.
v. Ask the person to repeat.
vi. Avoid asking "leading" questions that give the person the answer you want.

Building rapport with respondent- IDI

- Be one of them rather than an alien
- Do not be apologetic
- Always have a positive approach
  - *"I would like to ask you a few questions"*
  - *"I would like to talk with you for a few moments."*
  - ~~*"Would you spare a few minutes?"*~~
  - ~~*"Would you mind answering some questions?"*~~
- Stress confidentiality of responses
- Assure about the individual confidentiality (not taking names and address)
- Answer any questions frankly
- Interview the respondent alone – sensitive issues are involved

Please reflect on these pictures!

29

What about this interview?!

30

Good Qualitative Research Should…

- Capture the spirit of the program
- Create a partnership between the evaluator and the program participants
- Recognize and use the wisdom of program participants
- Improve services
- Illustrate the differences the program is making in people's lives
- Search for meaning behind opinions and numbers

Difficulties / Weaknesses of Qualitative Research

- Single qualitative studies cannot provide grounds for generalizing across cases.
- Qualitative research can be a high-risk, low-yield enterprise.
- It can take time to negotiate access, assemble a sample, develop trust and rapport, find out what is 'going on' or what people are thinking.
- 'Hanging around' and 'muddling through' can bring worries. Maybe one will not find 'reefs beneath one's feet' and drown in the maelstrom as a result!

Ethical Guidelines in Qualitative Research

- Explain the purpose of the research
- What is expected of a research participant, including the amount of time likely to be required for participation
- Expected risks and benefits, including psychological and social
- The fact that participation is voluntary and that one can withdraw at any time with no negative repercussions
- How confidentiality will be protected
- The name and contact information of the local lead investigator to be contacted for questions or problems related to the research

Ethical Guidelines in Qualitative Research

- Your duty and responsibility – regardless of review process!
- Informed consent
  - Participation is a voluntary choice of informed, competent individuals who understand the purpose of the study and its procedures
  - Clear about what study will and will not do
  - Oral / Written consent forms

Ethics in Research

National CB Workshop on OR in HIV/AIDS

28-30, March 2019, Sri Lanka

NSACP & VHS-CDC Project

MINISTRY OF HEALTH SRI LANKA

NATIONAL STD/AIDS CONTROL PROGRAMME

Presentation Plan

- Principles of Research Ethics
- Informed Consent, Confidentiality
- Responsibilities of Research Ethics Committees (REC), Sponsor, Researcher
- Conclusions

- Exercise: consent form

Experimentation

- We have been doing experiments since stone age like.....

Important violations

- At the end of World War II, the International Military Tribunal prosecuted Nazi war criminals, including physicians who performed experiments on concentration-camp prisoners.

  The tribunal's decision includes what is now called the **Nuremberg Code, a 10-point statement guiding physicians in the conduct of research on human participants.**

- In southern US more than 400 poor African-American men with latent syphilis were followed from 1932 to 1972 to study the natural course of syphilis. They were denied treatment even after discovery of penicillin in 1940s.

  The National Commission for the Protection of Human Subjects was established in 1974; the commission investigated and submitted a report titled **Belmont** Report which recommended the three ethical principles.

Lotus flower:
Symbol of Purity & Perfection

Ethics, Guidelines & Law

- Ethics – correct behaviour dictated internally by one's own moral integrity
- Guidelines – Norms for correct behaviour laid but not forced
- Law – Correct behaviour governed externally or enforced by State

Fundamental Principles of Human Research Ethics

1. Respect for persons
2. Beneficence
3. Justice

Principles of Research Ethics

Respect for persons

- Autonomy to make informed decisions & choices
- Dignity and respect for people & their culture

Beneficence

- Protection of participant is the responsibility of researcher
- Maximize benefit & minimise harm (physical, mental, social, legal, economic etc.)

Justice

- Special protection for the vulnerable groups
- Equitable recruitment for research participants

What does 'Respect' mean in Research Ethics

- The principle of 'respect' emphasises that every human being is unique, has the capacity to decide and the right to choose what is good or bad for him/her, based on correct and exhaustive information **(Voluntary Participation)**
- Like individual, this principle of 'respect' also recommends that the community of the individual participants are accepted 'as they are **(Respect Individual and Community Culture)**
- It is imperative that the individual participant and their communities are given relevant and correct information to understand reasons for participation, the risks and benefits involved and how the data will be used **(Informed Consent)**
- Community also has the autonomy to safeguard their people from the potential risks and involve themselves in the process of taking risk reduction measures **(Community Preparation)**

Respect for Persons (and Community)

- Autonomy, self-determination
- Capacity to decide, make choices
- The dignity of the people and the individual
- Respect for the community and local culture

What does 'Beneficence' mean in Research Ethics

- The principle of 'beneficence' emphasises that the respondent as a human being must be protected from all harms that eventually arises due to participation in the research **(Do No harm)**
- The risk to the community should also be minimised to the best possible extent for any of their members participating in the research **(Minimize Risk)**
- The participants and their community must understand how they will be benefited directly or indirectly from the research. But such benefits should not be an enticing factor to participate in the survey **(Maximize Benefit)**

Beneficence

- Physical, mental, and social well-being
- Risks reduced to a minimum
- Protection of the participant is the primary responsibility of the researcher
- Benefits for the communities where the research is conducted

What does 'Justice' mean in Research Ethics

- The principle of 'justice' appeals to the researcher to recruit participants **impartially, without discriminating on the grounds of social class, religion, differences in economic status or based on any other personal identities,** which the researcher may not feel comfortable with. **(Random Selection)**
- The researcher **should not also conveniently recruit respondents** based on their ready availability, vulnerability, and compromises they are ready to make. **(Random Selection)**
- The principle of 'justice' propagates **undertaking special protection measures for vulnerable populations in research**, like children, pregnant women & women in potentially risky circumstances, the poor, illiterates and those who do not have easy access to healthcare facilities, etc. **(Referral)**

Justice

- Distribution of risk and benefit
- Equitable recruitment of research participants
- Special protection for vulnerable groups

First Do No Harm

"Anathurak nokaranna"

"Primum non nocere"

"Pradhama na nash"

Vulnerable Research Participants (continued)

- Pregnant women, children, prisoners
- Mentally ill
- Those with limited education
- The poor
- Those with difficult access to health services
- Women in some circumstances
- Sex workers

International research guidelines, codes, regulations

- The Nuremberg code: **informed consent absolutely essential, qualified researchers use appropriate research designs, favorable risk/benefit ratio, participant must be free to stop at any time**
- The Declaration of Helsinki: **well-being of the subject should take precedence over the interests of science and society, consent should be in writing, use caution if participant is in dependent relationship with researcher, limited use of placebo, greater access to benefit**
- The Belmont Report: **Defined the three ethical principles "Respect for persons, Beneficence and Justice"**

International research guidelines, codes, regulations (contd.)

- **The US Code of Federal Regulations or The Common Rule:** Prior approval by ethics committee, written informed consent and documentation, equitable recruitment of research participants, special protection for vulnerable groups, continuing review of approved research
- **Council for International Organizations of Medical Sciences (CIOMS) Guidelines:** Informed consent, research in developing countries, protection of vulnerable populations, role of ethics committee, community participation
- **International Conference on Harmonization (ICH):** Standardize drug development and approval process, protocol development standards, review by ethics committee, researcher responsibilities, sponsor responsibilities

Sri Lanka Research Ethics Committees (REC)

- National and local institutional ethics committee
- All studies on clinical / drug / medical device trials need to be approved by National Medicine regulatory authority

What is Informed Consent?

Informed consent is consent given by a competent individual

who:

- Has received the necessary information
- Has adequately understood the information
- After considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement or intimidation

Essential elements of Informed Consent

- Research description (study objectives, duration, expected responsibilities, procedures involved, use of placebo, sponsor and responsible REC)
- Risks (Anticipated or foreseeable; physical, social and psychological; culturally appropriate)
- Benefits (Reasonably expected, no exaggeration, benefits available once research is ended)
- Alternatives (Alternative procedures or treatment; advantages and disadvantages; availability)
- Confidentiality (Degree of confidentiality; indicate persons or organizations who may have access to the information; special cultural circumstances)
- Compensation (Available compensation in case of injury; treatment available and cost; fair payment for time, travel or inconvenience; not coercive)
- Contacts (Contact for research-related questions; contact for concerns about rights as a participant; realistic and viable)

Voluntary participation (Absolutely voluntary; right to discontinue at any time; no penalty for refusal)

Development of Informed Consent Form

- Use local language
- Write for appropriate reading level (check readability score)
- Illustrate with appropriate concepts and images
- Perform a translation and back-translation
- Pilot test

- Exercise of developing a consent form

Principle	Application
Respect for persons ➢ Individuals should be treated as autonomous agents ➢ Persons with diminished autonomy are entitled to protection.	**Informed consent** ➢ Subjects, to the degree that they are capable, must be given the opportunity to choose what shall or shall not happen to them ➢ The consent process must include three elements: ☐information, ☐Comprehension, and ☐voluntariness.
Beneficence ➢ Human subjects should not be harmed ➢ Research should maximize possible benefits and minimize possible harms.	**Assessment of risks and benefits** The nature and scope of risks and benefits must be assessed in a systematic manner
Justice ➢ The benefits and risks of research must be distributed fairly.	**Selection of subjects** ➢ There must be fair procedures and outcomes in the selection of research subjects

Responsibilities of REC

- Initial review and approval of a research study
- Conduct regular review of ongoing research
- Review all modifications and amendments to approved research
- Monitor active research studies for compliance
- Investigate problems that could impact the participants

Responsibilities of Sponsors

- Select qualified researchers
- Provide necessary support
- Require appropriate ethical review
- Promote research integrity
- Comply with local ethical, regulatory and legal requirements
- Ensure the local relevance of the research
- Assist in capacity building
- Post-trial responsibilities

Responsibilities of Researcher

- ✓ Protection of research participants: Scientific correctness; appropriate informed consent; confidentiality protection
- ✓ Conduct research according to the protocol
- ✓ Conduct the research with integrity
- ✓ Compliance with REC requirements: report adverse experiences, protocol violations, participant complaints
- ✓ Post-study: long-term interests of participants

Researcher's Human Qualities

- Integrity
- Respect
- Compassion
- Professionalism
- Courtesy
- Sensitivity

Community Participation in Research

Responsibilities of Community representatives:

- Ensure that research is responsive to community needs and expectations
- Advocate for the well-being of research participants
- Ensure appropriate informed consent
- Promote access to research benefits

- However, they are not responsible for review and approval of research protocols
- Researcher responsibility: Before study inform community; during the study follow study progress; and after the study share the research findings

Ethical Issues in Clinical Research on HIV/ AIDS

- Informed Consent – Assent, fresh or re-consent
- Confidentiality
- Vulnerable populations
- Risk benefit ratio
- Standard of Care
- Ancillary care
- Reimbursement / inducement ?
- Post trial access
- International collaboration

Conclusions

- All study protocols need to be approved by appropriate RECs, for international projects often multiple committees
- Researcher needs to ensure study is conducted as per protocol, needs to follow REC regulations, report violations
- Quality time needs to be spent in development of informed consent form, and ensure strict practice of consent procedure
- Involvement of community is an added advantage

Key Resources

Sri Lanka Medical Association (SLMA)

https://slma.lk/committees/committees/ethics-review-committee/

Faculty of Medicine, University of Colombo, Sri Lanka

https://med.cmb.ac.lk/index.php/2012-05-16-05-25-21/ethical-review-committee

Ethics Review Committee, Medical Research Institute, Sri Lanka

http://www.mri.gov.lk/invitation-for-collaborative-research/ethics-commiitee/

FHI Research Ethics Training Curriculum, self-learning course and certification

Http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/index.htm

POPULATION COUNCIL
Ideas. Evidence. Impact.

Principles of scientific writing

Dr. Niranjan Saggurti

National CB Workshop on OR in HIV/AIDS
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Type

- Report
  - mostly descriptive, usually for donors, program managers
- Scientific papers
  - mostly analytical, contributes to scientific knowledge, academics, researchers

Format of a report

- Executive summary
- Introduction
  - Background, objectives
- Methodology
  - Study design, sampling, data collection, indicators
- Results:
  - Accessibility, Functioning, Quality
- Summary
- Implications

Format of a Scientific Paper

- Title
- Abstract: structured and not structured
- Introduction
- Methods
- Results
- Discussion
- References

What makes a Good Title?

A good title clearly describes the contents of the paper in the fewest possible words

Common Title Faults

- Too short
- Too long
- Ambiguous or inappropriate for a journal article
- Poor syntax or careless grammar
- Use of abbreviations or jargon

A Formula for Writing a Title

- Include the independent and dependent variables in your title:

  "The effect of X on Y"

  or

- Include the relationship between variables that you are trying to explain:

  "The relationship between X and Y"

Exercise 1

Identify the problems with the following titles (e.g., too long, ambiguous).

- Short Birth Intervals Don't Kill Women
- Prolonged Labor in Rural Ethiopia: A Community-based Study
- Willingness to Pay by Female Sex Workers for Female Condoms and Male Sex Workers for Male Condoms

The Abstract in Brief

The abstract focuses on three points:

1. What was the research question?
2. How did you investigate the question?
3. What did you find?

These three points are also the basis of your paper.

Purpose of the Introduction

- Gives background or context of study
- Reviews knowledge on topic
- Justifies need for the study
- Provides information on study objectives and hypothesis

Organization of Contents in the Introduction Section

1. Broad issues
2. Immediate problem
3. Justification for study
4. Objectives/hypothesis of study

Elements of the Methods Section

- Study design
- Sampling
- Study setting(s)
- Screening and recruitment
- Study procedures/field Implementation
- Measures
- Statistical/data analysis

Results Section

- Present results in the same order as the objectives, hypotheses
- Present only data that demonstrate the results of the study
- Do not present information only because it was collected

Discussion Section: Format

- Main **conclusion**
- Brief summary of most important evidence
- Interpretation of results
- Findings consistent or inconsistent with other studies
- Limitations of the study
- Implications for theory, policy, and programs

The section is more than a summary of findings or list of recommendations

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Research Project Management

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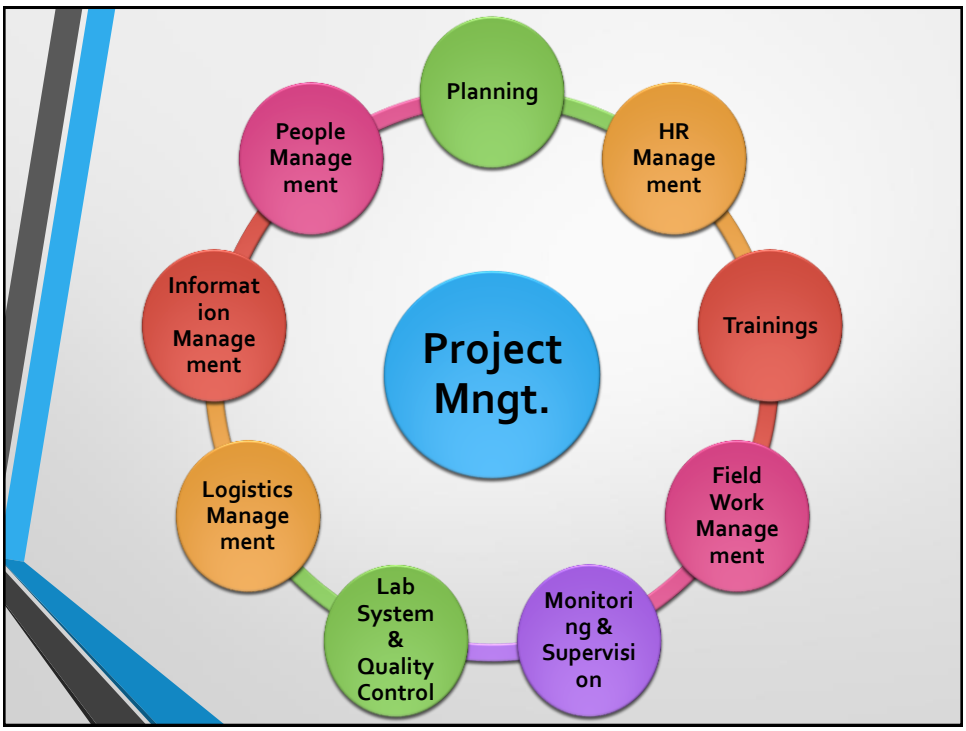

- Planning
- HR Management
- Trainings
- Field Work Management
- Monitoring & Supervision
- Lab System & Quality Control
- Logistics Management
- Information Management
- People Management

Planning a Research Study

- Scale of the study
- Timelines
- Budgets
  - Staff salaries
  - Meetings & Training costs
  - Printing costs
  - Cost of commodities
  - Field work costs including travel, stay, communication etc.
  - Cost of data collection, entry & analysis
  - Lab costs; Rents, etc.
- All the other management functions – Staff, Training, Field work planning, logistics, monitoring & supervision etc.

Timeline

Activity	1	2	3	4	5	6	7	8	9
Hiring staff Ethical approvals									
Tool development									
Pretesting of tools									
Adaptation of intervention manual									
Baseline Data collection									
Intervention roll out									
Endline data collection									
Data entry									
Qualitative interviews									
Data analysis									
Final report									
Dissemination meeting									

HR Management

- Recruitment Process
- Gender & Language considerations
- Recruitment Formalities
- Training & Screening Out
- Drop-out Management
- Quality Monitoring & Certificates
- Grievance Redressal
- Performance Monitoring

Trainings

- Training plan – batch planning
- Appropriate grouping of trainees – doctors, support staff, etc.
- Resource persons
- Training material – Training manuals, Facilitator's manual, Group exercises, instructions, resource material, stationary
- Venue arrangements – seating, AV, sound system etc
- Travel & stay of participants & resource persons
- Quality of training - Monitoring
- Training Reports

Field Work Management

- Number of field work days, no. of field staff & quantum of data collected per day
- Put more hands and finish the data collection in a short time – More efficient & decreases overhead costs; But, quality control across the investigators an issue
- Field preparedness
- Logistics & supplies for field work
- Field travel & stay during field work
- Communication & reporting
- Field supervision, handholding & verification
- Mechanisms for Adverse Event Management
- Quality of data collection/ interviews/ FGDs

Monitoring & Supervision

- Data-based monitoring
- Selection of supervisors
- Training of supervisors
- Field travel & reporting
- Monitoring Formats
- Action taken on feedback

Logistic Management

- List of consumables & commodities
- Unit costing, procurement plans
- Packaging & supply to field teams
- Quality of material
- Storage in the field
- Return & repair of damaged stocks
- Stock updates

Information Management

- Clear reporting system – who, how, when
- Reports – Trainings, Field work, supervision, etc.
- Coordination b/w various units, labs, field teams, stakeholders, etc
- Communicate to Ethics Committees & Approving authorities

People Management

- Know your stakeholders, professionally & personally
- Do not pre-judge people; Do not carry predetermined notions
- Be accommodative & cordial
- Appreciate other persons' situation before reacting; Empathise
- Be firm, but not rude
- Focus on Issues, Actions & Deliverables; Never personalise issues
- Focus on solutions rather than arguing on who is at fault
- Avoid friction as much as possible; Do not allow confrontation that affects all future work
- Do not engage in blame game
- Ensure confidentiality while giving feedback on individuals
- Provide support & encouragement

Be Alert, Prompt & Pro-active

- Be alert to issues, problems, exceptions & violations
- Be prompt in responding to an issue
- Be proactive in reaching out to people; Do not wait for hierarchical reporting

Communicate, Coordinate & Troubleshoot

- Manage effective communication – upwards & downwards
- Communicate in time using appropriate means
- Identify the right stakeholders to address an issue
- Coordinate with & among stakeholders
- Facilitate interaction in a congenial environment
- Enquire the facts from the right sources before reacting/ commenting/ concluding
- Take decisions that are professional & fair
- Involve the right stakeholders in troubleshooting

Comfort, Assure & Motivate

- Realise that everyone is under stress; Comfort others in need
- Assure your support at all times
- Highlight the larger common goal; Undermine personal flaws
- Motivate for individual & team excellence

Next Steps & Follow Up Plans

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Next Steps (1)

First Month

- Identification of PI, Co-PI, Collaborators, etc.
- Updating & Completing the draft protocols
  - Add literature review, background, etc.
  - Refine objectives & research questions
  - Do scoping based on financial assistance & feasibility
  - Analysis & Tabulation plan
  - Broad field work plan
- Development of tools, consent forms, etc
- Mentoring support from VHS-CDC Project
- Application to Institutional Ethics Committees & Obtaining Ethics Clearance

Next Steps (2)

Second Month

- Obtaining formal administrative approvals
- Receiving funding
- Planning & Preparation

Third Month

- Recruitment of staff
- Training of staff

Fourth & Fifth Months

- Field work
- Quality control
- Data entry & management

Sixth Month

- Data analysis & Report writing
- Dissemination of results
- Winding up admin formalities

Issues & Concerns?

Wish You All The Best!!!

References:

- The sessions will be supported with presentations and discussions.
- Handout for the presentations / resource materials will also be provided for primary references during the sessions.
- Handouts for the presentations and reference materials will also be provided in the form of soft copies.
- The reference materials included in this book are meant for additional reference purposes for further information to complement the training sessions.
- Any additional reference materials (other than provided in this reference book) may also be accessed and referred.