PACIFIC JOURNAL OF MEDICAL SCIENCES



VOLUME 6, No. 1, July 2009

PACIFIC JOURNAL OF MEDICAL SCIENCES (Formerly Medical Sciences Bulletin) ISSN: 2072 – 1625

1

Volume 6, No. 1, July 2009

A multidisciplinary journal for publication of medical and biomedical research findings on issues pertinent to improving family health and related issues of public health

Editor – in – Chief Dr. Phillip Kigodi

Associate Editors Associate Professor Andrew Masta Dr. Prem Rai Professor Francis Hombhanje

Managing Editors Professor Lohi Matainaho Associate Professor Victor J. Temple

Speciality Editors and Editorial Board Members

Dr. Adolf Saweri, Dr. Jacob Morewaya, Ms. Estelle Jojoga, Dr. Subhadda Perera, Dr. Jackson Lauwo, Dr. Wangi Linjim, Mr. Gairo Gerega, Dr. Irine Abramova, Dr. Paulus Ripa, Dr. K. Beaga, Mr. R. Kitau

INFORMATION

SUBSCRIPTIONS: Correspondences concerning subscriptions, purchase of single copies and back issues, lost copies and related business should be addressed to the Secretary, Basic Medical Sciences, School of Medicine and Health Sciences, University of Papua New Guinea, P. O. Box 5623 Boroko, N.C.D., PNG. Instructions to Authors are indicated at the back of the journal.

PACIFIC JOURNAL OF MEDICAL SCIENCES

(Formerly MEDICAL SCIENCES BULLETIN)

A multidisciplinary journal for publication of medical and biomedical research findings on issues pertinent to improving family health and related issues of public health

JULY 2009; ISSN: 2072 - 1625 VOLUME 6, No 1

TABLE OF CONTENTS

Editorial	4
PROCEEDINGS OF THE SCHOOL OF MEDICINE AND HEALTH SCIENCES RESEARCH WORKSHOP ON DESIGNING AND CONDUCTING RESEARCH	5
PAPERS PRESENTED AT THE WORKSHOP	ō
Welcome address by Prof. John D. Vince	ō
Relationship Between a Well Written Research Proposal and Successful Sourcing of Research Funds Dr. Wilfred Kaleva & Mr. Tony Lupiwa	7
Research Question and its Significance Assoc. Prof. Victor J. Temple	1
Study Designs and Selection of Appropriate Methodology Dr. Wilfred Kaleva & Mr. Tony Lupiwa	ō
Paper presented by: Dr. Wilfred Kaleva & Mr. Tony Lupiwa 15	ō
Choice of Subjects and Selection Procedures Inclusion and Exclusion Criteria - Clinical versus Community Populations <i>Dr. Jackson A K Lauwo</i>	2
Choice of Sampling Designs and Options Dr. Florence. Muga	7
Selecting Appropriate Variables Dr Paulus Ripa	9
Statistical Analysis and its Interpretation <i>Dr Paulus Ripa</i>	1
Ethical Issues in Medical Research Professor John D Vince	3
Doing Research with Limited Funding Dr. Irina Abramova	ō
Structure of Research Paper for Publication Dr. Prem P. Rai	3

Plagiarism in Biomedical Research Prof. Jean McPherson	63
Structure of Master of Medicine Thesis Dr. Adolf. Saweri	68
Referencing Styles Ms Dillie George	73
Entering and Processing Data: Database structure and Statistical analyses, Precision, Accuracy, and Validity <i>Mr. William Yeka</i>	80
How to Prepare Scientific Presentation Using MS Power Point Mr. Godfrey Morisa	84
PAPERS PRESENTED AT THE JOINT DIVISIONAL SEMINAR SERIES:	
PAPERS PRESENTED AT THE JOINT DIVISIONAL SEMINAR SERIES: DIVISIONS OF BASIC MEDICAL SCIENCES, HEALTH SCIENCES AND DENTISTRY FOR JANUAR' TO JULY 2009	Y
Prevalence and Determinants of Non-Adherence to Highly Active Antiretroviral Therapy among HIV/AIDS Patients in Heduru Clinic, Port Moresby General Hospital <i>Lisa Ijape and Victor J. Temple</i>	92
A Physiological Approach to Adolescence Behavior and How to Channelize it in Right Direction <i>Dr. Subhra Datta</i>	103
History of Dentistry in Papua New Guinea Dr. S.L. Perera 1	111
Assessment of the Costs of Medicines and Laboratory Tests in the Management of Opportunistic Infections in Patients with HIV and AIDS at Port Moresby General Hospital	
Nancy Bala and Phillip Kigodi	113
INSTRUCTIONS FOR AUTHORS 1	121

4

EDITORIAL

This volume of the Pacific Journal of Medical Sciences (Vol. 6, No.1, 2009) has devoted most of its pages on the issue of designing and conducting biomedical research. It brings out the proceedings of the recent Workshop on "Designing and Conducting Research" which was held at the University of Papua New Guinea (UPNG) School of Medicine and Health Sciences (SMHS) on the 4th and 5th of June 2009. This issue of the Pac J. Med. Sci. presents a synopsis of all the presentations made at the two-day workshop.

The editorial team wishes to sincerely thank the Administration of the SMHS, UPNG, for organizing the workshop. We thank all the resource persons for providing edited copies of their presentations for inclusion in this volume. Their efforts will undoubtedly stimulate and facilitate further research at the University of Papua New Guinea. We hope our readers (students and staff) find these materials useful in designing and conducting their research – which, in turn, may warrant many more similar workshops in the future.

Editor-in-Chief

PROCEEDINGS OF THE SCHOOL OF MEDICINE AND HEALTH SCIENCES RESEARCH WORKSHOP ON DESIGNING AND CONDUCTING RESEARCH

> Held at the School of Medicine and Health Sciences, Nursing Lecture Theatre, Thursday 4th and Friday 5th June 2009

PAPERS PRESENTED AT THE WORKSHOP

Welcome address by Prof. John D. Vince

Deputy Dean School of Medicine and Health Sciences (SMHS), University of Papua New Guinea (UPNG)

On behalf of the Executive Dean, Professor Sir Isi Kevau it is my pleasure to welcome you all to this very important Research Workshop in the School of Medicine and Health Sciences (SMHS), University of Papua New Guinea (UPNG).

Universities exist to foster learning and to produce graduates in the various disciplines, equipped with the knowledge and the attitudes required to function at the highest levels of professionalism. The SMHS exists to produce highly qualified professional graduates across disciplines and in the wide, spectrum of the health work force. The core function of a University is the provision of learning opportunities in an environment conducive to learning. The function is traditionally divided into "Teaching and Learning", and "Research". At one end of the spectrum is the activity of didactic teaching - University academic staff "pouring" information into students, whilst at the other end of the spectrum, is the "pure" researcher, shut away in a laboratory doing his or her own thing and quite often hardly noticed by the main student body. In reality of course adult learning inherently involves research in its broadest sense - the finding out of information for oneself. This can be done by consulting textbooks, learning resources, and Internet and intranet information. It can also be done by conducting research projects, directed at answering specific questions. Such research projects are becoming increasingly important in both undergraduate and postgraduate courses.

In spite of limited staff and less than optimal facilities, most would agree that the SMHS does reasonably well in formal teaching, and does provide opportunities for student directed learning. It is in the area of the design and supervision of research projects that there is a perception that the school could do better. Whilst acknowledging that there are members of staff with impeccable and impressive research credentials who produce research work of the highest standard, published in the international literature, it is probably true to say that many staff feel uncomfortable in their understanding of research design and methodology, and of epidemiology and statistics and in their ability to adequately and professionally direct their students in research projects.

5

Research- the search for new information requires a considerably different approach from classroom based didactic teaching and learning and in many ways is more difficult. Among other things it requires:

- A clear and concise, research question
- An understanding of research methodology
- The choice of a suitable and realistic research design to answer the question
- Rigorous intellectual and self discipline
- An understanding, appreciation and respect for ethical and legal issues in research
- An understanding of data collection and of data analysis and interpretation
- Knowledge of the relevant literature
- Knowledge of the accepted format for the writing up and presentation of the research
- Patience and perseverance
- An understanding of financial implications and requirements and of how to access research funds if these are necessary

Medical research covers a huge spectrum ranging from the search for new molecular genetic mechanisms for various and sometimes rare diseases, to the search for ways to modify human behaviour. The SMHS, has the capacity to support research across a range of relevant areas including laboratory based research, observational and descriptive research of patients, their illnesses, management and outcomes, and research into behaviour and health systems and public health programmes.

This Research Workshop is the first of its kind to be held by the School, and it is very encouraging indeed to note the very high attendance of Staff from all Divisions of the School. On behalf of the Executive Dean, Professor Sir Isi Kevau and the School, I commend Assoc Prof. Victor Temple, and his team, Dr. P. Kigodi, Dr. A. Saweri, Mr. R. Kitau, Dr. F. Muga, Dr. I. Abromova, Dr. P. Ripa, Dr. S. Perera and Ms E. Piskupe, for taking the initiative to organize this event. Many thanks also to Professor Lohi Matainaho for the generous support. I wish you all many congratulations and best wishes for а successful, enjoyable and productive next two days.

7

Relationship Between a Well Written Research Proposal and Successful Sourcing of Research Funds

Paper presented by: Dr. Wilfred Kaleva & Mr. Tony Lupiwa Research Co-ordination Unit, National Aids Council Secretariat, PNG

Introduction:

Research Co-ordination Unit in National AIDS Council Secretariat is in charge of research and the Research Advisory Committee gives Ethical approval for all HIV AIDS research in PNG.

Topics that will be discussed in this presentation include the following: Research proposal & Research funds, Applications for research funds, Share some information based on experience – applications for HIV AIDS research in PNG.

Well written research proposal:

How do you write a well written research proposal? You have to set up an appropriate plan. What is the problem you are trying to investigate? What are the research questions? What methodology will you use? What type of analysis will you use? Who are the members of the research team? How will the research be funded? What are the sources for funding the research?

Some important issues that you have to consider before writing the proposal:

What are the requirements of the funding organization? Is there an application form? Is there a standard format that they use?

Always have preliminary talks with stakeholders, and possible study participants. Is there a team

involved in the study? What expertise is there? Is there a need to involve a specialist or experienced researcher? For beginning/ young researchers a mentor is always needed. The mentor should be an experience researcher that is willing to listen, provide answers to questions and discuss appropriate issues related to all aspects of the research.

Core components of a good research proposal:

Abstract: Provide a brief summary or abstract of the project in non-technical language; which should include the aims and significance of the project, such as its potential for improving human health, etc.

Full research description:

The overall plan, for the project should include the following headings:

Background: What is the relevance of the study and evidence of need? Provide references to past research studies and literature. Relevant documents must be quoted:

For example, relevant documents on HIV/AIDS in PNG must include the following:

PNG National Research Agenda for HIV and AIDS 2008 – 2013

PNG National Strategic Plan on HIV/AIDS 2006 - 2010 National Gender Policy and Plan on HIV and AIDS 2006 – 2010

The 2007 Estimation Report on the HIV Epidemic in PNG

PNG UNGASS 2008 Country Progress Report

Previous studies quoted, in the area that you are interested in researching, especially from PNG, Pacific or similar developing countries.

Other examples, if the research is on Masculinity, violence, and sex, then known studies in PNG: The National Sex and Reproduction Research Team & Jenkins 1994, *National Study of Sexual and Reproductive Knowledge and Behaviour in Papua New Guinea*, 28; Lewis, Maruia, Mills & Walker 2007, *Final Report on Links between Violence against Women and the Transmission of HIV in PNG*;

NSRRT & Jenkins 1994; Wardlow 2007, *Men's Extramarital Sexuality in Rural PNG*; Wilde 2007, '*Turning Sex into a Game*';

Selection of research methods: This section must include the following:

The appropriate Study design with justifications, Sampling, Participant selection, Piloting plans, Data collection plan indicating sites and why they were selected, Data collection tools (questionnaires, surveys, focus groups, observation, ethnography) and method for Data analysis

You also have to include the following: Plans for validating results, Reporting and Dissemination, Risk Assessment, Ethics consideration, Budget

and its Justification, Timeline, and Capacity building component. In addition, a letter of support/ethics approval/ affiliation from a government, research institute or university is needed.

Appropriate approval is also needed from authorities, such as Provincial AIDS Committee (PACS), Medical Research Advisory Committee (MRAC), Research Advisory Committee (RAC), etc.

PARTNERSHIPS: this is needed especially for researchers with limited experience. It is important to include specialists in the area of research, example an experienced Social scientist for behavioural research.

Assessing research proposals:

A key question during the assessment of the research proposal is: Does the research proposal meet all the criteria required by funding organization? This is very important for obtaining ethical approval and funding of the research project. Initial screening is to ensure that time, appropriate documentation, attachments etc, are clearly indicated and included.

Peer review process: The assessment criteria:

All research proposals are assessed based on the following research criteria:

Relevance: Designed to address stated problem: e.g. STI or HIV and AIDS epidemic;

Based on social context, research context; Demonstrates understanding of and respect for local norms, this may also include networks and cultures of marginalized groups; Ethical consideration, gender issues appropriately addressed.

Evidence of need: Based on one of the prioritized areas of research, predetermined (as in the National Research Agenda for HIV/AIDS); Based on identified need as demonstrated by reference to past research studies or literature; Not repetitious of other research previously conducted or is currently conducted; Consistent with PNG National Strategic Plan (NSP) and Medium Term Development Strategy (MTDS).

Rigorous research methods including appropriate pilot (providing opportunities to make changes, including validation of data collection tool); appropriate data collection and sampling (probability sampling used where possible and appropriate), appropriate method for analysis of data, reporting of data and dissemination of research findings and report.

Appropriate research design for intended outcome: Cohort/longitudinal, before and after studies. case-control. observational. interventional/experimental. surveys and documentary; Qualitative studies used for exploration and understanding perceptions and beliefs, socio-cultural and other contextual and structural issues; as well as social impact; Quantitative studies used for measuring effectiveness, impact, causal relationships. burden of disease or degree of affect.

Cost effectiveness: Demonstrate costs (financial, time, work) complement potential benefits and outcomes of the study, it is

important to demonstrate how other resources already in place will complement resources requested in proposal.

Acceptability: Demonstrate the support and acceptability of the proposed work by potential participants and/or stakeholders. Consider the values of stakeholders and their ability to respond to new technologies. Plans to pilot and validate data collection tools. Indicate acceptability of the plans by the gate keepers (LLG, politician, authorities).

Feasibility: Demonstrate the ability to manage and complete the project, based on experience and expertise. Demonstrate the capacity of the applicant to undertake the proposed activities. Is there potential access to participants or community where research is to be conducted? How realistic is the budget?

Partnership: Demonstrate efforts and plans to work with national/local institutes, organizations including engagement with the local community. Indicate collaboration and consultation with experts on the topic and/or context. Show evidence for collaboration and endorsement from PACS in relation to the specific location where proposed research is to be based.

Ethics: Issues related to informed consent, confidentiality and codes of practice should be discussed. Where applicable, all issues relating to animals, blood products or biological samples must be appropriately addressed. Full respect for the human rights must be integrated at all levels of the proposal as appropriate. Timeliness: Need to present clear plans to conduct all steps of research in a realistic and timely manner including analysis, dissemination and reporting. The timetable should be included as a separate section in the proposal.

Risk assessment: Potential risks to all parties involved in the research project must the identified and appropriately indicated. Suggested plans to mitigate risks to all parties involved in conducting the research as well as participants/stakeholders should be included.

Principal Investigators and Collaborators: List the name and qualifications of the principal investigator(s) and the names and addresses of all collaborating investigators. List any relevant publications by the principal investigator(s). Copies of the CVs of investigators should be included in the documentation package.

Overall presentation of intended research study: Clear aims and objectives (measurable) of the study must be indicated. Clear identification of target group (s) should be indicated. Sourcing of funding: The source of the funds for the research project depends on a number of factors, such as: Quality of research proposal; whether the proposal addresses priority areas in the category of research (example, HIV AIDS research); whether the proposal addresses priority areas of funding organization (s).

For competitive grants, where proposal fits into the priority list, then the issue is whether the proposed study is a repeat of other studies. Repeat studies usually have low priority. Other factors may include the reputation of the organization or the principal researcher. High profile and reputable organizations and research institutions usually have higher priority.

Available funds: The availability of funds for such area of research is also a major issue.

Acquittals: This is an important aspect for further funding of a research project. Progress report, appropriate and timely acquittals of funds is a prerequisite for further funding of a research project.

Research Question and its Significance

Paper presented by Assoc. Prof. Victor J. Temple Division of Basic Medical Sciences.

School of Medicine and Health Sciences, University of Papua New Guinea

What is research?

Research is any form of systematic and organised investigation that is carried out to establish facts or collect information, and is usually related to a problem that needs to be solved [1]. Research must start with a question that addresses the issue to be investigated. A researcher must be able to find an important question that can be transformed and developed into a feasible and valid study plan. It should be noted that a topic of interest presented in the form of a question does not usually make a good research question.

What is a research question?

The research question is the problem that you wish to resolve in the research study. The research question defines the area of interest in your study and forms the foundation of your research. It is important that the research question be stated clearly before writing up the proposal and commencing the study [1, 2].

Most experienced researchers either intentionally or unintentionally do not focus on the research questions when preparing their research proposals. However, the golden rule for young and inexperienced researchers is that they should always spend reasonable amount of time to generate good research questions before writing the research proposal [1, 2, 3].

What are the sources for research questions?

There are several sources for the research questions. Sources such as, published literature. scientific papers, scientific conferences and meetings. seminars. questions from students, discussions with colleagues, patient observation, related or even unrelated areas of interest, news papers, observing the general view while riding on a bus or taxi, may all give rise to research questions, or may help to generate questions for research. Access to a good library and the internet is vital for any successful research.

How significant is the research question?

The research question is one of the most critical sections of a research proposal - it defines the proposal, it guides the arguments and inquiry, and it can arouse the interest of reviewers and funding agencies [1 - 4]. A poorly constructed research question usually leads to a poorly crafted research proposal, which is unlikely to be successful in obtaining a research grant.

There is no well defined format for crafting a conceptually innovative research question. However, there are some general guidelines that have been proposed [1 - 4]. According to these guidelines, a good research question should be evocative, relevant, clear and researchable. An evocative research question is one that can arouse the interest of reviewers and make them interested in reading the research proposal. The research question should be concise, readable and self-explanatory, with very few variables and clauses.

Some examples of research questions include the following:

Let us assume that the area of interest of the researcher is "Adherence to Highly Active Antiretroviral Therapy (HAART) by people living with HIV/AIDS (PLWHA) in the National Capital District (NCD)"

Two possible research questions are: What is the prevalence of non-adherence to HAART among PLWHA in NCD? Do poor nutrition, forgetfulness, stigma, employment status, marital status, and education affect adherence to HAART among PLWHA in NCD?

The first research question is more acceptable than the second. The reviewers of the proposals can easily focus on the main aspect of the proposal, rather than the variables that the researchers intend to study. All the variables listed in the second research question can easily be included within the proposal.

Let us assume that the area of interest of another group of researchers is the response of some patients to Scoline anaesthetic exposure to or organophosphorus pesticides and insecticides. Two possible research questions are: What dibucaine number is prevalent among individuals in NCD? What is the level of Pseudocholinesterase in healthy individuals in NCD?

Both research questions are acceptable, because the first question is related to the genetic variants, whereas the second is related to possible induction caused by exposure to esters of choline and organophosphorus compounds, which is also related to forensic questions.

What are the criteria for a good research question? The recommended criteria for research questions have the acronym FINER [1, 2, 4]:

Feasibility:

The sample size for the subjects must be adequate: thus the need to know how to calculate the sample size. The non-response rate and prevalence must be included in the calculation of sample size. It is important to set reasonable exclusion and exit criteria, in addition to reasonable time frame for the study.

Technical expertise must be adequate: thus, the need to ensure that members of the research

team have the appropriate skills, the equipment, the experience needed for recruiting the subjects and for measuring and analysing the data obtained.

Affordability in time and funds: It is important to make reasonable estimates of the budget and to identify the source(s) of funding for the project.

Manageability: One should ensure the scope of the project is not too ambitious. Thus, the researchers need to narrow the scope of the study and to focus on specific aims. The researchers should avoid trying to answer too many questions in one research project this can be counter productive.

Interest:

The research question must be interesting/ compelling. A well-framed research question which captures people's attention and excites their curiosity is an important factor not only in the process of proposal writing, but also in the entire planning and execution of the research project.

Novelty:

In order to generate interest, the research question must be new and relevant; research projects that merely repeat already established ideas are not novel or relevant. Novel research may ask whether a previous observation can be replicated, whether the findings in one population also apply to others, or whether improved measurement techniques can clarify the relationship between known risk factors and a disease.

Ethics:

Ethical implications must be considered when formulating a research question. The researchers must obtain all necessary information on ethical issues from the appropriate committees in their institution, or the governmental/ non-governmental agencies. Examples of such committees include the Ethics and research grant committee in the School of Medicine and Health Sciences (SMHS), the Medical Research and Advisory Committee (MRAC) in the National Department of Health (NDOH), and the Research Advisory Committee (RAC) in the National AIDS Council Secretariat (NACS).

Relevance:

Relevance is the most important of all research question characteristics. Researchers must consider the various outcomes of the research project and think of how each possibility might advance scientific knowledge, influence clinical management / health policy, and affect/ guide further research.

What are some of the common problems / obstacles in the process of framing a good research question? [1, 3, 4].

The research question may be too broad: one of the best options is to reduce the variables of interest or to narrow the focus of the study.

When there are not enough subjects from which to select. One of the options is to modifying the inclusion and exclusion criteria by expanding the inclusion criteria and reducing the exclusion criteria.

The budget for the research project is too high. Some of the preferred options are to use an alternative and simple study design, to reduce the number of subjects, to reduce the time frame set for the research project.

The methodology needed is beyond the technical skill of the researchers. One of the preferred options is to collaborate with colleagues having the technical skill and depending on the extent of their involvement to include them as co-researchers. Alternatively, at the end of the project they must be appropriately acknowledged in all publications of the data.

When the research project does not seem to be interesting, relevant, or novel: The researcher should consult with senior researchers and 'dig deeper' in literature review for more information about the relevance of the project.

When the project is found to be unethical: One possible option is to revise the research question, so as to avoid all the unethical issues.

Primary and Secondary Research Questions:

Some research project may have more than one research questions. One should endeavour to have a single primary research question, which should be the focus of the project for which study plan can be drawn and sample size can be estimated. The secondary research questions can emerge as the project progresses.

Conclusion:

It is important to ensure that the research question is Feasible, Interesting, Novel Ethical and Relevant (FINER) before focusing your time and effort in writing the research proposal that you intend to submit to reviewers for funding support.

Reference:

- Cummings SR, Browner WS, and Hulley SB. "Conceiving the research question." In Hulley SB, Cummings SR, Browner WS, Grady D, Hearst N, and Newman TB. Designing Clinical Research. 2nd edition.Philadelphia: Lippincott Williams & Wilkins, 2001.
- Fletcher RH, Fletcher SW, Wagner EG. Clinical Epidemiology: the essentials. 3rd edition. Baltimore: Williams and Wilkins, 1996.
- Clinical and Translational Health Institute (CTSI); Formulating a research question, Pathways to Careers in Clinical and Translational Research (PACCTR) Curriculum Core
- Sackett DL, Haynes RB, Guyott GH, Tugwell, P. Clinical Epidemiology: a basic science for clinical medicine. 2nd edition. Boston: Little,Brown and Company,1991.

15

Study Designs and Selection of Appropriate Methodology

Paper presented by: Dr. Wilfred Kaleva & Mr. Tony Lupiwa Research Co-ordination Unit, National Aids Council Secretariat, PNG

Observational design:

Observational studies involve the observation of a subset of population at one point in time (cross sectional) or over two or more points in time (longitudinal study or cohort study). A longitudinal study assesses the research subjects over two or more points in time; by contrast, a cross sectional study assesses the research subjects at one point in time. Retrospective study is another term used to indicate a Case control study.

Cohort study or panel study is a form of longitudinal study used in medicine or social science. A Cohort is a group of people who share a common characteristic or experience within a defined period (e.g., are born, leave school, lose their job, are exposed to a drug or a vaccine, etc.). Thus, a group of people who were born on a day or in a particular period, say 1948, form a birth cohort.

The comparison group may be the general population from which the cohort is drawn, or it may be another cohort of persons thought to have had little or no exposure to the substance under investigation, but are otherwise similar. Alternatively, subgroups within the cohort may be compared with each other.

Example of Cohort: PNG: Male circumcision - followed for three years to see the rate of STI

infection among the cohort, compare with noncircumcised group.

In medicine, a cohort study is often undertaken to obtain evidence to try to refute the existence of a suspected association between cause and disease; failure to refute a hypothesis strengthens confidence in it. Crucially, the cohort is identified before the appearance of the disease under investigation. The study groups, so defined, are observed over a period of time to determine the frequency of new incidence of the studied disease among them. The cohort cannot therefore be defined as a group of people who already have the disease.

Prospective (longitudinal) cohort studies between exposure and disease strongly aide in studying causal associations, though distinguishing true causality usually requires further corroboration from further experimental trials.

The advantage of prospective cohort study data is the longitudinal observation of the individual through time, and the collection of data at regular intervals, so recall error is reduced. However, cohort studies are expensive to conduct, are sensitive to attrition and take a long follow-up time to generate useful data.

The results that are obtained from long-term cohort studies are of substantially superior quality to retrospective/cross-sectional studies, and cohort studies are considered the gold standard in observational epidemiology. The results that are obtained from long-term cohort studies are of substantially superior quality to retrospective/cross-sectional studies, and cohort studies are considered the gold standard in observational epidemiology. Moreover, cohort studies are informative for efficiently studying a wide-range of exposure-disease associations. Some cohort studies track groups of children from their birth, and record a wide range of information (exposures) about them. The value of a cohort study depends on the researchers' capacity to stay in touch with all members of the cohort. Some of these studies have continued for decades.

Other examples include: PNG Institute of Medical Research (IMR): Vaccine trials; Malaria - treatment/ control; STI / Malaria.

Epidemiologic question that can be answered by the use of a cohort study is: does exposure to X (say, smoking) correlate with outcome Y (say, lung cancer)? Such a study would recruit a group of smokers and a group of non-smokers (the unexposed group) and follow them for a set period of time and note differences in the incidence of lung cancer between the groups at the end of this time. The groups are matched in terms of many other variables such as economic status and other health status so that the variable being assessed, the "Independent variable" (in this case, smoking) can be isolated as the cause of the "Dependent variable" (in this case, lung cancer). A statistically significant increase in the incidence of lung cancer in the smoking group as compared to the non-smoking group is evidence in favor of the hypothesis. Rare outcomes, such as lung cancer, are generally not studied with the use of a cohort study, but are rather studied with the use of a case – control study.

Shorter term studies are commonly used in medical research as a form of clinical trial, or means to test a particular hypothesis of clinical importance. Such studies typically follow two groups of patients for a period of time and compare an endpoint or outcome measure between the two groups.

Randomized control trials (RCT) are a superior methodology in the hierarchy of evidence, because they limit the potential for bias by randomly assigning one patient pool to an intervention and another patient pool to nonintervention (or placebo). This minimizes the chance that the incidence of confounding variables will differ between the two groups.

It is sometimes not practical or ethical to perform RCT to answer a clinical question. To take our example, if we already had reasonable evidence that smoking causes lung cancer then persuading a pool of non-smokers to take up smoking in order to test this hypothesis would generally be considered quite unethical. The largest cohort study in Africa is the "Birth to twenty Study", which began in 1990 and tracks a cohort of over 3,000 children born in the weeks following Nelson Mandela's release from prison. A "prospective cohort" defines the groups before the study is done, while a "retrospective" does the grouping after the data is collected.

Cross-sectional studies, (also known as Crosssectional analysis) form a class of research methods that involve observation of some subset of a population of items all at the same time, in which, groups can be compared at different ages with respect to "Independent variables", such as IQ and Memory. The fundamental difference between cross-sectional and longitudinal studies is that cross-sectional studies take place at a single point in time and that a longitudinal study involves a series of measurements taken over a period of time.

Cross-sectional studies are used in most branches of science, in the social sciences and in other fields as well. Cross-sectional research takes a 'slice' of its target group and bases its overall finding on the views or behaviors of those targeted, assuming them to be typical of the whole group.

Cross-sectional studies in medicine: Crosssectional studies can be thought of as providing "snapshot" the frequency а of and characteristics of a disease in a population at a particular point in time. This type of data can be used to assess the prevalence of acute or chronic conditions in a population. However, since exposure and disease status are measured at the same point in time, it may not always be possible to distinguish whether the exposure preceded or followed the disease.

In a cross-sectional survey, a specific group is looked at to see if a substance or activity, say smoking is related to the health effect being investigated, for example, lung cancer. If a significantly greater number of smokers already have lung cancer than those who don't smoke, this would support the hypothesis that lung cancer is correlated with smoking.

Cross-sectional analysis studies the relationship between different variables at a point in time; for instance, the relationship between income, locality, and personal expenditure. Unlike time series, cross-sectional analysis relates to how variables affect each other at the same time and period.

Case-control study: This is a type of epidemiological study design. Case-control studies are used to identify factors that may contribute to a medical condition by comparing subjects who have that condition (the 'cases') with patients who do not have the condition but are otherwise similar (the 'controls').

Case-control studies are a relatively inexpensive and frequently-used type of epidemiological study that can be carried out by small teams or individual researchers in single facilities in a way that more structured experimental studies often cannot be. They have pointed the way to a number of important discoveries and advances, but their retrospective, non-randomized nature limits the conclusions that can be drawn from them. The great triumph of the case-control study was the demonstration of the link between tobacco smoking and lung cancer. Sir Richard Doll was able to show a statistically significant association between the two in a large case control study.

Opponents, usually backed by the tobacco industry, argued (correctly) for many years that this type of study cannot prove causation, but the eventual results of cohort studies confirmed the causal link which the case-control studies suggested, and it is now accepted that tobacco smoking is the cause of about 87% of all lung cancer mortality in the United States.

For establishing cause-and-effect relationships, e.g., between types of sexual behavior developing cervical cancer, no study design is more highly regarded than the randomized experiment. For medical interventions, the 'gold standard' is the double blind randomized controlled trial, a specific type of experiment.

While such trials may be ideal for testing the efficacy of (what are hoped to be) beneficial interventions, such as surgeries or drug treatments, there are many instances in which trials would be impossible, impractical, and/or unethical. For example, it would generally be seen as unethical to randomly assign research subjects to be exposed to toxic substances in order to evaluate the substances' effects.

Studying infrequent events such as death from cancer using randomized clinical trials or other controlled prospective studies requires that large populations be tracked for lengthy periods to observe disease development. Government funding is unlikely to support longitudinal studies of this nature because of the low likelihood that the population will develop the disease. Case-control studies use patients who already have a disease or other condition and look back to see if there are characteristics of these patients that differ from those who don't have the disease.

The case-control study provides a cheaper and quicker study of risk factors; if the evidence found is convincing enough, then resources can be allocated to more "credible" and comprehensive studies.

One major disadvantage of case-control studies is that they do not give any indication of the absolute risk of the factor in question. For instance, a case-control study may tell you that a certain behavior may be associated with a tenfold increased risk of death as compared with the control group. Although this sounds alarming, it would not tell you that the actual risk of death would change from one in ten million to one in one million, which is quite a bit less alarming. For that information, data from outside the case-control study must be consulted.

Comparison with cross-sectional studies: Cross sectional studies involve data collected at a single point in time, often using survey research methods. In epidemiology, cross-sectional studies often involve secondary analysis of data collected for another purpose. Major sources of such data are often large institutions like the Census bureau or the Centre for Disease Control and Prevention (CDC) in the United States. Such studies can cover study groups as large as the entire population of the United States, but others are small and geographically limited. Cross-sectional studies can contain individuallevel data (one record per individual, for example, in national health surveys). Others, however, might only convey group-level information; that is, no individual records are available to the researcher. Alternatively data can be aggregated at the group level, example, by zip code, urban zone, or even by states/provinces or country.

It should be noted that although cross sectional studies confirm that people who consume large amounts of alcohol also show high rates of many other diseases, they cannot provide confirmation that the first variable is a cause and the second variable is its effect. An important secondary difficulty is that cross-sectional studies often fail to 'control for' confounding factors, third variables that affect or even determine the relationship between the putative cause and effect.

Another complication facing epidemiologists conducting secondary analysis of crosssectional data is that often data are only available on an aggregate or "ecological" basis. For example, statistics on infant mortality and low birth weight might not be available on a level below the city or county. Inferences about individuals cannot reliably be made from ecological data. Because case-control studies are based on individual-level data, they do not exhibit the problems associated with aggregated cross-sectional data.

In the case-control study, the association is determined for each individual case-control pair then aggregated. This provides a more specific

analysis of the possible associations, and potentially determines more accurately which possible causes are directly related to the effect being studied, and which are merely related by a common cause.

One benefit of cross-sectional studies is that they are considered to be "hypothesis generating", such that clues to exposure/disease relationships can often be seen in these studies, and then other studies, such as case-control, cohort studies or even sometimes randomized trials can be implemented to study this relationship.

Experimental designs:

Design of experiments, or experimental design, is the design of all information-gathering exercises where variation is present, whether under the full control of the experimenter or not. (The latter situation is usually called an observational study.) Often the experimenter is interested in the effect of some process or intervention (the "treatment") on some objects (the "experimental units"), which may be people, parts of people, groups of people, etc. Design of experiments is thus a discipline that has very broad application across all the natural and social sciences.

Understanding Quantitative research:

Variables:

Independent variable (for cause), Dependent variable (for effect);

In experiment designs – referred to as treatment and outcome variables, treatment variable (sometimes called experimental variable).

Control variable – variable whose effect we want to remove or control (Covariate).

In an experimental design two comparison groups are set up, the treatment group and the control group.

A researcher administers a treatment, or manipulate an independent variable on only one of the groups (called experimental or treatment group). The researcher then administers treatment to both groups after which, the groups are compared on some outcome or dependent variable, such as Mean, or total number of yields. The intention is the differences found between the groups that are due to (caused by) the treatment or independent variable. The attribute dependent or outcome differences between groups to independent or treatment differences variable differences between groups. Attribution based on assumption that groups are same in all respects. Two groups must be alike in all respects except that they receive different treatments (so any difference can be attributed to treatment). "Alike-in -all" respects assumption important to experimental designs.

How can the comparison groups be set up so that they are same in all respects? Experimental designs use random assignments of participants to comparison groups. Fundamental principle of quantitative reasoning involves the random assignment of participants to comparison groups. Random assignment of participants to treatment does not guarantee alikeness or equality between comparison groups but maximizes the probability they will not differ in a systematic way.

Types of trials: Trials may be open, blind or double-blind.

Open trial: In an open trial, also called an openlabel trial, the researcher and the patients know the full details of the treatment. This type of trial is open to challenge for bias, and they do nothing to reduce the placebo effect. However, sometimes they are unavoidable, as placebo treatments are not always possible.

Placebo effect: The placebo is a sham medical intervention intended to lead the recipient to believe that the intervention may improve his/her condition. In one common placebo treatment, a patient is given an inert "sugar pill" and told that the pill may improve his/her condition. The fact that the pill is inert is withheld from the patient. The intervention may cause the patient to believe that the treatment will change his/her condition; this belief sometimes causes the patient's condition to change, a phenomenon known as the "Placebo effect".

Blind trial: Clinical trials control for this effect (placebo) by including a group of subjects that receives a sham treatment. The subjects in such trials are blinded as to whether they receive the treatment or a placebo. Clinical trials are often double blinded because the researchers also do not know the subjects that are receiving the active or placebo treatment. Single-blind trial: In a single-blind trial, the researcher knows the details of the treatment but the patient does not. Because the patient does not know which treatment is being administered (the new treatment or another treatment) there might be no placebo effect. In practice, since the researcher knows, it is possible for the researcher to treat the patients differently or to subconsciously have hint to the important treatment-related details of the patients, thus influencing the outcome of the study.

Double-blind trial: One of the researchers allocates a series of numbers to "new treatment" or "old treatment". A second researcher is told the numbers, but not what they have been allocated to. The second researcher does not know which treatment is being administered, and so cannot possibly tell the patient, directly or otherwise. Also, the patient cannot put pressure on the researcher asking to be given the new treatment. In this system, there is also often a more realistic distribution of sexes and ages of patients. Therefore double-blind trials are preferred, as they tend to give the most accurate results.

Triple-blind trial: Some randomized controlled trials are considered triple-blinded, although the meaning of this may vary according to the exact study design. The most common meaning is that the subject, researcher and the person administering the treatment (often a pharmacist) are blinded to what is being given. Alternately, it may mean that the patient, researcher and statistician are blinded. The team monitoring the response may be unaware of the intervention being given in the control and study groups. These additional precautions are often in place with the more commonly accepted term "double blind trials", and thus the term "triple-blinded" is infrequently used. However, it connotes an additional layer of security to prevent undue influence of study results by anyone directly involved with the study.

Selection of appropriate methodology or study design:

The methodology or research design that is selected for a particular study may be determined by the following: What is the purpose of your study? Is it to establish a baseline? Is it evaluation? Is it to establish the effect of treatment or intervention? Is it to establish a trend? Is it to measure impact? Is it basic research? Is it to determine prevalence of a disease? Is the study subject to bias responses? How will bias be minimized? What are the research questions? What is the appropriate methodology that one can use to collect data that will answer the research questions? How will the data be analyzed?

The type of analysis depends on the research questions and data collected.

What is/are the expertise of the members in the research team? Is the research question feasible? Is the research question desirable? What about the availability of funds, is the research affordable? Is the study exploratory?

Appropriate response to these questions is important in the final selection of the project. Some of these issues will be addressed

methodology and study design for the research

in detail by others during this workshop

Choice of Subjects and Selection Procedures Inclusion and Exclusion Criteria - Clinical versus Community Populations

> Paper presented by Dr. Jackson A K Lauwo Division of Health Sciences,

School of Medicine and Health Sciences, University of Papua New Guinea

What are clinical trials?

Clinical trials are research studies usually about new medicines or new treatment formulations in human subjects that must be carried out in carefully determined protocols in order to achieve reliable results while ensuring safety of the participants. There are quite a number of clinical trials including; patient oriented research, such as mechanisms of human disease, therapeutic interventions, clinical drug trials and development of new treatment technologies; Brigitte Bloechl-Daum and Markus Mueller [1]. While clinical trials are carried out mostly in the hospital settings, epidemiologic, behavioral studies and health services research are usually extended to the community at large.

Choice of subjects:

The choice of subjects for clinical trials or for community survey studies of a particular kind is a difficult exercise that requires thorough screening from different perspectives. Common guiding principles are aimed to achieve the objectives of the clinical trials or survey studies with representative and reliable outcomes without causing harm or impinging on ethical issues or rights of the subjects. During clinical trials in particular, maximum attention is paid not only to protect subjects but also, as with the case of women, to ensure safety of the unborn or developing off- springs during pregnancy.

Let us focus for example on a clinical trial that involves a new drug or a new formulation and examine briefly why selection of subjects needs to be carefully designed taking into account important *inclusion* and *exclusion* factors. Drugs are chemical entities that act like a ,"double edged sword", i.e. they can be therapeutic if employed in relatively small and measured amounts, while if used in relatively large quantities they would cause fatalities.

Toxicity of drugs: Drugs such as the cardiac glycoside – digoxine, has a narrow therapeutic window of between 0.5-1.5ng/ml plasma concentrations. Concentrations of 2.5ng/ml or higher would produce serious arrhythmias toxicities, [2,3]. Phenytoin, an anticonvulsant drug used to treat epilepsy at therapeutic plasma concentrations ranging between 10-20µg /ml, would produce toxicities related to;

sedation, nystagmus and ataxia if its plasma concentration is greater than 20µg /ml [4,5]. These few examples subscribe to the dual properties of medicines and therefore underscore the need for thorough, accurate and reliable clinical trials so as to avoid toxicities inherent to the substances.

Teratogenicity and carcinogenicity:

In addition, clinical trials aim at ruling out Teratogenicity, the potential of a new medicine or treatment in causing embryonic malformations like the thalidomide [6]. New drug substances must be screened to see whether or not they exhibit the carcinogenic potential to human subjects [8] such as that experienced with arsenic [7].

Genetic Polymorphism & Toxicity:

Some drug substances affect different ethnic groups differently and thus the need to extend clinical trials to include many such genetically different peoples in order to elicit side effects and adverse reactions that are ethnic groups specific and deemed to be serious and fatal. For instance, Isoniazid a combination drug in tuberculosis chemotherapy has many side effects including CNS effects such as neuropathy, hepatitis. The side effects are worse in genetically ethnic groups known to be "slow metabolizers" of the drug, 59% of South Indians, 60% of Caucasians, 55% of blacks or 12% of Japanese and 22% of Chinese [9].

Objectives of clinical trials:

The fundamental objectives of clinical trials are to improve health care for both men and women. It is therefore important that all sexes are carefully considered during trial sample selections. The enrolment (inclusion) of pregnant or lactating female subjects in a clinical trial or their exclusion from such a study must carefully consider risks and benefits of the treatment, the severity of the disease, preclinical animal results, the stage of pregnancy and the potential for harm to the foetus or infant [1]. This particularly important when we make reference to historical disasters similar to the thalidomide crisis or other toxicological drug problems as described above.

Influence of gender on subject selection:

Where a given gender is excluded, the reason should not be merely due to unfounded discrimination or convenience. According to Bloechl-Daum and Mueller, [1], one gender could be excluded from a study sample due to: health reasons, research question relevant only to the other gender, evidence showing no gender influence on outcomes, existence of data for excluded gender, or subjects selection is constrained due to purpose of the research.

Influence of age on subject selection:

Diazepam (Valium[™]), a drug commonly used as a tranquilizer to treat individuals suffering from anxiety, is known to eliminate from the body quite differently when comparing young adults between 20 and 40 years and older people between 60 and 80 years. These two age groups have elimination half lives of about 40 and 80 hours respectively, [11]. Hence; with diazepam for example, it is important to fix or narrow down the age group of included study subjects in order to minimize age - related confounding differences during clinical trials. Any subject falling outside the determined age group shall be excluded from the studies.

Presence of disease and other drugs:

A typical example where presence of disease and other drugs would significantly influence the outcomes of clinical trials has been demonstrated in a study of the pharmacokinetics of phenylbutazone, an anti-inflammatory drug used to treat arthritis and gout. Hepatic disease and presence of other drugs seemed to vary the elimination half life of the drug quite significantly when compared to its half life in healthy subjects who were not taking other drugs [12]. These factors will influence the results of clinical trials and where applicable subjects with diseases or subjects taking other drugs should usually be excluded from study samples. There could be cases where the presence of a disease would serve as good inclusion criterion in a clinical study for example, a clinical study on the effectiveness of a new antimalarial drug would require subjects infected with malaria parasites rather than just healthy participants. Some study may need healthy participants. A study on the pharmacokinetic drug-drug interactions as with the case of Antiretrovirals (ARVs) and Antimalarials would require healthy subjects. This is important to rule out the impact of disease and focus only on the influence of drugdrug interactions on the pharmacokinetics of the drugs.

Qualifying for clinical trials:

Before joining a clinical trial, a participant must qualify for the study by fulfilling laid down inclusion criteria. This shall enable researchers to obtain sample results that are reliable and representative to a larger population.

Ethical clearance:

A unique *inclusion* or *exclusion* criteria refers to availability or non availability of ethical clearance from an authoritative institution, health or appropriate government authority that carefully examines the above criteria and decides to grant or not grant ethical clearance for the research to proceed. Usually, culture, religion, race, mental or physical disability, sexual orientation etc are not characteristics for exclusion of subjects from research studies [14].

The following *inclusion* or *exclusion* criteria refer to factors that must be considered, and where applicable standardized so as to produce useful results, minimize inter-subject variability of the outcomes and ensure safety of participating subjects. The criteria are also linked to the undesirable properties of medicines and drug substance discussed in the preceding section of this article.

Examples of choice of subjects and procedures:

(a) A clinical trial case on the: Pharmacokinetic
 Interactions between ARVs and Antimalarial
 Drug Combinations – NCT00697892-94110
 (Clinical Trial 193721).

Source: San Francisco General Hospital, San Francisco CA 94110, United States of America. The objective of this study was to determine in healthy subjects whether certain ART medications (lopinavir/ritonavir and efavirenz) affect the pharmacokinetic levels of certain antimalarial drugs (artesunate /amodiaquine and artemeter/lumefantrine) and vice versa.

Inclusion Criteria were: absence of HIV infection, male or female aged 21- 60, ability to provide informed consent, body weight +/- 20% (+/-) min. 50 kg wt., healthy, without acute or chronic illnesses, no diabetes, hypertension, no CAD or psychiatric illnesses, and no renal or hepatic impairment.

Additional Inclusion Criteria were:

Female subjects of reproductive potential,

Must agree to be on birth control at least one month prior to study;

Must agree to be on birth control for 6 weeks after completion of study;

Must have negative pregnancy test within 24 hours before taking study drugs;

Normal laboratory tests results;

Exclusion criteria:

Use of illicit drugs or alcohol; Any (OTC) or prescribed drugs unless approved by the principal investigator or study physician; Use of drugs that inhibit/induce CYP450 Isoenzymes; Pregnant or breastfeeding subjects; History of acute or chronic illnesses, such as diabetes, hypertension, CAD, psychiatric illnesses, renal or hepatic impairment; Evidence of heart disease; Informed consent not explained understood and signed.

(b) A case for community populations: Impact of HIV/AIDS – Stigma and Discrimination on the Access to VCT and Other Services in Selected Populations of the National Capital District (NCD), PNG.

Procedures for recruiting subjects from Community Populations:

Sensitivity to political interests of the country; Sensitivity to cultural issues of the involved community; Preliminary meetings with key elders (men and women; To explain the objectives & benefits of the study; To ensure ownership of study/outcomes part by comminute; Personal security of investigators and participants in the study; Involvement of trained interviewers close to the community; Communicating Language and its application; Reminder on participants protection by the law; Assurance of confidentiality; Consent note explained, understood & voluntarily signed; Ethical clearance granted

The study was randomized and Included were:

Youths & Young adults – 15 -24 years; Lined up spectators of sports & games (rugby, soccer, netball, volley ball etc); Every 8th male in a row; Every 8th female in a row; Consent form understood & voluntarily signed

Excluded were: Subjects outside the 15 -24 years; Family members; sisters/brothers, wife/husband; those unwilling to participate (No

coercion); Consent form not understood & not signed

Conclusion

Choice of subjects and selection procedures has been discussed in this article. Criteria for participants in both clinical trials and community surveys have been displayed in a nutshell. Critical reasoning behind certain criteria has also been discussed. Preparations of subjects and their inclusion or exclusion from different studies was explained, all for the interest of achieving most optimal, representative and therefore reliable study outcomes, while ensuring security of participants in the community. Issues of personal safety with reference to participants themselves, and wellness of their developing offsprings particularly where pregnant women are involved, were given a paramount attention. Ultimately, it is important to appreciate the fact that inclusion and exclusion criteria are not used to reject certain categories of people, but rather to identify suitable participants and ensure safety in all aspects of the research studies.

References

- 1. Brigitte Bloechl-Daum and Markus Mueller. Guidelines regarding The Inclusion of Women in Clinical Research. Department of Clinical Pharmacology, Medical University of Vienna, Austria. http://www. Year, website and date accessed.
- 2. Ralph A Kelly and Thomas W Smith. Pharmacological Treatment of Heart Failure. In: Goodman & Gilman's Pharmacological

Basis of Therapeutics 9th Ed, New York, McGraw - Hill, 1996, pp 809-838.

- 3. Dan M Roden. Antiarrhythmic Drugs. In: Goodman & Gilman's Pharmacological Basis of Therapeutics 9th Ed, New York, McGraw -Hill, 1996: pp 839-874.
- 4. W M Burnham. Agents Modifying Movement Control. In: Harold Kalant & Walter H E Roschlau (Eds), Principles of Medical Pharmacology, 6th Ed, Oxford University Press, 1998: pp 241-249
- 5. W M Burnham. Antiseizure Drugs. In: Harold Kalant & Walter H E Roschlau (Eds), Principles of Medical Pharmacology, 6th Ed, Oxford University Press, 1998: pp 250-261
- 6. Thalidomide. Claire Elizabeth Lewis, In: Encyclopedia Encarta, MS Corporation, 2005
- 7. Curtis D Klaassen. Heavy Metals and Heavy-Metal Antagonists In: Goodman & Gilman's Pharmacological Basis of Therapeutics 9th Ed, New York, McGraw-Hill, 1996: pp 1649-1671
- 8. Curtis D Klaassen. Principles of Toxicology and Treatment of Poisoning In: Goodman & Gilman's Pharmacological Basis of Therapeutics 9th Ed, New York, McGraw – Hill, 1996: pp 63-75
- 9 Kalow, W. Ethnic differences in drug metabolism. Clin. Pharmacokinet., 7:373-400, 1982
- 10. Reasonably designed Inclusion and Exclusion criteria and applicable Human

Rights legislation Jan 2003.pdf .The Interagency Advisory Panel on Research Ethics Pre.ethics.gc.ca

11. Age and gender related differences in diazepam pharmacokinetics; J. Clin. Pharmacology,19:15-19, 1979.

 Malcolm Rowland & Thomas N Tozer (Eds), Clinical Pharmacokinetics Concepts and applications, 3rd Ed, Lippincott Williams & Wilkins,1995:p210

Choice of Sampling Designs and Options

Paper presented by: Dr. F. Muga Division of Clinical Sciences,

School of Medicine and Health Sciences, University of Papua New Guinea

DEFINITIONS: A sample is a subset of a population, whose properties has been, or is to be, generalized to the whole population [1]. Sampling refers to the process of selecting a sample from a population [1]. A sampling unit is

Example: A study of SMHS lecturers' experiences with the new PBL system

The population would be all the lecturers at SMHS

The sample would be the lecturers chosen to take part in the study

Sampling is the process by which the researcher selects the lecturers who will participate in the study

The sampling unit would be a lecturer

The sampling frame would be the list of all lecturers from which some would be selected

the unit of selection in the sampling process [1]. The sampling frame is the set of sampling units from which a sample is to be selected [1]. The sampling fraction is the proportion of sampling units to be selected from a specified sampling frame [1].

The sampling fraction would be the fraction or percentage of lecturers to be selected, e.g. 1 in 3 lecturers

WHY DO WE NEED TO SAMPLE?

A sample is a subset that represents a population.

When the population is very, very small, sampling may be unnecessary and it would be better to study the whole population, e.g. if you were investigating:

The immunization status of infants whose parents are both under the age of 14; The prevalence of renal stones among PNG people aged 100 years or more; The Intelligence Quotient (IQ) of people who have been Prime Minister of PNG; The mental health status of female Departmental Heads in PNG

Most research, however, involves fairly large populations, and it would not be practical to study every single member of the population. Therefore, samples are used instead. To be useful, a sample must be carefully chosen and be appropriate for the particular study where it is to be used. *"The first important attribute of a sample is that every individual in the population from which it is drawn must have a known non-zero chance of being included in it; a natural suggestion is that the chances should be equal"* [2].

For example: If a study involves experiences of SMHS lecturers, the population cannot include non-academic staff and each lecturer's name must appear only once in the list of lecturers; In a study of the prevalence of cancer of the cervix among UPNG students the population cannot be all UPNG students, it must be all female UPNG students.

ADVANTAGES OF SAMPLING:

Compared to studying the whole population:

Samples are cheaper, since fewer numbers are involved; Samples are less time-consuming, due to the smaller numbers; Less manpower is needed; When properly selected, samples give results that are as good as would be obtained by studying the whole population. In fact, the results can be even better than studying the whole population due to greater accuracy, less missing data etc. "A well chosen sample will contain most of the information about a particular population, but the relation between the sample and the population must be such as to allow true inferences to be made about a population from that sample" [2].

DISADVANTAGES OF SAMPLING:

The possibility of errors during selection, so that the sample does not truly reflect the population; The possibility of those not included feeling discriminated against, especially if they perceive there are advantages to taking part in the study; Possible administrative/legal problems, if policy requires a whole population to undergo the intervention, e.g. head count during census; The likelihood of missing small but important groups, e.g. minority members, female MPs, etc

After deciding you need to sample, you need to decide how to sample, i.e. which sampling method to use. If the wrong sampling method is used, you will not be able to draw relevant conclusions from your findings so please ensure your sampling method is the appropriate one for your study before you start collecting data.

Before deciding on the type of sampling to use, ask yourself the following questions:

What information am I looking for? Do I need to investigate the whole population or can I use a sample? Why? How big a sample do I need for my data to be useful? How representative does my sample have to be? Therefore, what is the best sampling method to use for this particular research? [3] There are many different methods of sampling, but they are generally divided into two large groups, namely Probability Sampling methods and Non-Probability sampling methods.

Non-ProbabilitySamplingincludes:Convenience sampling and Purposive sampling.

Probability Sampling includes: Simple random sampling; Stratified random sampling; Systematic sampling; Cluster sampling and Multi-stage sampling.

NON-PROBABILITY SAMPLING:

CONVENIENCE SAMPLING

Description: Convenience sampling involves selecting sampling units based purely on what is most convenient for the researcher. How it is done: The researcher picks the sampling units that are nearest or easiest-to-access.

EXAMPLES OF CONVENIENCE SAMPLING

Research Question: How many students in Port Moresby experience domestic violence at home?

Method: Waiting at Malaoro Market at 2.30pm and interviewing the first 100 students you see on their way home from school.

Research Question: What is the ratio of schools to households in Port Moresby?

Method: Counting the number of schools and houses between PMGH and Boroko Food world.

Research Question: What do MPs in PNG think of polygamy?

Method: Interviewing the MPs attending the funeral of a prominent Highlands elder, which you are also attending

Research Question: What are the commonest diagnoses among inpatients at PMGH?

Method: Reading the charts of the first 20 inpatients, starting with the nearest ward (W-6)

Research Question: Are SMHS lecturers happy with their accommodation?

Method: Interviewing the lecturers living behind the Medical Library at SMHS who are willing to participate

Research Question: Are Port Moresby residents racist towards Chinese?

Method: Interviewing your neighbors

ADVANTAGES OF CONVENIENCE SAMPLING

Compared to Probability Sampling, Convenience Sampling is Cheaper, Easier, Quicker and More convenient.

DISADVANTAGES OF CONVENIENCE SAMPLING

The sample obtained is not representative of the population so you cannot draw conclusions about the population based on the results of the sample.

PURPOSIVE SAMPLING

Description: Purposive sampling involves the non-random selection of sampling units based on their meeting specific, pre-determined criteria, usually matching those of a group of interest.

How it is done: The researcher specifically looks for subjects that meet the pre-determined criteria

EXAMPLES OF PURPOSIVE SAMPLING

Research Question: Do wives of mentally ill patients believe in sorcery more than other wives?

Method: From a population of wives of men who have never had mental illness select a sample who are matched for age, province of origin, level of education, duration of marriage, etc with wives of mentally ill men. (The wives of the mentally ill are the cases and the other wives are the controls)

Research Question: Are ex-servicemen who were injured in combat more likely to become alcoholic than their colleagues who did not sustain injury?

Method: From a population of ex-servicemen who were involved in combat but were not injured, sample those who are matched with their injured colleagues for age, province of origin, level of education, religion, family history of alcoholism, marital status, duration of deployment in combat zone, duration since combat, etc (The injured are the cases and the non-injured are the controls)

ADVANTAGES OF PURPOSIVE SAMPLING: It ensures the inclusion of specific variables you are interested in.

DISADVANTAGES OF PURPOSIVE SAMPLING:

The results cannot be generalized beyond the narrow focus of interest; You do not know in advance whether or not you will get enough (or any) subjects qualifying; It can be very tedious if there are many variables to be matched

PROBABILITY SAMPLING

SIMPLE RANDOM SAMPLING

Description: This is a method of sampling where every sampling unit is selected at random and every unit has the same chance of being selected

HOW IT IS DONE:

A sampling frame (i.e. the list from which the samples will be drawn) is created; Each member of the list is allocated a number; The desired number of subjects is drawn randomly using any one of several methods

METHODS OF RANDOM SELECTION:

There are many ways of selecting units randomly, such as:

Putting the numbers in a hat or tin, shaking thoroughly and picking them one at a time without looking; Each number must be returned to the hat or tin afterwards, so the probability of being picked remains constant. Repeats are ignored

Printing the numbers on balls and spinning them to see which ones come on top (like the lotto machine). There must be one ball for each subject in the sampling frame and the balls must return to the pool each time. Repeats are ignored; Using a Table of Random Numbers; With smaller numbers, coins or dice may be used

USING A COIN to select patients as cases or controls for a new drug trial:

Create a sampling frame (list of all patients in study); Toss a coin once for each sampling unit (patient); If the coin lands Head up, that patient is a Case; If the coin lands Tails up, that patient is a Control; So if during the first 8 throws the coin lands Heads, Heads, Tails, Head, Tails, Head, Heads, Tail, then subjects number 1,2,4,6 and 7 will be cases and subjects number 3,5 and 8 will be controls.

USING A DIE to select patients as cases or controls for a new drug trial:

A sampling frame is created as before. A die is cast. If the die lands with 1,2 or 3 facing up, the subject is a case. If the die lands with 4,5, or 6 up the subject is a control. So if the die is cast 8 times and numbers on top are 2,3,2,6,1,5,6,3, then the first eight subjects are Case, Case, Case, Control, Case, Control, Control, Case

Because a die has 6 faces, it can also be used when there are 3 groups to be randomly sampled, e.g. if a list of patients with the same illness are to be randomly put on Drug A or on Drug B or on Placebo.

If the die lands with 1 or 2 up, put patient on Drug A. If the die lands with 3 or 4 up, put patient on Drug B. If the die lands with 5 or 6 up, put patient on Placebo. So if the die is cast ten times and the numbers on top are 2,3,1,2,3,4,6,1,5,2, the first ten patients are allocated to A, B, A, A, B, B, Placebo, A, Placebo, A.

USING A TABLE OF RANDOM NUMBERS:

A Table of Random Numbers is often used because it is impossible for human beings to truly randomly select numbers. Tables of Random Numbers can be found in textbooks of statistics. A portion of a Table of Random Numbers is shown below [1]

HOW TO USE THE TABLE OF RANDOM NUMBERS:

Create a sampling frame (list of potential subjects) and decide how many subjects you want to select.

Number the members of the list from 1 onwards: If there are less than 10 members, number them from 1 to 9, i.e. in single digits. If there are more than 9 but less than 100, number them from 01 to 99, i.e. in double digits. If there are more than 99 but less than 1000, number them from 001 -999....; Get a Table of Random Numbers (found in textbooks of statistics). The Random numbers are divided into Rows and Columns. Pick any row and column at random and note the number there, then select the corresponding subject on the sampling. Work down the column till you get the number of subjects you require. Ignore any repeats and if the sampling frame has less than 10 members ignore any 0 in the column, since it does not have a corresponding item in the sampling-frame.

81437	79282	09838	14647	04536
38787	22219	673 <mark>6</mark> 0	89328	20001
70606	09417	13999	55960	06708
29730	45408	47195	89119	40244
35145	80340	95114	68463	89156
00573	47790	64065	60205	80643
54058	74717	02382	44211	63006
31286	64330	75909	77787	56056
59918	57913	44220	63174	16438
15459	31573	52389	01216	64665

Table 1: Abbreviated from Lwanga, Tye and Ayeni, 1999, [1]

TABLE OF RANDOM NUMBERS

Example: Suppose you want to select 5 professors out of a total of 9 for interview:

Create a sampling frame, i.e. write a list of all 9 professors. Number them 1,2,3,4,5,6,7,8 and 9. Use the Table of Random Numbers above. It shows ten rows and 25 columns. Pick a row and a column at random and note the number that corresponds to them. For example, you might select row 2 column 14. The corresponding there is 6. (Alternatively you can simply close your eyes and stick a pin into the paper and see what number is under or closest to, the tip of your pin.);

Using this 6 as your starting point, go to your sampling frame and select the 6th professor on the list; Working downwards note, the number immediately below the 6. In this case it is 9. Select the 9th professor on the list. Note the number immediately below the 9. It is another 9, but because the 9th professor has already been selected, you ignore this 9 and move to the next number below, which is 1. Select the 1st professor on the list. Note the number immediately below the 1. It is 6, but since the 6th professor has already been selected, ignore this 6 and move downwards to the next number, which is 8. Select the 8th professor on the list. Move down to the number immediately below the 8. It is 0, but since there is not professor number 0, ignore the 0 and move downwards to the next number, which is the number 2. Select the 2nd professor on the list. Your five randomly selected professors are therefore professors number 6, 9,1,8 and 2 on the list.

For larger samples with 10 to 99 members in the sampling frame:

Suppose you want to select 9 professors out of a total of 97 professors. Create a sampling frame, i.e. a list of all 97 professors. Number them 01, 02, 03, 04, till you reach 97. Randomly pick the starting point as before. For purposes of illustration, let's assume the same starting point as before, i.e. row 2-column 14. The number there is 6 and the number immediately to the right of the 6 is 0. Therefore our first selection is 60. Select the 60th professor on the list. Move downwards and select the two digits immediately below the 60, i.e. 99. Since your list of professors only goes up to 97, ignore this 99 and move downwards. The next two digits are 95, so you select the 95th professor on your list.

Move downwards and select the two digits immediately below the 95, i.e. 14. Select the 14th professor on the list. Move downwards and select the two digits immediately below the 14, i.e. 65. Select the 65th professor on the list. Move downwards and select the two digits immediately below the 65, i.e. 82. Select the 82nd professor on the list. Move downwards and select the two digits immediately below the 82, i.e. 09. Select the 9th professor on the list. Move downwards and select the two digits immediately below the 09, i.e. 20. Select the 20th professor on the list. Move downwards and select the two digits immediately below the 20, i.e. 89. Select the 89th professor on the list.

Since you have reached the end of the column, you move to the next two columns on the right (i.e. the 16th and 17th columns) and note the numbers there. In this case the numbers are 1 and 4, but since the 14th professor has already been selected, you move downwards to the next two digits, i.e. 89. Since the 89th professor has also been selected already, you move downwards to the next two digits, i.e. 55. Select the 55th professor on the list. Your nine professors selected would be professors number 60,95,14,65,82,9,20,14 and 55.

If you were selecting from a sampling frame of more than 99 but fewer than 1000 professors, you would number them 001, 002, 003, 004, 005999:

You would then use the Table of Random numbers as before, but this time instead of using two digits, you would use three digits. Assuming for illustration purposes that the starting point was the same as before, i.e. row 2 and column 14, your three digits would be 6 0 8 (i.e. you take the 6 which is in row 2, column 14, and also take the two digits to its immediate right, i.e. 0 and 8 which are in column 15 and column 16 respectively). Your first selection would then be the 608th professor on the list. Movina downwards. the three diaits immediately below the 608 are 995, so you would select the 995th professor. The next three digits below 995 are 1 4 6 so the next selection would be the 146th professor on the list. The professors after that would be numbers 656, 824, 097 and so on, till you had obtained as many subjects as you needed.

Note: the decision whether to number the lists 1,2 ,3.... or 01,02,03... or 001,002,003 ... depends on the number of members in the sampling frame, not on the number of subjects you wish to select, so if you have a total of 999 professors, you will still number them 001, 002,003 etc., even if you are going to select less than 10 of them for your study.

MORE EXAMPLES OF SIMPLE RANDOM SAMPLING

Research Question: What do MPs in PNG think of polygamy?

Method of selection: Get a list of all the MPs in Papua New Guinea. There are more than 99 but less than 1000 MPs in total. Number them from 001 onwards. Use a table of random numbers to select the desired number of MPs to interview.

Research Question: What do SMHS students know about H1N1?

Get a list of all the SMHS students (there are more than 99 but less than 1000 students). Number them from 001 onwards. Use a table of random numbers to select the desired number of students to interview

Research Question: How do PNG cardiothoracic surgeons perform compared to their Australian counterparts?

Method of selection of patients to PNG or Australian surgeons:

Get a list of all the patients scheduled for surgery during Operation Open Heart. Get a coin. Decide which team is heads and which is tails, e.g. PNG surgeons are heads and Australian surgeons are tails. Starting with the first patient on the list, toss a coin to determine which team will operate on this patient. Continuing down the list, toss the coin as many times as there are patients. Each time the coin lands heads up, the patient is allocated to the PNG surgeons, if tails to the Australian surgeons. Repeat the process till all patients have been allocated to either the PNG or the Australian surgeons.

ADVANTAGES OF SIMPLE RANDOM SAMPLING:

Easy to learn and perform; Eliminates researcher bias; Each unit has the same chance of being selected, so the sample is representative of the population; Easier to do than sampling methods that involve several stages, such as cluster sampling and multistage sampling

DISADVANTAGES OF SIMPLE RANDOM SAMPLING:

Small but significant groups may be missed, e.g. female MPs, if they are very few compared to male MPs. It is a tedious process if large numbers are involved, both in constructing the sampling frame and in selecting the sample.

STRATIFIED RANDOM SAMPLING

DESCRIPTION: Stratified Random Sampling involves dividing the population into different strata (groups) according to sex, age, geographical location etc and then using simple random sampling to select samples from within each stratum [1].

HOW IT IS DONE:

The different strata are identified (using variables such as age, sex, province of origin). A sampling fraction is decided upon. Each

stratum is treated individually and independently of the other strata. Within each stratum, simple random sampling is carried out, e.g. using coins, dice or a Table of Random Numbers, till the appropriate numbers of subjects are obtained.

Note: The same sampling fraction must be used in all strata. For instance, if they are stratified by gender and 1 in 4 males are selected, then 1 in 4 females must be selected. If they are stratified by province of origin and a sampling fraction of 1 in 5 is used, then the selections must include 1 in 5 from each province, even though this means the larger provinces will have more subjects included than the smaller provinces.

EXAMPLES OF STRATIFIED RANDOM SAMPLING

Research Question: What do SMHS students know about swine flu?

How to use stratified random sampling:

Identify the strata, e.g. by course of study -MBBS, B. Pharm, BCN, etc. Decide on a sampling fraction, e.g. 20% of students. Create sampling frames (lists of students) for each course and within each list, allocate numbers from 01 onwards (or from 001 onwards, if more than 99 students in course). Calculate what 20% of students in each course are. Using a Table of Random Numbers, select 20% of MBBS students, 20% of B. Pharm, etc;

Research Question: What do PNG MPs think of polygamy?

How to use stratified random sampling:

Identify the strata, e.g. by Region – Momase, Highlands, Southern and NGI. Decide on a sampling fraction, e.g. half the MPs. Create 4 sampling frames (i.e. a list of Momase MPs, a list of Highlands MPs, a list of Southern MPs and a list of NGI MPs). For each Region, calculate how many MPs make 50% of the total. Using the Momase list and a Table of Random Numbers, select the appropriate number of MPs determined in step 4. Repeat Step 5 for each of the other three Regions.

Research Question: Are SMHS lecturers satisfied with their accommodation?

How to use stratified random sampling:

Identify the strata, e.g. Lecturers living at Waigani Campus, at SMHS, at Korobosea and in their own houses. Decide on a sampling fraction, e.g. 20% of lecturers. Create sampling frames (lists of lecturers) for each stratum. Within each list, allocate numbers from 01 onwards. Calculate how many lecturers you will select from each of the strata (= 20% of the lecturers in each stratum). Using a Table of Random Numbers, select 20% of lecturers living at Waigani, 20% or lecturers living at SMHS, 20% of those living at Korobosea and 20% of those living in their own houses;

ADVANTAGES OF STRATIFIED RANDOM SAMPLING:

Each unit within a stratum has an equal chance of being selected; Proportionate representation of all strata, including minority groups, can be ensured; It gives a more accurate picture of the population when different groups within it may differ widely from one another

DISADVANTAGES OF STRATIFIED RANDOM SAMPLING:

Many sampling frames must be created, one for each stratum; It takes longer than simple random sampling

SYSTEMATIC SAMPLING

DESCRIPTION: Systematic sampling involves selecting a pre-determined fraction of the population or sampling frame in a fixed, systematic, non-random way. Every *n*th unit is selected, where *n* is 2 or more.

How to carry out Systematic Sampling:

Create a sampling frame (list). Decide on the sampling fraction, e.g. every 7th person on the list. Randomly select the first unit between 1 and 7, e.g. the 2nd unit. Select the 7th person after the initial one, i.e. the 9th person. Select the 7th person after the 9th person, that, i.e. the 16th. Select the 7th person after the 9th person, that, i.e. the 16th. Select the 7th person after the 30th, 37th etc, till you have the number of subjects you need

EXAMPLES OF SYSTEMATIC SAMPLING

Research Question: How many Grade 12 students at ABC Secondary School smoke marijuana?

Method of selection by systematic sampling:

Get a list of all Grade 12 students at ABC Secondary School. Number the students from 1 onwards. Decide on the sampling fraction, e.g. 1 in 20 students. Randomly select a starting number from 1 and 20, e.g. 11. Systematically select the 11th student on the list, the 31st student, the 51st student etc. till there are no more to select. If the starting number had been 20, you would have selected the 20th, 40th, 60th student, etc.

ADVANTAGES OF SYSTEMATIC SAMPLING:

It is easy to do. The sampling is evenly spread throughout the entire population.

DISADVANTAGES OF SYSTEMATIC SAMPLING:

The results may be biased if there is a periodicity in the population that may coincide with that of the selection

EXAMPLE OF PERIODICITY COINCIDING WITH SELECTION

Research question: How many Grade 12 students at XYZ High School drink alcohol?

Method: Systematic sampling - every 20th student, starting at number 1

Problem: The listing from the school is not random. There are exactly 40 students in each class and the class prefect's name is always first on the list. Therefore, as you select students number 1, 21, 41, 61, 81, etc, half of them will be prefects (number 1, 41, 81, etc). If your starting point is any other number apart from 1, there will be no prefects in your sample. This would affect the interpretation of your results, since prefects may differ from other students in their drinking habits.

CLUSTER SAMPLING

DESCRIPTION: Cluster Sampling involves dividing the population into Clusters (homogenous groups), usually based on geographical location, before sampling is carried out

HOW IT IS DONE:

The population is divided into clusters. Some of the clusters are randomly selected. ALL the units in the selected clusters are studied

EXAMPLES OF CLUSTER SAMPLING

Research Question: Are Port Moresby residents racist towards Chinese?

Method of cluster sampling:

Divide Port Moresby into clusters of homogenous units, e.g. Gerehu, Morata, Sabama, Korobosea, Waigani, Town, Boroko, etc. Randomly select a sample of clusters, e.g. Gerehu, Korobosea, and Town. Interview ALL the residents of Gerehu, Korobosea and Town.

Research Question: Are patients in Port Moresby satisfied with the services at public health centres?

Method of cluster sampling:

Divide Port Moresby according to the location of the different health centres. List the different health centres. Randomly select a sample of health centres, e.g. by picking names out of a hat. Visit the selected health centres and interview ALL the patients there.

ADVANTAGES OF CLUSTER SAMPLING:

There is no need for a sampling frame of the whole population, so it is cheaper and quicker than stratified random sampling or simple random sampling; It is cheaper than stratified random sampling and simple random sampling since the researcher does not have to travel to many centres but instead concentrates on a few centres in detail

DISADVANTAGES OF CLUSTER SAMPLING:

It has higher rates of sampling error than in simple random sampling

Note: Cluster Sampling is not the same as Stratified Random Sampling. In Cluster Sampling all members of the randomly selected clusters are included, while in Stratified Random Sampling, all the strata are included but within these strata only some, randomly selected, members are included.

MULTI-STAGE SAMPLING

DESCRIPTION: Multi-stage sampling involves multiple stages of random sampling.

HOW IT IS DONE:

A list of large-sized sampling units is prepared. Random samples are selected from this list, paying attention to relative sizes of units. A list of the selected units is prepared. Random samples are selected from this list. These samples may be studied or may be further listed and a further random sample obtained for study.

EXAMPLES OF MULTI-STAGE SAMPLING

Research Question: How extensive is the use of condoms in Africa?

Method of Multi-Stage Sampling:

Divide Africa into countries (about 52 countries). Select countries at random, e.g. Kenya, Sierra Leone, Ghana. Create a list of districts in each of the selected countries. Select districts at random within each country. Within the selected districts, create a list of towns then randomly sample the towns. From the selected towns, randomly sample residential streets and from the selected streets, randomly sample households. Interview the members of the household about condom use.

Research Question: How friendly are doctors in PNG to patients?

Method of Multi-Stage Sampling:

Create a list of all the provinces in PNG. From this list of provinces, randomly select a sample, e.g. Central, Enga, WHP, and Manus. Create a list of hospitals in each of these selected provinces. From each list of hospitals, randomly select a hospital. Create a list of doctors working in each of the selected hospitals. From each list of doctors, randomly select a sample of doctors. Observe these randomly selected doctors to see how friendly they are towards their patients (whether they greet the patient, smile, etc). ADVANTAGES OF MULTI-STAGE SAMPLING:

There is no need for a sampling frame of the whole population, so cheaper

DISADVANTAGES OF MULTI-STAGE SAMPLING:

The risk of sampling error greater is than with simple random samples of the same size

SUMMARY:

A sample is a subset of a population and when properly selected can yield results that are similar to those that would be obtained by studying the entire population.

The different types of sampling include Convenience, Purposive, Simple Random, Stratified, Cluster, Systematic and Multi-stage Sampling.

All types of sampling have advantages and disadvantages.

Choice of sampling method should be guided by the needs of the particular research it will be used in.

The sampling method should be decided on before data is collected.

References

 Lwanga SK, Tye C-Y, Ayeni O (Eds), 2nd Edition, Teaching health statistics: Lesson and seminar outlines. Geneva: World Health Organization; 1999

- Swinscow TDV. Statistics at Square One. 9th
 ed. London: BMJ Publishing Group; 1997
- Fletcher RH, Fletcher SW, Wagner EH.
 Clinical epidemio: the essentials Baltimore: Williams & Wilkins; 1988
- Hill AB, Hill ID. Bradford Hill's Principles of medical statistics. 12th ed. London: Edward Arnold;1991.

Selecting Appropriate Variables

Paper presented by: Dr Paulus Ripa Medical Education Unit,

School of Medicine and Health Sciences, University of Papua New Guinea

In the planning stages of a research project when we have defined our study question (aims and objectives) we then need to ask how we are going to collect the information that will meet our objectives. The information we collect on our subjects are known as variables and it is important that we select the appropriate variables to collect information. In this presentation I will therefore try to define firstly what a variable is and what different types there are and then look at how to select appropriate variables for a given research project.

What is a variable and what are the different types of variables?

Variables are what we measure or record in a study and are basically of two types. One type of variable may be in the form of numbers; e.g. age in months or years or height in metres or centimetres hence known as **numerical** or **quantitative** variables. The second type of variable may be non-numerical or classified as groups and are known as categorical variables. Examples include gender of subject (male/female) or country of origin etc.

Numerical Variables: Numerical variables are sometimes also described by several other names e.g. interval/ratio data or quantitative data). There are two types of numerical variables; these are Continuous and Discrete variables.

A Continuous variable is measured by units that can be subdivided infinitely. It can develop more and more accurate measurements depending on accuracy of instrument e.g. Height = 2.5 cm.

Discrete variables are those that are measured by units that cannot be subdivided e.g. number of children. For practical statistical purposes this distinction between continuous and discrete variables does not matter.

Categorical variables: These be divided into two types; Ordinal and Nominal variables).

Ordinal variables: These are variables that are ranked in increasing or decreasing order e.g. Tumour staging or level of income etc.

Nominal variables: These are variables that can be separated into groups in which order has no meaning, e.g. gender, province of origin etc.

On some occasions different statistical tests may be applied to the two types of categorical variables

Formulation of variables:

It is important to formulate variables properly at the outset in order to collect the maximum information possible. I will basically outline a few common pitfalls in formulating variables.

It is possible for a researcher to convert numerical variables to categorical variables, but categorical variables cannot be converted to numerical variables. Where possible collect variables as numerical data as more precision can be obtained in statistical analysis using numerical data than if converted to categorical data.

Any variable in which information can be collected as a numerical variable should be collected in that manner and during analysis can be converted into a categorical variable if required.

If such conversion of data occurs then the following points should be noted:

The groups must not overlap e.g. if grouping ages must be from 1 - 4.9, 5 - 9.9, etc. rather

than 1-5 and 5-10 etc. There must be continuity from one group to next. The groups must range from lowest to highest value. The groups should be of equal width. The groups must have validated basis or have logical reason for its grouping.

Some other issues with formulating variables include formulating variables that have variable objectivity in measurements. For instance if we want to measure a subjects knowledge of a disease define how do we poor knowledge/adequate knowledge? How does one define poor compliance with TB treatment? Is it missing a defined proportion such as 30% or 50% of treatment? One of the recommended options is to search the literature to see if validated definitions exist for the appropriate variables of interest.

Dependent and independent variables:

It is also useful to know the relationships of variables to one another as one variable may be influenced by another and the outcome measure may be the result of interaction between different variables.

Dependent variables are those that are influenced or modulated by other which are usually independent variables. Incidence of lung cancer would be the dependent variable to smoking. However it must be borne in mind that such association is not proof of causation which requires more stringent proof.

Confounding variables:

In health research the relationship between variables and their effects on the outcome being measured is often complex.

For instance when one considers the relationship between betel nut chewing and oral cancer one may consider a simplistic relationship between the two. However in reality often the outcome being oral cancer is the result of complex interplay between betel nut chewing, age, genetic factors, smoking etc which may all contribute to the outcome itself or influence the other variables.

Such factors are known as confounding and therefore during planning and formulating variables one must think about how variables may influence each other.

Such confounding factors can be adjusted for either by the study design (by randomisation and matching techniques) or during the analysis of data. Such methods include simple stratification methods or more complex multivariate analysis such as logistic regression modelling.

In conclusion properly selecting and formulating variables for a study is very important as this determines how the data is collected and analysed and what conclusions are then derived to address the objectives of the study.

References:

- Designing & conducting health systems research projects by C M Varkevisser et al with WHO & KIT publishers Amsterdam 2003
- Statistics for Social Science research by George Argyrous
- Statistics at Square One by TDV Swinscow revised MJ Campbell BMJ books-1996

Statistical Analysis and its Interpretation

Paper presented by: Dr Paulus Ripa Medical Education Unit

School of Medicine and Health Sciences, University of Papua New Guinea

In this presentation I would like to briefly discuss the role of statistical analysis, the steps to take in analysing data and its interpretation. I want you to bear in mind that I am not a trained statistician and that my presentation is based on a working and somewhat superficial knowledge of statistics acquired in doing small research projects and supervising students. I would also point out that I am only addressing some very basic s but fundamental aspects of statistical analysis whilst leaving out some perhaps unnecessary and more detailed aspects of analysis. What is the role of statistics in health research? Two types of statistical analysis are used; descriptive statistics and inferential statistics.

Descriptive statistics is used to make a mass of data easy to understand by using figures, tables and diagrams.

Inferential statistics is used when results from a study performed on a sample is used to draw conclusions about what these results mean for the population from which the sample was drawn.

In most scientific studies it is usually impossible to study the whole population of interest either due to cost or logistic difficulties. Statistical methods allow us to understand how results from a representative sample can be extrapolated to the population of interest.

Inferential statistics has 3 main roles in Health research:

To test a hypothesis; To estimate magnitude of effect of a variable on the outcome; To adjust for confounding factors.

Hypothesis testing:

Hypothesis testing is used to establish whether there is a significant difference or relationship between two variables or their effect on the outcome measure. For instance you would want to use inferential statistics to answer the following questions; Does smoking increase the chances of getting lung cancer? Is treatment X better than treatment Y?

Estimating magnitude of effect:

One may not only want to know if smoking is significantly associated with lung cancer but wish to know by how much smoking increases the risk of developing lung cancer. Is it by a factor of five times or ten times compared to non smokers?

Adjustment for confounding:

You may have to adjust for confounding factors in a study if some characteristics may not have been controlled for in the study design but may affect results. This can be adjusted for using statistical methods.

Procedure in statistical analysis:

Before analysis your data needs to be correctly entered into a spreadsheet, usually in a statistical program and would need to be checked to ensure that no mistakes were made during entry (which is common and happens all the time). These issues are being dealt with by other speakers.

The first step in analysis is performing descriptive statistics which is useful not only in describing your data but also in preliminary preparation for application of inferential statistical methods.

Descriptive statistics include the following analysis, Frequency distributions, Cross tabulations, Histograms and Box plots, and Scatter diagrams. The importance of visually looking at how your data looks is a major prerequisite to proper analysis.

The first procedure is to run frequencies on all your data and look at them (preferably in print).

This gives a count (and %) of each variable being measured. The following is an example from a case control study of mothers attending antenatal clinics vs. those not attending clinics before delivery at PMGH¹. The data shows the number of cases in the first box. We know from such a table that there is no missing data. The second table shows the proportion of babies with low birth weight. This procedure should be applied on all your variables.

Statistics

lov	v birthweig	ht
Ν	Valid	144
	Missing	0

low birthweight

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	yes	25	17.4	17.4	17.4
	no	119	82.6	82.6	100.0
	Total	144	100.0	100.0	

Frequencies for numerical data can be summarised as mean or median and spread of data can be expressed as standard deviation or interquartile range. Mean or median are known as measures of central tendency and give some idea of what the typical measurement is in a data set whereas standard deviation/interquartile range are measures of dispersion showing how the data is spread around the mean or median.

Cross tabulation:

The next step is to summarise all numerical data and perform cross tabulation on nominal data. Cross tabulation allows us to look at interaction of various categorical variables. For instance we would like to see from the aforementioned data set whether formal education had any influence on attendance of antenatal clinic.

		Any Forma		
		no	yes	
No clinic attendance		16 (70%)	32 (26%)	48
Clinic attendance		7 (30%)	7 (30%) 89 (74%)	
Total		23 (100%)	121 (100%)	144

Such a table shows us for instance that a higher proportion (70%) of women who didn't attend antenatal clinic had no formal education whereas only 26% of educated women had failed to attend antenatal clinic.

Risk:

Such cross tabulation also can help in defining measures of association based on risk for some outcome measures. For instance is there increased risk between smoking and lung cancer and by how much?

Risk is expressed in case control studies as odds ratio and in Cohort studies as relative risk. In interventional studies it more meaningful to be expressed in terms of absolute risk reduction (or number needed to treat). A separate handout has been provided to show how these various measures of risk can be calculated

Histograms and Box plots

For numerical data after running frequency distributions the data needs to be visually displayed as a histogram as well as a boxplot.

Check histogram if to see if it is consistent with a normal distribution; if so the summary statistics can be expressed as mean for central tendency and standard deviation as measure of spread of data. However if there is gross skewing or grossly non normal in distribution it is more helpful to express data as median & interquartile ranges.

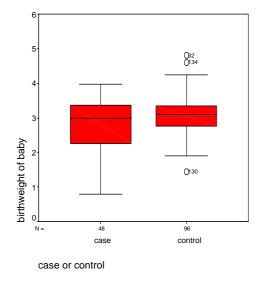
It also helps later on in deciding whether or not to use parametric or non-parametric statistics for hypothesis testing.

The histograms show the first one on the showing a distribution that is consistent with a normal distribution where as the second one is not normally distributed.

Histogram For GROUP= case 10 For GROUP= control 30 20 Frequency Std. Dev = .87 Frequency Std. Dev = .55 Mean = 2.69 Mean = 3.07 N = 48.00 N = 96.00.75 1.25 1.75 2.25 2.75 3.25 3.75 1.50 2.00 2.50 3.00 3.50 4.00 4.50 1.00 1.50 2.00 2.50 3.00 3.50 4.00 1.75 2.25 2.75 3.25 3.75 4.25 4.75 birthweight of baby birthweight of baby

Histogram

The box-plot is also important to look at and an example is shown below.



The box represents the middle 50% of the data or the interquartile range (50 – 75th Centile). The line in the middle of the box represents median. The box plot shows if the data is symmetrical. It also indicates the outliers in the data. The summary statistics of the data should be express as Median and Interquartile range if the outliers are significant. Purpose of Inferential statistics in clinical research:

Inferential statistics can now be used on the data and may be used for testing a hypothesis, estimating the magnitude of effect or adjusting for confounding factors in a study.

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

Let us first consider the purpose of using inferential statistics and the use of confidence intervals (CI). in analysis. Expressing results as within 95% CI is now preferred because it includes both hypothesis testing and estimating magnitude of effect (precision of estimate).

What does 95% CI mean? Let us use an example of a hypothetical cohort study in which bottle fed babies were found to have a fivefold risk of developing diarrhoea compared to breast fed babies. The results of this study were expressed as a Relative risk (RR) of 5 with 95% CI of 2-12.

This result can be expressed as follows; the risk of bottle fed babies developing diarrhoea is 5 times that of breast fed babies in the study sample. The risk in the population is not known. We can however find that 95% of the time any bottle fed baby will face an increased risk of developing diarrhoea any where from 2 to 12 times that of breastfed babies in the population.

A narrow 95% CI is usually more precise, e.g. a 95% CI of 4 - 6 with a RR of 5 would be more precise than that of a 95% CI of 2 - 12. In measures of association (risk) if the 95% CI includes 1 it means there is no statistical significance (p>0.05).

On the other hand if a statistical test is used to compare differences (e.g. in students t test) if the 95% CI includes 0 it is not statistically significant (p>0.05)

Statistical tests:

Different statistical tests are used for different reasons. The statistical test used also depends on the type of variables, i.e., categorical or numerical data. If it is numerical data, then you have to decide if the data is normally (Gaussian) distributed or skewed.

There are two types of statistical tests; Parametric and Non-Parametric tests.

The Parametric tests are more powerful statistical tools for quantitative data that conforms to normal distribution. The Non-Parametric tests are used when the data do not fulfil the normality assumptions (skewed data).

Included as an appendix is a flow diagram for choosing the types of statistical tests for analysis of data; Follow the flow diagram to see which test to use in a given situation

Interpretation of result when comparing differences:

The data below compares the differences in birth weight (BW) of babies born to pregnant mothers who booked in antenatal clinic against unbooked pregnant mothers.

Babies of booked mothers: Mean BW = 3.0kgs (± 0.6kgs)

Babies of unbooked mothers: Mean BW = 2.7kgs (± 0.9kgs)

Results of t test show that the mean difference is 0.3kgs with a 95% CI of difference of 0.15kgs to 0.62kgs.

This data indicates that though in the sample the difference in BW is 0.3 kgs, in the general

population from which this sample is taken we are confident 95% of the time that any baby of a booked mother will weigh anywhere from 0.15kgs to 0.62 kgs more than baby of an unbooked mother.

Because the 95% confidence interval does not include zero it is statistically significant; in this case it is p=0.007.

Multivariate analysis:

In studies that involve human beings the outcome factors are usually the result of many interacting factors. It is therefore not entirely correct to perform only bivariate analysis on the effect of a single variable on an outcome measure alone. Multivariate analysis is often

required to adjust for confounding factors and to determine independent predictor variables for a given outcome. These techniques however require help from a statistician or somebody with considerable expertise in statistical analysis.

References:

- Designing & conducting health systems research projects by C M Varkevisser et al with WHO & KIT publishers Amsterdam 2003
- 2. Argyrous G. Statistics for Social Science research
- Statistics at Square One by TDV Swinscow revised MJ Campbell BMJ books-1996

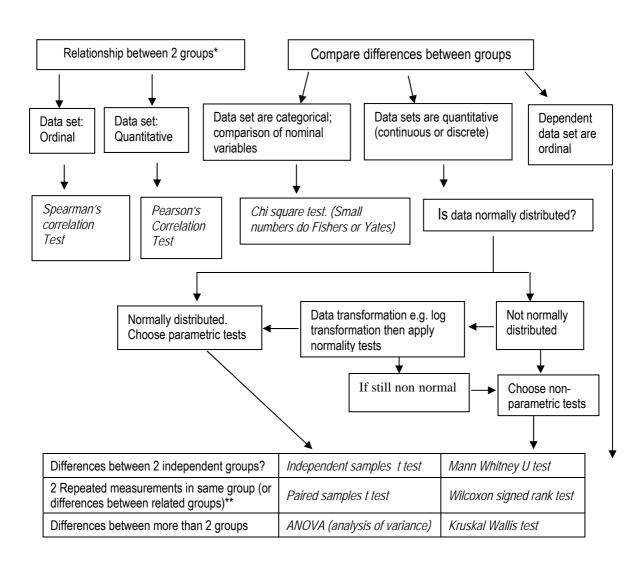
OTHER MORE COMPLEX TESTS ARE NOT INCLUDED E.G. SURVIVAL CURVES OR OTHER MULTIVARIATE METHODS.

* Relationship determining the effect on a dependent continuous variable by several other independent variables is tested using *Linear Regression*.

* Effect of several independent variables on a binary outcome (i.e. only two possible outcomes such as death or no death) is tested using *Logistic regression*. Logistic regression is often used to adjust for confounding factors (adjusted odds ratios).

48

Appendix: which test to use? Flow diagram for choosing a statistical test Dr Paulus Ripa



Ethical Issues in Medical Research

Paper presented by Professor John D Vince Division of Clinical Sciences,

School of Medicine and Health Sciences, University of Papua New Guinea

At the outset I make the disclaimer that I am not a Medical Ethicist! I have, however, been involved in medical research in various capacities over a number of years and therefore

have some understanding of some of the issues involved in the topic.

Whilst it is difficult to define ethics and ethical practice precisely, most would agree that it is essentially about "Doing the Right Thing". Related to medical research and put slightly differently, "If you wouldn't collect sensitive information or do a procedure or collect a specimen or give a treatment from or to yourself, your wife, children, or other family members you shouldn't be collecting it or doing it on others".

As Kerridge, Lowe and McPhee point out [1], the application of ethical principles to research involving human subjects requires that such research should fulfil the following principles:

It should be scientifically valid. There should be a clear hypothesis to be tested. The methodology used must be capable to testing this hypothesis. It should be of some potential benefit to the subject. It should be of some potential benefit to the community. It should not unnecessarily repeat previous work

Although these principles would seem obvious it is surprising how often researchers at various levels are unable to state precisely the question they wish their research to answer.

The wide spectrum of research types and methods used in medical research falls into two broad categories, observational and experimental studies. Observational studies include case studies, descriptive studies and case controlled studies. In these the issue of informed consent is important, and issues of confidentiality are vital to protect the identities of individuals, communities and, in some instances, institutions. Experimental studies are therapeutic- testing of new treatment modalitiesor non therapeutic. In such studies fully Informed consent is of paramount importance.

The application of medical ethical principles to therapeutic research implies that such trials:

Should only be carried out when there is genuine uncertainty about the benefits of the treatment being offered. The new treatment should be compared against the best available treatment. Should allow for the subjects to withdraw, or that the trial be stopped if it becomes obvious during its course that one treatment is better than the other.

The use of placebo controlled trials to test drugs or treatments for a condition for which proven treatment already exists is no longer generally accepted as ethical. There may however, be exceptions to this and as Kerridge, Lowe and McPhee describe [1] controversies have arisen over the application of "pure" ethical principles to practical situations in resource poor environments. Placebo controlled trials of antiretroviral agents in the prevention of perinatal transmission of HIV in African patients were considered by some to be unethical, when a proven effective drug – Zidovidine (AZT) was available, but it was argued by others that the major differences in health indices and socio between the affluent and economic status poorly resourced countries meant that different research methodologies were acceptable if the research endpoint was of benefit to the inhabitants of the country. [2-6].

It might be thought that members of the medical and scientific professions would, almost by definition, adhere to ethical principles. Such unfortunately is not the case. At the Nuremberg trials of war criminal s after the Second World War several doctors were tried and found guilty of performing horrendous experiments on prisoners in Nazi concentration camps. The revelation of such practices led to the enunciation of the Nuremberg Code in 1947, which laid down the fundamental principles of human rights of the subjects of human research, including the principle that informed consent was mandatory [7].

The Declaration of Helsinki [8] was developed by the World Medical Association based on the 10 principles of the Nuremberg Code and the 1948 Declaration of Geneva, which stated Physician's ethical duties. First published in 1964, the declaration has undergone several revisions, the latest in 2008. The principles of the Helsinki declaration are as follows:

It is morally binding on Physicians. It overrides national or local laws if it provides for a higher standard of protection of humans. Respect for the individual. Right to self determination; Right to make informed decisions regarding participation initially and during the research; Investigators' duty is solely to the patient or volunteer. Subjects' welfare always takes precedence over the interest of science and society. Ethical consideration takes preference over laws and regulations. The operational principles require:

Thorough scientific knowledge of the background for the research; Careful assessment of risks and benefits; Reasonable likelihood of benefit: Suitably trained investigators; Proved protocols - independent ethical review and oversight; Information made publicly available; Consideration of possible conflict of interest; Interest of the participants after the study is complete should be addressed.

The Helsinki declaration forms the basis of other Codes of Ethical Practice such as the international Ethical Guidelines for Biomedical Research involving Human Subjects (Council for the International Organization of Medical Sciences [9]); In spite of their existence there have been numerous examples of research which has clearly breached these ethical codes of practice. They include the exposure of soldiers and civilians to irradiation, the use of ethnic minorities, intellectually handicapped, institutionalized and poorly educated subjects, various forms of coercion, the intentional infection of subjects with disease, and the withholding of information and of treatments. Examples of such studies are the Tuskegee Syphilis study [10] "arguably the most infamous biomedical research study in US history" [11] and the Willow-brook hepatitis study [12].

In the Tuskegee study, largely uneducated poor Afro American share croppers with syphilis, and a control cohort of uninfected men form the same background were enrolled in a study aiming to assess the natural history of syphilis and to determine if the currently used treatments (including the highly toxic arsenic) were beneficial. The study began in 1932. By 1947 it was accepted that penicillin, discovered in 1941, was a highly effective treatment, associated with few side effects. The study subjects were not given this treatment and were apparently discouraged from obtaining it. Added insult was the invitation to have "special free treatment" which was in fact a lumbar puncture for the investigation of changes in the cerebrospinal fluid. It was only in 1972 that the trial was stopped within 24 hours of a whistleblower leak to the press. Many of the original subjects died from syphilis or related complications, a number of their wives had been infected and a number of children born with congenital syphilis. President Clinton formally apologized to the study participants on behalf of the US government in a ceremony in 1997.

In the Willow-brook study, Children in an institution for the intellectually handicapped were infected with hepatitis (initially from faecal extracts) to assess the value of preventive treatment with Gamma globulin. Whilst there was a waiting list for admission to the institution, the children of parents who signed the consent form which stated that the researchers "should like to give your child this new form of prevention with the hope that it will afford protection" were given immediate admission to the study unit. The study was controversial and, whilst clearly breaching accepted ethical codes, demonstrated for the first time that there were two types of Hepatitis – A and B, with different incubation periods - raising the difficult issue of what should be done with information obtained from unethical studies.

In the National Women's' Hospital Cervical Cancer study women with carcinoma in situ provided information which were was subsequently shown to be incorrect and were not provided with adequate follow up. Several women developed invasive cancer of the cervix as a result. The ethical oversight of the study was found to be woefully inadequate [13, 14]. In the Melbourne Orphanage studies carried out over a number of years, babies and children in orphanages were infected with herpes simplex during a trial of an ineffective vaccine, some were given an experimental whooping cough vaccine which failed animal safety tests, and some were given adult doses of an influenza vaccine when it was recognized that there could be side effects [15].

These examples - and others - clearly demonstrate that in addition to the codes of practice there is a requirement for independent oversight of research, as enunciated in the operating principles of the Helsinki Declaration. All institutions, in which research is carried out, should therefore have an Institutional Research Ethics Committee and these committees should in turn report to state or national committees. The function of an Institutional Ethics Committee is to ensure that ethical standards are maintained in order to protect the interests of the patients or volunteers in the research, the Investigators and the Institutions. There is an increasing realization of the importance of "independence" and the involvement of nonmedical persons and in some cases the subjects of research themselves on such committees. The Australian National Health and Medical Research Council suggest that Institutional Ethics Committees should include men and women of different ages and include at least one member from each of the following categories: Laywoman not associated with the institution, Layman not associated with the institution, Minister of religion (of any faith), Lawyer, Medical graduate with research experience.

It is of interest to note that although there is currently some restructuring of the Papua New Guinea Medical Research Advisory Committeethe committee that has the ultimate oversight of medical research in the country – 10 of the 12 members is based in the National Health Department or research institutions. The community representative and the minister of religion are the only truly 'independent' members!

Forty percent of Papua New Guinea's citizens are children less than the age of 15 and 15% less than 5 years. Since the prime causes of mortality and morbidity are infectious disease with a significant contribution from malnutrition, they form an important group on which research may be centered. They are also of course a highly vulnerable group and young children are unable to give fully informed consent - a fundamental concept.

Researchers must rely on parents to give informed consent to collect information or biological material from their children. This places a particular responsibility on researchers. Whilst it may be entirely ethical to collect a sample of blood from a consenting adult for experimental purposes after full explanation and consent, my own view is that it is, in most instances, unethical to collect such a sample from a child, unless it can be done in the course of routine blood sampling as part of "best practice". To perform a painful procedure on a child purely for research purposes breaches basic ethical principles. There are certain situations (perhaps, for example, in assessing antibody response to vaccination) where sampling may be justified (on the basis of likely benefit to the community), but even in such circumstances efforts should be made to minimize such sampling.

Even more care is required in determining the ethics of research on intellectually handicapped persons, psychiatrically disturbed patients or others unable to provide informed consent. In such situations the institutions caring for these individuals must be fully aware of their responsibilities to safeguard the rights of their charges. In regard to research using animals, it is my personal belief that animals have rights and that human beings have a responsibility towards animals. We share the world with them, we have the great majority of our DNA in common, and we depend on them for our existence. It is well recognized that animals have been used in experiments which are cruel, inflicting physical and psychological pain and which would not be permitted on humans. It is also recognized that the results of experiments on non human animals are not necessarily applicable to human animals. Some would argue that some advances in medicine would not have been possible without the use of experimental animals. I understand that there are some very special circumstances where there are no alternatives to animal research, but with the increased availability, sophistication, and ability of cell culture techniques, computer modelling and DNA technology, I believe these circumstances are becoming fewer and fewer. When animals are used, they should be treated humanely, and respectfully, and all attempts made to avoid suffering. A simple mantra for animal research would be "If you wouldn't do this to your pet dog, or cat, or mouse, you shouldn't be doing it to this animal". Animal experimentation should be strictly regulated (as indeed it is in many countries) and all animal experiments must be cleared with both the Institutional Ethical Committee and the national research ethical body.

Researchers involved in a study obviously have an interest in its completion and they may therefore lose some objectivity in interpreting the accumulating results. For this reason all clinical trials of new therapies, vaccines, or surgical procedures should be independently and regularly monitored by a Data Safety Monitoring Board, so that results suggesting or indicating adverse events and outcomes can be detected and a decision made as to the merits of continuing or of stopping the trial.

What are some of the important practical issues relating to research ethics for members of the School of Medicine and Health Sciences? Informed consent must be obtained, whether it is from patients or volunteers agreeing to have information recorded or blood samples taken or from the Port Moresby General Hospital or its various departments agreeing to the collection of laboratory or other data. The issues of confidentiality and safety of information often require the use of coding of questionnaires or data sheets. Measure to reduce and if possible eliminate the possibility of clerical errors should be taken. Duplicate or triplicate copies should be made and kept is safe locations, and a fail proof way of subsequently decoding the information records if such should be deemed appropriate in the future should be ensured. The Protection of Individual Property legislation implies that specimens taken from individuals should be used only for the purposes for which they are (This originally intended. has complex implications for the storage of samples which have been taken for a particular study, to be used for other possible studies in the future).

The SMHS has a well established Research Committee one of the functions of which is to ensure that research projects conform to established ethical principles. An outline of all research projects should be submitted to the committee. Projects which involve the collection of human tissues including blood, or the collection of potentially sensitive data should be submitted in detail. The Research Committee will then, if appropriate, advise the submission of projects to the MRAC (of which the school committee chairman is a member). In addition it is important to note that all studies involving HIV/AIDS must be submitted to the National Aids Council Research Advisory Committee for its independent approval.

Ethics in medical research can be a tortuous, fascinating and difficult subject, but as a broad principle it can be summarized by the phrase "Do As You Would Be Done By". If we follow this rule, we cannot go far wrong in our research.

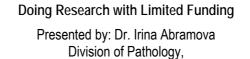
Acknowledgement:

Being no expert in the area of Medical Ethics, I acknowledge my indebtedness to the Chapter on Biomedical Research in Kerridge, Lowe and McPhee's Ethics and the Law for the Health Professionals.

References

- Kerridge I, Lowe M, McPhee J. Biomedical Research. In: Ethics and Law for the Health Professions. Katoomba: Social science Press.1998:356-474.
- Lurie P, Wolfe SM, Unethical traiols of interventions to reduce perinatal transmission of the human inmmunodeficiency virus in developing countries. N Eng J Med 1997;337:883-885.
- Ange IM. The ethics of clinical research in third world N Eng J Med 1997; 337:847-849
- 4. Editorial. The ethics industry Lancet 1997;350: 897
- Gambia Government/Medical research Council Joint ethical Committee. Ethical issues facing medical research in developing countries Lancet 1998; 351: 286-287

- Varmus H, Satcher D. Ethical complexities of conducting research in developing countries. N EngJ Med 1997;337:1003-1005
- Shuster E, Fifty years later: the significance of the Nuremberg Code N Eng J Med 1997;337(20):1436-1440)
- Declaration of Helsinki. Wikipedia <u>http://en.wikipedia.org/wiki/Declaration</u> _of Helsinki
- Council for the International Organization of Medical Science. International ethical guidelines for biomedical research involving human subjects Geneva 1993.
- Tuskegee Study of Untreated Syphilis in the Negro-Male
 <u>en.wikipedia.org/wiki/tuskegee_Study_of</u>
 _Untreated-Syphilis- in _the_Negro_Male
- Katz RV, Kegeles SS, Kressin NR et al The Tuskegee legacy project: willingness of minorities to participate in biomedical research. J Health Care Poor Underserved 2006; 17(4):698-715.
- Krugmam S. The Willowbrook hepatitis studies revisited: ethical aspects Rev Infect dis 1986; 8(1)157-162.
- McNeill PM. Committee review and the cervical cancer enquiry. In Ch 3: The development of committee review in the United States, Britain, Australia and New Zealand. The ethics and Politics of Human Experimentation; Cambridge University Press New York 1993 p 76-79



School of Medicine and Health Sciences, University of Papua New Guinea

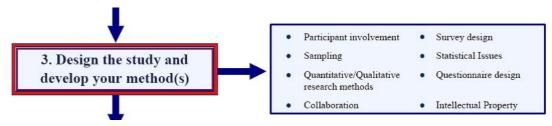


Figure 1. Research Process Flowchart www.rddirect.org.uk

A budget of a health research project heavily depends on a choice of research methods.

Those used in medical research can be classified as questionnaire based, examination based, laboratory tests and instrumental methods. The two latter are the most expensive ones so as they may require expensive reagents and/or equipment.

Quantitative / Qualitative data: Demographic data, Laboratory data, Examination data, Questionnaire data

Questionnaire based methods are among the cheapest ones but could be time consuming. Purposefully developed questionnaire can become a powerful research tool, so as it can provide data for a comprehensive analysis of an impact of the different factors to this or that pathologic condition or disease, e.g. age and sex, ecological factors, diet, social status, concomitant diseases, type of treatment, number of pregnancies, space interval between births, etc.

Examples of Questionnaire data:

- Symptoms / Complaints, History (medical, social, family, etc), Pregnancies, Nutrition, Live conditions – environment, rural/urban,
- Live level / family income, Level of education, Habits, Other – depending on a study goal

NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES)

A program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations Example of Questionnaire variables from NHANES

Continuous NHANES Variable List Questionnaire Variables

Variable Name	Variable Label
BPQ010	About how long has it been since {you/SP} last had {your/his/her} blood pressure taken by a doctor or other health professional?
BPQ020	{Have you/Has SP} ever been told by a doctor or other health professional that {you/s/ he} had hypertension, also called high blood pressure?
BPQ030	{Were you/Was SP} told on 2 or more different visits that {you/s/he} had hypertension, also called high blood pressure?
BPQ050A	HELP AVAILABLE (Are you/Is SP) now taking prescribed medicine?
BPQ070	About how long has it been since {you/SP} last had {your/his/her} blood cholesterol checked?
BPQ080	{Have you/Has SP} ever been told by a doctor or other health professional that {your/ his/her} blood cholesterol level was high?
BPQ100d	(Are you/Is SP) now following this advice to take prescribed medicine?
MCQ160B	Has a doctor or other health professional ever told {you/SP} that {you/s/he}had congestive heart failure?

National Health and Nutrition Examination Survey http://www.cdc.gov/nchs/nhanes.htm

Data collected via interviews, physical examinations and lab tests are then entered in one common database which allows analyze interrelations between different variables and assess an impact (risk factors) of different variables on the resulting condition (disease).

Data obtained with the help of the above methods could be further analyzed using Excel or SPSS or other appropriate software which can perform descriptive statistics (mean, deviation, median, etc.) or more advanced tests.

T-test for independent variables is an example of more advances statistical analysis. It allows to compare differences between independent groups, (e.g. males and females, villagers and town-dwellers, experimental and control groups, etc.) in continuous variables (Hb level, cholesterol level, any measurable laboratory test result).

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

T-test for independent variables: SPSS

e Edit	View Data Tra	ansform	Analyze Graphs Utilitie	es W	/indow Help
; 4		J <u>1</u> [Reports Descriptive Statistics	; 🖪	<u>s</u> 0
<u>.</u>			Compare Means	•	Means
	iv	dv	General Linear Model	•	One-Sample T Test
1	1 Experimental 2 Experimental 3 Experimental		Mixed Models	•	Independent-Samples T Test.
2			Correlate	•	Paired-Samples T Test
3			Regression		One-Way ANOVA
4	Experimental	12	Loglinear	• T	
5	Experimental	8	Classify Data Reduction		
6	Experimental	9			
7	Control	7			
8	Control	4	Scale +		
9	Control	9	Nonparametric Tests		
10			Survival 🕨		
11	Control	10	Multiple Response	•	

Larry P. Wiley, SPSS Tutorial:http://academic.uofs.edu/department/psych/methods/cannon99/level2b

SPSS: Results of the t-test (comparing means from independent groups)

T-Test

Group Statistics

Γ		Treatment	N	Mean	Std. Deviation	Std. Error Mean
S	Score	Experimental	6	10.6667	2.50333	1.02198
		Control	e	7.1667	2.31661	.94575

		Tes Equa	ene's t for ility of ances			t-test	for Equality of	Means		
									Interva	i% dence I of the rence
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Score	Equal variances assumed	.006	.942	2.514	10	.031	3.5000	1.39244	.3975	6.603
	Equal variances not assumed			2.514	9.941	.031	3.5000	1.39244	.3949	6.605

Independent Samples Test

Larry P. Wiley, SPSS Tutorial: http://academic.uofs.edu/department/psych/methods/cannon99/level2b

Examples of comparison between independent groups:

Villagers vs. town-dwellers; Coastal area vs Highlands; Iron pills vs. no treatment; Parity 0 vs 1,2,3,4,5,6; Remote areas – towns; Vegetarians vs. meat-eaters

Conclusions

Health research project database may contain different types of data – collected via physical

examinations, lab tests, questionnaires. Reasonable use of a questionnaire tool allows decreasing research project cost without affecting its quality.

Structure of Research Paper for Publication Paper presented by Dr. Prem P. Rai Division of Health Sciences,

School of Medicine and Health Sciences, University of Papua New Guinea

Introduction

Research is an essential component of the university teaching and integral to building a successful academic career. Conducting research, writing and publishing scientific papers are what the academia is all about. Research paper is the most common method for scientists to communicate with other scientists and health professionals about the results of their research. The thought of writing a scientific paper can be a daunting task especially to young researchers. The renowned American journalist and writer Gene Fowler summed it well when he said, "Writing is easy. All you do is to stare at a blank sheet of paper until drops of blood form on your forehead". However, with enough research and practice a scientific paper can be written that is both meaningful and important.

Research paper presents an objective account of the results, with an analysis and interpretation of data and ideas in order to answer a specific question. Analysis is the process of organizing and summarizing data in order to answer a question whereas interpretation refers to a discussion of the meaning and implications of your answers for the issues that your paper addresses.

Major sections of research paper

A scientific paper consists of four major sections, with the acronym IMRAD: introduction, methods, results, and discussion. In the introduction section the author introduces the topic that was researched and also mentions previous research that has been done on this topic. He explains why his research is relevant, and states his hypothesis. The second section of the paper is called the methods section. In this section all the materials used in research are listed and research methodology described. How the research was conducted is explained precisely so that it could serve as guide for other scientists to be able to duplicate the original research and arrive at the same conclusions. The third section is known as the results section in which results from the research including statistical information and data produced are presented. Attempts should be made not to explain or interpret the results in this section. The last section of the paper is called the discussion section. In this section the author interprets the meaning of the results and discusses its significance. He also points out any limitations or problems (variables) he ran into during his research and how that may have affected his results.

The important attributes of a good research paper are: a clear statement of problem, logical coherence, a good flow, and use of experimental design appropriate to the nature of the problem, absence of factual errors, conclusions supported by the data, adequate referencing, and contribution to knowledge.

Structure of research paper

Research papers are written and presented in an orderly and logical manner using a standard format. This format is: title, authors, abstract, introduction, materials and methods, results, discussion, acknowledgements,

references/literature cited. The first requirement is to select the journal you want to publish your work in. The scope and scientific content of the paper, the intended audience, and whether the journal is local or international are the aspects that should be considered before writing the paper. Also considered is the nature and form of the research article, whether it is an original research paper, short communication, case report, review paper, letter to the editor, or book review, etc. Journals provide in each issue, and on their web sites, instructions to the authors on the format for submitting papers. This should be consulted prior to writing the paper.

Title

The title should be short and informative. A good title should describe the contents of the paper in fewest possible words. Sometimes a title that describes the results is more effective. For example: "Effect of smoking on academic performance" could be titled "Students who smoke get lower grades"; "Betel nut chewing and pregnancy" could be phrased as "Women who chew betel nut during pregnancy have lower frequency of anemia", etc. Another example of a short but descriptive title is "Biologically active components of a Papua New Guinea analgesic and anti-inflammatory lichen preparation".

Many journals require a running title to be printed at the top or bottom of every page of the article when it is published. Usually, this is short and between 30 and 50 characters.

Authors

The person who did the research and wrote the paper is usually listed as the first author. Other people who contributed to the research work are listed as co-authors. In case of supervised research (e.g. students' research) supervisors are listed as authors. The journal should be consulted for style used in citing authors and their institutions.

Abstract

An abstract is the essence of the paper and provides a 'preview' of what's to come. It is included in the beginning of the paper, but it is good to write the abstract after rest of the paper is written. The abstract should state the purpose of the study, hypothesis, basic methods, main findings including statistical data if any, and principal conclusions. It should be a concise single paragraph not exceeding 150-200 words.

Abstract is usually written in past tense. It should be complete and able to stand on its own. It should not contain any abbreviations, citations or foot notes, or refer to any other part of the paper such as figure or table. Abstracts are also published separately by bibliographical sources such as Biological Abstracts, Chemical Abstracts, etc. They allow other scientists to quickly read and decide which articles they want to read in depth. Most journals require authors to provide 3 to 5 or more key words to assist indexers in cross-indexing the article. Key words are normally placed beneath the abstract.

Introduction

The introduction should mainly address the following questions: why was this study undertaken, what is the state of existing knowledge, and what are the hypothesis and/or objectives of the study. The introduction should state exactly the objectives of the study and reasons for selecting them. The rationale behind the work should be explained with the intention of defending it. The relevant literature should be reviewed and summarized showing state of present knowledge on the subject.

The introduction is written using past tense. The ideas should be organized, making one major point with each paragraph. Sub-headings should be avoided. Background information is provided

only as needed to support a position. There is no need to present a comprehensive review here, only the pertinent references should be cited. Usually one to four paragraphs should be enough in the introduction section.

Materials and Methods

Materials and methods can be reported under separate subheadings or can be incorporated together. In this section there should be enough information to allow another scientist to repeat the study. It is advisable to look at other papers published in the field to get some idea on what is included in this section. To be concise, the methods section should be organized under meaningful subheadings and techniques used described in sufficient detail. Established methods should be referenced but no description is necessary (for example Bradford essay for estimation of protein). For published but not well known methods, a reference as well as a brief description should be included. Only specialized chemicals, biological materials, and any equipment or supplies that are not commonly found in laboratories should be included in the list of materials. There is no need to list test tubes, pipettes, beakers, etc., or standard laboratory equipment such as centrifuges. However, if use of a specific type of equipment, a specific enzyme, or a culture from a particular supplier is critical to the experiment, then single it out, otherwise no.

In bio-sciences different solutions are used to perform an experiment. These solutions should be referred by name and described completely, including concentrations of all reagents, and pH of aqueous solutions, solvents, etc. The methodology should be completely described, including such specifics as temperatures, incubation times, etc. When reporting experiments involving human subjects, authors should indicate whether the procedures complied with relevant ethical considerations and were according to ethical guidelines of the responsible ethical committee of the institution.

Results

In presenting the results the objective of the research must be kept in mind. Results that do not relate to research objective should not be mentioned. A completely objective report of the results should be given in this section. No attempt should be made to interpret results or explain anything; this should be saved for discussion section. Results should be presented in a logical sequence; the data should be analyzed and converted in the form of a figure, graph, table, or in text form. Graphs or tables should be used only where appropriate. Text should complement any figures or tables, not repeat the same information. As always, past tense is used when reporting the results.

In text, each figure is referred as "figure 1", "figure 2," etc.; and tables are numbered as well. The figures and tables should be numbered consecutively. The figures and tables are placed at the end of the report (following literature cited), or may be placed within the text of results section. Each figure must have a caption (caption goes under the figure) and each table must have a heading (title with description goes above the table). Figures and tables must be sufficiently complete that they could stand on their own, separate from text.

Discussion

The objective here is to provide an interpretation of the results and support for all of conclusions, using evidence from the experiment. Data should be interpreted in depth and the significance of the findings should be clearly described in the discussion. When а phenomenon is explained mechanisms that account for the observation must be described. If results differ from expectations, explanation as to why that may have happened should be given. If results agree, then the theory that the evidence supported should be described. The biggest mistake that many authors make in discussions is to present a superficial interpretation that more or less re-states the results. This should be avoided. The discussion should emphasize the new and important aspects of the study and the conclusions that follow from them. A good paper ends with strong conclusions.

Conclusions should be linked with the goals of study. Recommendations for future directions, such as how the experiment might be modified to accomplish another objective, may also be made

References

When writing a research paper, authors use information from other published sources in order to prove certain points. Any time information from another source is used, it must be shown in the paper where that information was found. This is called "citing" or "referencing." If the information is used without citing its source, it is "plagiarism." It is illegal to plagiarize someone else's work or ideas.

There are several different formats for citing sources in a research paper. In a proper research paper, only primary literature is used (original research articles authored by the original investigators). Caution should be exercised in using web sites as references as they may not be authoritative. If an on line journal is cited, the journal citation should be mentioned (name, volume, year, page numbers). Main publication sources include periodical, book and edited book. In citing a journal name of journal, often abbreviated according to Index Medicus and italicized, year, volume number, and pages of article should be indicated. When a book is cited, name of publisher and city of publication is given, and in citing an edited book the title of book, names of editors, and pages of chapter, city and publisher are mentioned.

Some examples of in text citation are: "Fertility estimates derived from the 1980 National Census (4)"; "Fertility estimates derived from the 1980 National Census⁴"; "Fertility estimates derived from the 1980 National Census (Bakker, 1980)", etc. The 'et al' should be used if there are more than two authors (Ferrier & Lunkes, 2003; Wiersdorff et al, 2000). When authors are cited by their surnames they can be listed in alphabetical order in the reference section.

There are two main systems of citing references: Harvard system and Vancouver system. The PNG Medical Journal and the Pacific Journal of Medical Sciences published from Papua New Guinea use the Vancouver system of referencing. Examples of literature citing according to Vancouver system is presented here.

Journal articles:

Welsch R. The distribution of therapeutic knowledge in Ningerum: implications for primary health care and the use of aid posts. *PNG Med J* 1985; 28: 205-210.

Book:

Gillett JE. The health of women in Papua New Guinea. PNGIMR: Kristen Press, 1991

Chapter in a Book.

Chaney SG. Principles of nutrition II: Micronutrients. In: Delvin TM, editor. Textbook of Biochemistry with Clinical Correlations, 4th ed. Brisbane: Wiley-Less, 1997: 1107 – 36.

Published proceedings paper.

Kruse-Jarres JD. Basic principles of zinc metabolism. *In*: Kruse-Jarres JD, Scholmerich J, editors. Zinc and diseases of the digestive tract. Proceedings of the International Falk workshop, Germany, 1996: 3 – 15.

Thesis:

Macfarlane J. The relationship between cultural beliefs and treatment-seeking behavior in Papua New Guinea: implications for the incorporation of traditional medicine into the health system. DIH Thesis, Centre for International Health, Curtin University of Technology, Perth, Australia, 2005. *Web:*

NCHS (National Center for Health Statistics) (1996)

http://www.cdcgov/nchswww/howto/sitelec/citele

Acknowledgements

This section is optional. It is however customary to thank those who helped with the experiments, or made some important contributions to success of work. The financial or material support should be acknowledged. Personal acknowledgements normally precede those of institutions or agencies.

Summary

The process of writing a scientific paper should start with some planning. After writing the paper, it should be carefully revised, first for content and then for style. The useful tips for writing a good research article can be summarized as follows: decide on the journal to which the article will be submitted and study its format, read "instructions to authors" section of that journal, write the first draft freely consistence with the journal's requirements, edit the paper, double check the facts, trim the hedges, revise and rewrite. The draft paper should be given to peers and/or colleagues to read and comment. The draft paper should be revised again based on the feedback received. The paper is ready for submission.

Finally, if the paper is accepted for publication, enjoy the fruit of your labor. It is as an academic accomplishment.

Useful References for further details:

Victoria E. McMillan, <u>Writing Papers in the</u> <u>Biological Sciences</u>, Bedford Books, Boston, 1997

Robert S. Day, <u>How to Write and Publish a</u> <u>Scientific Paper</u>, 4th edition, Oryx Press, Phoenix,1994.

Plagiarism in Biomedical Research

Paper presented by Prof. Jean McPherson Medical Education

School of Medicine and Health Sciences University of Papua New Guinea

To plagiarise is to "pass off (another's ideas, writings or inventions) as one's own" [1]. Whilst imitation is the sincerest form of flattery [2], plagiarism is theft. Plagiarism may be inadvertent, but all researchers, artists, writers and publishers have a moral and ethical responsibility to ensure that all their work is properly attributed. Few of us can claim uniquely original ideas or hope to emulate the ancient Greek scholar Archimedes, who reportedly proclaimed "Eureka!" (I have found it) when he stepped into a bath and noticed that the water level rose - he had suddenly understood that the volume of water displaced must be equal to the volume of the part of his body he had submerged [3]. The progress of research is generally far more painstaking than this, and even our best and most original research is usually built on the work of others in the field. Proper acknowledgement of the role of others in the development of our understanding and of our research efforts does not in any way detract from the value of our research.

The explosive development of information technology over the last 10 – 20 years has brought plagiarism to the forefront of many aspects of our professional lives. Internet search engines can find text and images within seconds and the results of such searches can be copied and pasted into personal documents with ease. Student plagiarism has become a major problem for academic institutions, and the development of plagiarism-detection software is now a major growth industry.

Turnitin [4] is a software program which was developed in 1996 to monitor the recycling of research papers in undergraduate classes. It can be used by students to check their work before submission and by academics when marking assignments. The related iThenticate plagiarism-checking software was introduced in 2003 and is used by publishers, research facilities, government agencies, financial institutions, and legal firms [5]. Thus, whilst advances in information technology have made it easier to commit plagiarism, there have been parallel developments in approaches to detect plagiarism.

Scientific fraud includes the fabrication of data (and/or physical evidence), the falsification of data, and plagiarism [6]. It may be committed when performing and/or reporting research. An example of fabrication was an investigator at the Massachusetts General Hospital who published (1973 - 1977) claims that he had subcultured permanent lines of cells from patients with Hodgkin's disease; he subsequently confessed that these claims were fabricated [6]. Falsification of data involves the manipulation (fudging, cooking, tweaking) of data to fit the investigator's conclusion; for example by omission of some results. It may come to light simply because the reported results cannot be reproduced [6].

Plagiarism in research may be inadvertent and unintentional, although this is less likely if the investigator is fully familiar with his or her research area. A psychological concept known as cryptomnesia [7] (a memory in one's consciousness which is not recognised as a memory but as a new and original thought) has been used as a defence in both scientific and musical plagiarism cases [8]. The availability of plagiarism-checking software [4,5] is of value to the honest researcher, as it allows a paper to be checked, prior to submission for publication, against virtually all of the current and recent literature.

Plagiarism may also be opportunistic, for example it may be triggered by seeing or reviewing a research paper from another scientist. junior investigator at Yale А surreptitiously photocopied a paper on insulin receptor abnormalities in patients with anorexia nervosa which had been shown to him by the Chief of his department (an invited reviewer for the NEJM). Although his departmental chief recommended the paper be rejected, it was later published after the NEJM sought a further opinion. Meanwhile the junior investigator submitted a paper in a closely related area to the Am J Med. By chance, his paper was seen by the author of the original NEJM paper; it contained plagiarised text and a formula, but it was still published by the Am J Med. Under pressure, the work of the Yale investigator was eventually audited by the University. His findings could not be verified from his laboratory records and Yale issued a retraction [9].

The practice of "gift authorship" represents a further, and intentional, variant of plagiarism [10, 11]. A "gift author" is defined as someone who is listed as an author but has not contributed to the research. Such a gift may be in exchange for some favour, including authorship of another paper; it may be done so as to benefit from the perceived "halo effect" of a senior figure; or it may result from a demand from a senior colleague, or as "departmental policy".

A paper published in the *Br J Obs Gyn* (full term delivery after relocation of ectopic pregnancy)

received wide publicity as an important advance at the time of publication. However, an enguiry set up by the Medical School found no evidence to support the findings and the first author (a consultant Obstetrician) was subsequently suspended from duty. Another author, who was also the Editor of the journal and the President of the Royal College of Obstetrics and Gynaecology stated "my name was put on the paper and I agreed to it. ... I had no part in the clinical part or the writing of the paper. I was not involved in any deception." [12, 13] The acceptance of, or demand for, gift authorship is plagiarism and is, of course, a form of deception. Guidelines and criteria exist for authorship credit and authors may be required to provide statements as to their personal involvement and level of responsibility [14].

Ghost authors [11] are individuals who have contributed to a piece of work (research) but have not been credited; those who appear as authors under these circumstances have committed plagiarism.

One further variant of plagiarism has been identified. Self-plagiarism, also known as "recycling fraud", involves the reuse of significant, identical, or nearly identical portions of one's own work without acknowledging that one is doing so or without citing the original work [15, 16]. Whilst this is sometimes considered as mainly an ethical issue, it may represent infringement of copyright if the recycled material closely resembles previously published text. It has been said that it represents dishonesty rather than intellectual theft [17]. Identifying selfplagiarism is often difficult as limited reuse of material is legally and ethically accepted. A similar dishonest practice involves partitioning of one study into multiple publications; this is often called salami-slicing [15].

The prevalence of plagiarism in the biomedical scientific community is difficult to precisely define. In a survey of all English language articles in Medline from 1982 - 2002, two reviewers characterised retractions as misconduct (falsification, fabrication, plagiarism) or unintentional error (*eq* mistakes in sampling, procedures, data analysis, accidental omission of information) [18]. They found that retractions were rare, with 395 identified over nine million papers; in the same period, 2772 errata were published. Of the retractions, 27.1% were for scientific misconduct, 61.8% were because of unintentional errors and 11.1%% could not be characterised. One may, or may not, agree with the premise that 395 retractions, including 106 (27% of 395) instances of scientific misconduct over 20 years is "rare"; however the concluded authors that this probably represented the "tip of the iceberg", as most were reported from highly scrutinised and cited journals.

In a further study, questionnaires were sent to 524 editors-in-chief of a prominent group of science journals asking about the severity and frequency of 16 ethical issues in their journals [19]. The general level of concern was low, and most concern was expressed in relation to redundant (salami) publication, with 28% considering it a "significant" problem. Undisclosed author conflicts of interests were considered a significant concern by 13%; plagiarism was a significant concern for 11%. The authors note that the response rate was low (44%) and that the "general level of concern about the 16 issues was low". Most Editors indicated that problems were uncommon.

An examination of authorship of papers in biomedical publications in 1966 [20] found evidence of honorary (gift) authorship in 19% of papers and ghost authorship in 11%; there was evidence of both gift and ghost authorship in 2% of published papers. This review examined papers published in six peer-reviewed US journals: three, large-circulation, general medical journals and three smaller-circulation journals. Honorary and ghost-authorship was commoner among review articles than research papers, but did not differ significantly between largecirculation and smaller-circulation journals.

Research involves understanding our field of interest and building upon the work of others. Acknowledging the contributions others have made to our understanding is a matter of personal integrity and honesty; failure to acknowledge those others and taking credit where it is not due is unprofessional and fraudulent. The ethical principles apply to all fields of endeavour; Simon Bryant, the Executive Chef at the Hilton Hotel in Adelaide stated [21], after reflecting on his use of cooking books, that *"Sometimes I think I have an original idea, and then I think 'no' ..."*.

References

- The Oxford Reference Dictionary. Ed: Hawkins JM. Edition of 1987.
- 2. Commonly attributed to Charles Caleb Colton (1780-1832). *Lacon (1820-1822).*
- <u>http://En.wikipedia.org/wiki/Eureka (word)</u>. Accessed 1st August, 2009.
- <u>http://www.turnitin.com/static/index.html</u> Accessed 3rd June, 2009.
- <u>http://www.ithenticate.com/</u> Accessed 3rd June, 2009.
- 6. US History Encyclopedia: Scientific Fraud. <u>http://www.answers.com/topic/scientific-</u> <u>fraud</u> Accessed 2nd August, 2009.
- 7. Cryptomnesia. <u>http://www.answers.com/topic/cryptomnesiaps</u> <u>ychoanalysis</u>. Accessed 2nd August, 2009.
- Brown AS and Murphy DR. Cryptomnesia: Delineating inadvertent plagiarism. J Exp Psychol. 1989. 15; 432-442. Accessed via <u>http://teachpsych.org/otrp/resources/keith-</u> <u>spiegel94.pdf</u> (Accessed 2nd August, 2009.)
- Bias and fraud in medical research: a review. Pollock AV and Evans M. *Journal Royal Society of Medicine* 1985: 78; 937-940
- The authorship dilemma: who gets credit for what? Murray B. Amer Psychol Assoc. 1998:29(12).

<u>http://www.apa.org/monitor/dec98/credit.ht</u> <u>ml.</u> Accessed 4th August, 2009.

11. Authorship.

<u>http://en.wikipedia.org/wiki/Academic_auth</u> <u>orship</u>. Accessed 5th Aug, 2009.

- Obstetrician suspended after research inquiry. Court C & Dillner L. *BMJ* 1994: 309; 1459
- 13. Gift authorship: a poisoned chalice? Editorial *BMJ* 1994: 309; 1457
- Uniform requirements for manuscripts submitted to biomedical journals. Writing and editing for biomedical publication. International Committee of Medical Journal Editors. <u>www.icmje.org</u> Accessed 4th June, 2009
- World Association of Medical Editors <u>www.wame.org/ethics</u>. Accessed 4th June, 2009.
- Plagiarism and self-plagiarism. <u>http://en.wikipedia.org/wiki/Self-plagiarism</u>. Accessed 1st August, 2009.
- Resnik DB. The Ethics of Science: an introduction. 1998. Accessed 5th August, 2009, via <u>http://en.wikipedia.org/wiki/Selfplagiarism</u>.
- Retractions in the research literature: misconduct or mistakes? Nath SB *et al. MJA* 2006: 185(3); 152-154.
- Science journal editors' views on publication ethics: results of an international survey.
 Wager E and Fiack S *et al. J Med Ethics* 2009: 35; 348 – 353.
- Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. Flanagin A and Carey LA *et al.* JAMA. 1998: 280(3); 222-224.
- 22. The Cook and the Chef. ABC TV. June 3rd, 2009.

Structure of Master of Medicine Thesis

Paper presented by: Dr. A. Saweri Division of Clinical Sciences.

School of Medicine and Health Sciences, University of Papua New Guinea

Master of Medicine is now over 30 years old. Many changes had taken place in the last 20 years. THESIS requirement is one of these changes. Historically at first Master of Medicine was wholly "Thesis" based. Then it disappears completely from the programme, though some discipline still had "projects" as part of their Master of Medicine Programme. Then it was reintroduced as "non-compulsory" part of the programme. The last 10 years saw it become compulsory- "no thesis no exam". Whilst the School has made these changes to the programme: The candidates are left in limbo. There is no written guideline to the candidates as to the format and the depth of the thesis. They received varied support from each discipline, some very intense others minimum. The assistance came from individuals who volunteered their time and expertise at irregular rate and varied quality.

As consequences the Theses: Appear in many forms and formats. They come in dribs and drabs and there was No "set minimum standard". Some candidates produce excellent work and ably illustrated and bound, others look shabby. This gives the impression that the School lacks pride & conscience and if not remedied it turn into a glorified high school.

I am suggesting that the School:

Prepares Thesis Research Guidelines; Adopts Standard format for Master of Medicine and other Theses produced from this School; That the set format be compulsory; The University produces official bound copy for the Libraries; The draft of this format is presented.

The front page: the short title and the author's name are displayed either on plain paper background or a 'wall paper' of the author's choice.

The next page is the 'Title Page': Here the Title of the research thesis is restated and elaborated. It should include statements that support the short title.

For example: "Fishy Tale; A retrospective study of fish tonnage landed at the Fisherman's Wharf at South Paradesia between 2000 and 2008".

This study forms a partial fulfilment of the requirement for the acquisition of degree Master of Medicine (in...) of the University of Papua New Guinea, Gwarume Bada

The page numbering should start with lower case Roman numeral.

After the Title Page comes the page for quotation of author's choice. Quotation is not compulsory, but is nice thing to have.

"The mad rush was deafening. Above the waves and in the depth below; they came from far and wide. It is a matter of life and death. A matter of eating or be eaten. Fate long bestowed since the sea was young, Predator become prey, the game changes pace. The one predator ungainly in water tops them all, Unmeasured greed and appetite. Destroy what he could not carry. Problem is he cannot live without us. But we can live without him." Matabudi

This page is dedication page. This is also noncompulsory, but some sentimental authors like to dedicate their work to someone or to some cause.

"This work is dedicated to all the gwarumes who gave their lives so that others could live. If only those, whose lives were thus saved, could return the favour by keeping our home clean and pristine"

Following the dedication page is "declaration page". This page is compulsory and so too the wordings in light brown *italics*.

DECLARATION

I, Gwarume Bada, declare that this work is my own work and that it has not been presented in part or in Toto to any other Institution for the purpose of acquisition of a certificate, diploma or degree. Signed..... Gwarume Bada Port Moresby, Madang, Lae etc. May 23, 2009.

ACKNOWLEDGEMENT:

This is straight forward. All those who have helped with the work, supervisors, clerks,

nursing officers, advisers, family support, etc are acknowledged. Ensure that everyone is properly acknowledged including what type of work they did e.g. typing or data entering and so on.

Summary or Abstract:

Summary is preferable to Abstract, either could be used provided that it is brief and to the point. This should be not more than 2 pages long and typed in single spacing.

The next page is the glossary and page for the abbreviations used in the entire work.

The page following this is the content page(s), depending on how many pages there are.

This is also the last page with page numbering in lower case Roman numeral, *i*, *ii*, *iii*, *iv*, *v*, *vi*, *vi*

After this page(s) the numbering begins with Arabic numeral e.g. *1, 2, 3, 4, 5,* and so on. The spacing becomes 1.5 and the Sections are headed by the word *"Chapter"* and labelled sequentially 1, 2, 3 etc. Important to note that each chapter starts on a new page

CHAPTER 1: Introduction

Fish for most times are cannibals, but many would guard their young in extra ordinary fashion. It is now known that young sharks devour their (un-hatched) siblings in the egg incubator, so that at hatching their predator instinct is fully developed. Other newly hatched and fingerlings had to fend for themselves. Big fish eat small fish, and bigger ones eat the middle sized and so on.

Land dwelling carnivores also learn to catch fish and some became very good at it. This was the cycle that has been set since the earth was young and has been going on well till a new comer with insatiable greed threatens the very existence of this environment [1].

This greedy new comer is man. He calls himself Home sapiens or wise man but his action is anything but wise. Worse still he does not know that his actions will lead to his own demise. At first he was all right; he took only what he needed and left our homes undisturbed. His technique was clumsy; he could not breathe under water and swam awkwardly. To his credit his technique of catching us improved steadily and with it, regrettably his greed. He uses steel tools, sweeping nets and poisons the water but the worse offence is he only takes a small fraction of the kill; the rest is left for the birds and bottom feeders [2].

This newcomer does not realize that by killing our children and destroying our home and the homes of generations to come, he also endangers himself and his kin. He does not realize that we can live without him but he cannot live without us and or our homes.

The sooner this greedy monster realizes that the damage done to our future will also damage his own, the better for us all. This study is aimed at measuring the damage done if any to our home environment.

CHAPTER 2: Literature Review

Octopus SP, Gropper SG, et al. looked at the health of bottom feeders around South Chockoland Bay in 2002 and found many skin changes that worried the locals [3]. These researchers found large amount of silver nitrates exuding from a number of steel containers stranded on the reef above which are slowly rusting and discharging their cargo of fertilizers into the sea.

Marlin JP et al from the Gropers' Institute of Marine Sciences had recorded the effects of increased rainfall in the Eastern Kofishore catchments area in the past five years and found that the sediments have settled far out into the South Markdowns Sea [4]. They concluded that if this continues for a few more years, then the slit will eventually kill most of the supply of our (home) building material and the food larder.

Dugong GB and Turtle M reported acute reduction of sea grass growth in the West Kakruka Province [5]. This phenomenon could be hard to control for once it starts it would be near impossible to stop. Many living in the area are worried about the long-term effects. It has already reduced the flow of tourist to the area to a trickle and many local industries have closed down. The most disturbing finding is that of Morray-Eel WP et al who found increasing incidence of foetal and infant malformations such us double headedness, deformed gills and fin structures [6]

CHAPTER 3: Aims and Objectives

The main aims are to record the devastation caused by increased Homo sapiens activities on the waters of Paradesia and the adjacent reefs East and West of the Island State. To do this we need information on the sea itself but also the land catchment area.

The logging of the old growth (pristine forest) and the use of fertilizers in the farm and orchard areas have also profound effect on the sea.

The increasing population of Homo sapiens on the South Eastern Shore has also increased pollution of the surrounding seas.

Armed with this record we would confront the Homo sapiens and request that they scale down their destructive activities.

CHAPTER 4: Materials and Methods.

We will examine records kept by the Homo sapiens of the extent of logging and area of deforestation, the farm output and amount of fertilizers used. The surface run offs and the industrial effluent and sewerage treatment plants in the area will also be assessed. Water quality will also be analysed including Turbidity measurement (Trevaly Scale) both during dry season and after a heavy rains.

Two questionnaires will be fielded one for Home sapiens living in the coastal villages along the coast of South Paradise Sea and the other for the Marine Communities in the South Paradesia Sea. This would measure some of the impact they cause and being suffered by the Marine Community.

CHAPTER 5: Results.

A total of 3000 questionnaires were fielded 1500 for Home sapiens and Marine each communities. Records of (fish) catches were collected from private and government institutions about the tonnage of fish landed on several major wharves on the South Paradise Coast. Weather and Satellite Maps were also obtained from the Homo sapiens (Maps 1-3).

There were 35 coastal villages on the Coast of South Paradise Sea; from Stonbruk Promontory in the North West to Niugunana Bay in the South East and have a population of 300500 people. Collectively they owned 765 fishing dinghies used for subsistence fishing.

	1960	1970	1980	1990	2000
Tuna	200	400	1000	2000	500
Shark	100	500	2000	3000	100
Marlins	500	500	300	1000	300
Reef fish	200	700	1000	1500	100
Red Emperor	100	500	800	1500	100
Turtle	50	20	10	20	5
Other fish types	700	500	900	3000	500

Table 1: Tons of fish caught.

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

CHAPTER 6: Discussion

This chapter brings together the aims and objectives and interprets the findings. Do the findings support results or conclusions from previous studies, or the results support or reject the 'aims and objective of the theses

The aims and objective of this 'sample' case was to record the devastation caused by increased Homo sapiens activities on the waters of Paradesia and the adjacent reefs East and West of the Island State.

CHAPTER 7: Conclusion and Recommendation.

The South Paradise Sea, from Stonbruk Promontory in the North West to Niugunana Bay in the South East has been over-fished. The large scale logging activities over the land catchment area has caused increased silting and water turbidity that destroys the corals. This is aggravated further by the runoffs from the farms and factories in the area that increase the algae blooms. If no active measures are taken now the entire echo system will collapse.

It is recommended that the Home sapiens take immediate action to limit the number of

Commercial fishing fleet and strictly control licensing and fishing quotas for each fleet. Fishing by the Coastal villages are harder to control but they will find that their catch will dwindle over time and they either starve or find other means to support themselves. After all they are Homo sapiens.

REFERENCES:

The rules for referencing if there is more than one sentence copied verbatim from the reference text then that text should be typed in "Text box" and in single spacing.

The style of referencing: This need to be either in Harvard styles in which case the names of authors are entered alphabetically or in Vancouver style where they appear sequentially as in the text.

In this sample case the citation in the text is in Vancouver style [1]. For Harvard's style of referencing (citation) consult the internet. Any reference text more than two paragraphs should be placed in the appendix to avoid plagiarism charge.

APPENDIX:

Any large material as reference should be placed in the appendix as addendum and number them sequentially.

Appendix 1

Name of Con	npany	Fleet size	Annual
			Catch
1	Albatross inc. Ltd	5	10000
2	Kingfisher & Sons Ltd	7	17000
3	Swan & Zwaan Pty Ltd	15	30000
4	Egrets & Nestling Pty Ltd	11	14000
5	Kestrel & Co Pty Ltd	14	24000
6	Arend & Sons Pty Ltd	12	10400
7	Eagle & Eyrie Inc	16	30220
8	Sand Piper Co Ltd	7	22000
9	Pelicans Inc Pty	8	15000
10	Ibis & Ibis Co. Ltd	5	19000
11	Tern & Gull Ltd.	4	15000
12	Skua & Co Pty Ltd	6	14000
13	Frigates & Sons Pty Ltd	7	14000
14	Heron & Beaks Pty Ltd	4	13000
15	Bittern and Bittern Pty Ltd	11	11000
	Total fleet size & annual catch	132	258620

Referencing Styles

Paper presented by Ms Dillie George Medical Librarian University of Papua New Guinea

There are quite a number of referencing styles however for the purpose of this Workshop I will discuss two of them: the Harvard and Vancouver styles.

The Harvard style of referencing is also known as the 'Author-Date' style, and is used in Business, Engineering, Science and the Social Sciences. Harvard has a number of variations; however, these differences concern mainly punctuation and capitalisation.

All students coming from the University of Papua New Guinea (UPNG) Waigani Campus have been introduced to the Harvard style of referencing. The Harvard guide has been adapted and some parts are reproduced with permission.

The Vancouver style of referencing is also known as the 'Uniform Requirements' style, and is used in Medicine and the Biomedical Sciences.

In the UPNG School of Medicine and Health Sciences (SMHS), both the Vancouver and Harvard systems of referencing are used. The Harvard system is used by the Public Health and Nursing Divisions, while the Vancouver system is used by the Pacific Journal of Medical Sciences. The Vancouver system is also taught in the Informatics classes for second and third year students in the MBBS program by the Medical Librarian. Outside of the University, the Vancouver system is used by the Papua New Guinea Medical Journal.

For the MBBS Informatics classes, we have been fortunate in that the Librarian at the Biomedical Library of the University of Newcastle, Ms Anne Robinson, has permitted us to use the Vancouver style guide that she prepared. Basically, this guide is reproduced here with some changes in the examples used to suit our circumstances in this workshop.

Vancouver Style Referencing Guide [1]:

When you *summarise*, *quote* or *paraphrase* another author, you need to acknowledge their work in your research paper/assignment: <u>in the text</u> where you mention it, <u>in the reference list</u>, AND <u>in the bibliography</u> at the end of your research paper/assignment.

In-text Referencing:

References in your text should be identified by *numbers in brackets*, e.g., (3).

The number originally assigned to a reference should be re-used if that reference is cited again later in the text. If you are citing multiple references at a given point in your text, these should be separated by a *hyphen in the case of inclusive numbers* (e.g., 5-7), or *commas in the case of non-inclusive numbers* (e.g., 8,10,12).

Take care to place citation numbers at the point of most relevance within the sentence.

Reference numbers should be placed <u>outside</u> of full-stops and commas, and <u>inside</u> of colons and semicolons.

Reference List:

Should only contain references to those works which you have cited in your text; should appear at the end of your text; should be arranged numerically by citation number

Bibliography:

This should contain references to those works which you consulted for the purposes of writing your essay or report, but which you did not cite directly in your text. These should be listed alphabetically by author's surname, or title, if no author is given.

A. CITING PRINT SOURCES:

How to Reference a Journal Article:

List the first six authors followed by et al. Example: The National Library of Medicine (U.S.); Next is to list all the authors.

Titles of journals should be abbreviated according to the style used in *Index Medicus* or PubMed.

Example: Benjamin AL. The use of seatbelts in Port Moresby 12 years after the seatbelt legislation in Papua New Guinea. PNG Med J 2007 Sep-Dec; 50(3-4):152-6.

How to Reference Books:

Personal author/s: Example: Murray PR, Rosenthal KS, Kobayashi GS, Pfaller MA. Medical Microbiology. 4th ed. St. Louis: Mosby; 2002.

Edited book (Add the word "editor" or editors" after the authors' surnames).

Example: Gilstrap LC 3rd, Cunningham FG, VanDorsten JP, editors. Operative Obstetrics. 2nd ed. New York: McGraw-Hill; 2002.

Corporate author/publisher:

Example: Royal Adelaide Hospital; University of Adelaide, Department of General Practice. Compendium of research and practice development, 1999-2000. Adelaide (Australia): Adelaide University; 2001.

Book chapter:

Example: Morris JC, Ferrendelli JA. Metabolic encephalopathy. In: Pearlman AL, Collins RC, editors. Neurological pathophysiology. 3rd ed. New York: Oxford University Press; 1984. p. 303-26.

Conference paper (List details as for chapters in books):

Example: Thomas MC, Swirepik J. Environmental flow management in New South Wales, Australia. In: Hydrology in a changing environment: proceedings of the British Hydrological Society International Conference. Exeter: British Hydrological Society; 1998. p. 281-287

Dictionary:

Example: Stedman's medical dictionary. 26th ed. Baltimore: Williams & Wilkins; 1995. Apraxia; p. 19- 20.

B. CITING ELECTRONIC SOURCES:

Journal article in electronic format:

Example: Morse SS. Factors in the emergence of infectious diseases. Emerg Infect Dis [serial online] 1995 Jan-Mar [cited 2008 March 26]; 1(1):[24 screens]. Available from: URL: http://www.cdc.gov/ncidod/eid/vol1no1/morse.ht

Book in electronic format:

Example: CDI, clinical dermatology illustrated [monograph on CD-ROM]. Reeves JRT, Maibach H. CMEA Multimedia Group, producers. 2nd ed. Version 2.0. San Diego: CMEA; 1995.

Computer file:

Example: Hemodynamics III: the ups and downs of hemodynamics [computer program]. Version 2.2. Orlando (FL): Computerized Educational Systems; 1993.

Homepage/web site

Example: Cancer-Pain.org [homepage on the Internet]. New York: Association of Cancer

Online Resources, Inc.; c2000-01 [updated 2002 May 16; cited 2002 Jul 9]. Available from:

http://www.cancer-pain.org/.

Part of a database on the Internet:

Examples: MeSH Browser [database on the Internet]. Bethesda (MD): National Library of Medicine (US); 2002 - [cited 2003 Jun 10]. Metaanalysis; unique ID: D015201; [about 3 p.]. Available from: http://www.nlm.nih.gov/mesh/MBrowser.html

Files updated weekly.

MIMS Online [database on the Internet]. MIMS Australia; 2008 – [cited 2008 March 26]. Serepax; 3(b) Antianxiety agents; [about 6 p.]. Available from:

http://0www.mims.hcn.net.au.library.newcastle.e du.au/ifmx-nsapi/mims

data/?MIval=2MIMS abbr pi&product code=46 5&product_name=Serepax

<u>Note</u>: For more help and examples of using the Vancouver style to cite different types of publications, have a look at the following sites:

National Library of Medicine Vancouver citation style<u>http://www.nlm.nih.gov/bsd/uniform_require ments.html</u>

Uniform Requirements for Manuscripts Submitted to Biomedical Journals http://www.icmje.org/

Harvard Style Referencing Guide [2]:

When you *summarise*, *quote* or *paraphrase* another author, you need to acknowledge their

work in your research paper/assignment in 2 places: <u>in the text</u> where you mention it AND <u>in</u> <u>the bibliography</u> at the end of your research paper/assignment.

<u>Note</u>: All references which are summarized intext must be provided in full in the bibliography; similarly, all references given in the bibliography must be cited within the text.

In-text references or citations have a pattern. It doesn't matter if there is an author or an editor; if there is a date or no date; if it's a web page, a journal article or a chapter in a book, the pattern remains the same.

 When the author's name occurs naturally as part of the sentence, place the year of publication in parentheses (brackets) after the name.

Example: In her well-known study, Shaw (1998) states that ...

 When the name is not in the text, place the surname and year in parentheses at an appropriate point (often best placed at the end of a sentence)

Example: A recent study has shown that certain medications can assist in the treatment of Alzheimer's disease (Murrell 1999).

If you write about the same work several times in a paragraph, it is often sufficient to cite it the first time and again at the end of paragraph, rather than several times throughout one paragraph. When more than one work is cited, separate the details with semi-colons. Example: (Braddon 1995; Harvey 1993). You may list authors in either date or alphabetical order.

Example: Harvey (1993) and Braddon (1995) showed that ...

4. When there are two or three authors, reference all authors. Examples:

(Slater & Johnson 1996)

(Johnson, Greene & Slater 1997)

Johnson, Greene and Slater (1997) theorised that ...

 When there are more than three authors, only use the surname of the first author followed by 'et al.' (and others). Examples: (Blackett et al. 1995)

Blackett et al. (1995) found that ...

6. Page numbers may be included.

You must include page numbers in the intext reference if you directly quote from another source. Simply add the page number after the year. Example: (Lawson 1989, p. 154)

When do you use p. and pp.?

P means *page* and is used for *one page;* pp means *pages* and so you use it for *a range of pages.* If your quote runs from page 2 to page 3, this would be written as: pp. 2-3

When there is more than one work by the same author published in the same year they should be distinguished from each other by attaching a lower case letter to the publication date.

Example: (Robinson 1992a; Robinson 1992b)

 When there is no publication date, use n.d. for no date. Examples: (Rankin n.d.)

Rankin (n.d.) disagreed with ...

 When there is no author, items should be cited using the title. Do NOT use Anon. or Anonymous.

Examples: (Oxford dictionary for scientific writers and editors 1991)

Oxford dictionary for scientific writers and editors (1991) defines ...

10. When referring to a source quoted in another work, reference both in the text.

The results of a study by James (1978 cited in Randall 1989) demonstrate that ...

(James 1978 cited in Randall 1989) demonstrated that....

(You will only list the work by Randall in your bibliography)

Bibliographies:

Must be in *alphabetical order by the author's surname* (For works with no author, list by the title and include in the alphabetical list);

Must have all the required elements listed in the correct order

Must use correct and consistent punctuation

A. CITING PRINT SOURCES:

How to reference journal/newspaper articles?

Journal Article:

Example: Cohen, J 1997, 'Can cloning help save beleaguered species?', Science, vol. 276, no. 5317, pp. 1329-1330.

Newspaper Article:

List details as for journal articles, using date instead of volume and issue number;

Example: Rifkin, J 2000, 'Halt before we reap the whirlwind', Sydney Morning Herald, 25 July, p. 15.

How to reference books:

Single author/editor:

Example: Rosner, BA 1990, Fundamentals of biostatistics, 3rd edn, PWS-KENT Publishing, Boston, MA.

Two or more author(s)/editor(s):

Example: Jacobs, PA, Price, WH & Law, P (eds), 1970, Human population cytogenetics, Edinburgh University Press, Edinburgh.

No author/editor:

If there is no author or editor, use the title as the first element in the citation, followed by the year.

Example: Oxford dictionary for scientific writers and editors, 1991, Clarendon, Oxford.

Chapter in Book:

Example: Furlani, PR & Bastos, CR 1990, 'Genetic control of aluminium tolerance in sorghum', in N El Bassam, M Dambroth & BC Loughman (eds), Genetic aspects of plant mineral nutrition, Kluwer Academic Publishers, Dordrecht, The Netherlands, pp. 215-219.

Conference Paper (List details as for chapters in books):

Example: Thomas, MC & Swirepik, J 1998, 'Environmental flow management in New South Wales, Australia', Hydrology in a changing environment: proceedings of the British Hydrological Society International Conference, British Hydrological Society, Exeter, pp. 281-287.

B. CITING NON-PRINT SOURCES (Multimedia):

Videos:

List details as for book, and include the form of the item, e.g., videorecording, after the title.

Example: DNA 1990. sequencing videorecording, Taped Technologies, Logan, Utah.

C. CITING ELECTRONIC SOURCES:

Full text journal article from database:

Example: Wrubel, R 1998, 'Biotechnology: right or wrong?' Bioscience, vol. 48, no. 3, pp. 210(2), viewed 9 March 2000, Infotrac Expanded Academic ASAP item: A54085570

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

Full text journal article from an electronic journal:

Example: Wilson, ME 2000, 'Environmental change and infectious diseases', *Ecosystem Health,* vol. 6, no. 1, pp. 7-12, viewed 17 May 2004, Blackwell Science Synergy.

Chapter in an online book (ebook):

Treat this as you would <u>a chapter in a print</u> <u>book</u> and then add the access date and url.

Example: Chapman, S & Dhillon, GS 2002, 'Privacy and the internet: the case of Double Click, Inc.' in G Dhillon (ed), *Social responsibility in the information age: issues and controversies,* Idea Group, Hershey PA, pp. 75-88 viewed 14 December 2005, <u>http://0www.netlibrary.com.library.newcastle.</u> <u>edu.au/Details.aspx</u>

Web pages:

Example: Caplan, AL 1995, *If gene therapy is the cure, what is the disease?* University of Pennsylvania, viewed 10 March 2000, <u>http://www.med.upenn.edu/%Ebioethic/genet</u> ics/articles/1.caplan.gene.therapy.html

Web pages with no authors:

Example: Cell division, 2000, Altruis Biomedical Network, viewed 23 February 2004,http://www.cellbiology.com/division.htm Web pages with no date:

Example: Wolniak, SM n.d., *An introduction to mitosis*, University of Maryland, viewed 21 February 2004,

http://www.life.umd.edu/cbmg/faculty/wolniak /wolniakmitosis.html

References

- University of Newcastle Library Services, Academic Division [homepage on the Internet], 2006 [updated 2008 March, cited 2009 May 27]. Vancouver style referencing guide; [2 p.]. Available from: <u>http://www.newcastle.edu.au/service/library/s</u> <u>ubject/biomedical-sciences/Vancouverstyle-guide.pdf</u>
- University of Newcastle Library Services, Academic Division [homepage on the Internet], 2006 [updated 2008 March, cited 2009 May 28]. Harvard referencing system; [10 p.]. Available from: <u>http://www.newcastle.edu.au/service/library/b</u> iol1030/harvard.html

80

Entering and Processing Data: Database structure and Statistical analyses, Precision, Accuracy, and Validity

Paper presented by Mr. William Yeka Family Health International, PNG

Imagine a filing cabinet full of forms holding a vast amount of information from a study. In this one filing cabinet there may be several different drawers each containing thousands of forms holding different information collected over several years. The filing cabinet and its contents represent a <u>database</u>. A single drawer in the filing cabinet containing one type of forms represents a <u>data file</u> or <u>table</u> in database terminology. The whole filing cabinet does not do anything, it just holds information. It's the same with a database.

A data file (or table) can be though of as a filing cabinet with a very rigid structure, a twodimensional table or ledger. While a filing cabinet is filled with forms, an electronic data file has each <u>row</u> of the table being a <u>record</u> and each <u>column</u> being a <u>variable</u> or attribute called <u>field</u> (see figure below). Fields are often given descriptive names or abbreviations to make them easier to refer to (eg. labno for laboratory number).

	Study	Labno	Ples_pat	Doa	Wt	Kus	Hot	Sob	Vom	Рw	[fields
	RG	1	KOPAFO/BENA	08/01/89	7.9	4	4	3	0	0		
	RG	2	SAFAIUFA/BEN	08/01/89	7.6	3	3	3	0	0		
	RG	3	GONOPIU/LOWA	08/02/89	6.0	3	3	3	3	3	•	
	RG	4	KETAROB/BENA	08/02/89	8.2	3	3	3	0	3		
	RG	5	GOROKA	08/01/89	9.3	3	3	3	3	3	ļ	records
	RG	6	MATAUSA/BENA	08/15/89	6.1	3	3	3	0	3		
	RG	7	GOROKA	08/03/89	5.1	4	4	3	0	0		
	RG	8	ASAROUF/LOWA	08/02/89	7.3	4	4	0	0	0	_	
	RG	9	FAYAN/HENGAN	08/04/89	9.7	4	4	0	0	0		
	RG	10	MORORA/ASAR0	08/03/89	3.4	4	5	0	0	3		
	RG	11	MANTO/ASARO	08/06/89	9.9	5	5	5	0	5		
	RG	12	BIHUTE/LOWA	08/09/89	9.2	3	3	0	0	0		
	RG	13	YANOFI/HENGA	07/20/89	5.2	0	5	0	0	0		
Rgp	at		F	lecord: 1/9	155		E	Exclus	ive		j	

The fields (variables) in a table have a structure that you have to be familiar with and determine when working with a file. The structure of a data file comprises the <u>variable or field names</u>, its <u>type</u> and its <u>width</u>.

The 5 most common variable (or field) types are:

Character (string): – any characters on keyboard Numeric: - numbers, decimal as well as + or – Date: - accept date and / to separate them Logical: - T or F for True or False or Y/N Memo: - accepts any amount and type of data For e.g., the field named <u>doa</u> (date of admission) in the example above is a <u>date</u> field which has width 8 to accommodate 6 digits and 2 back slash (/) in a date field as in 10/11/09. A date field can even have width 10 to accommodate 4 digits for year as in 10/11/2009.

There are two types of databases namely 1) a simple database and 2) a relational database. A simple database has only one data file (or table) with data originating from only one case report form (CRF). A relational database consists of more than one file originating from more than one CRF that is related to others using a key field. For example in a relational database you <u>do not</u> have to keep collecting data about a person's identity such as name, age, sex, educational level, etc. every time you fill a different form. This is because you can <u>link</u> data using key identifying variables such as id number, case number or lab number.

Documentation required

Aim to use standard coding schemes, e.g., for binary variables with yes/no answers, the codes 1 (for yes) and 0 (for no) should be used. It is important when recoding that you get the right denominators. Some answers may be applicable to all individuals while other may not be applicable to all.

Sometimes the field names in a data file may refer to question number in the survey questionnaire. During data manipulation and analysis these numbers may not be so helpful. You should therefore use more meaningful names by renaming them using the appropriate command e.g., in Stata use the rename command as follows:

rename q101 age

rename q102 educ

rename q103 sex

Warning! Make sure you keep the original dataset intact and save changes into a new file

Existing variables can be used to generate new variables using appropriate commands e.g., *generate* in Stata followed by the new variable name and what it will be based on.

The following example illustrates the use of a function – year () to generate a new variable called "yearoflab" which will contain the year when each woman went into labour:

generate yearoflab = year(doa)

And the use of an arithmetic operator (-)

generate duration = dod - doa

This will work if you had a date of discharge (dod) field

In most cases you will initially set new variable to equal existing one and then change its values based on specific conditions. When you do this then you will use the <u>recode</u> or <u>replace</u> command to change the values. To illustrate the recode command, type:

generate agegroup = age

recode agegroup .=9 0=9 14/17 = 1 18/24=2 25/49=3

Note that there were <u>blank spaces</u> in <u>age</u> field which were recorded as <u>missing values</u> (.) in the new variable "agegroup". These were recoded as "9" together with the one that had "0".

To illustrate the use of *replace* command, type:

generate pcrresult = .

replace pcrresult = 1 if pcr_res=="P"

replace pcrresult = 0 if pcr_res=="N"

replace pcrresult = 9 if pcr_res=="U"

Research documentation:

It is essential that you have the corresponding questionnaire or case report form as well as a codebook before you begin to process and analyze data. Without access to these documents, it would be absolutely impossible to understand the variables in a dataset. For those planning studies, make sure that your questionnaire or CRF is pre-coded meaning that the codes to be entered in a data file are also shown on the forms, if not make sure you have a data dictionary.

Tabulating categorical variables:

You can obtain frequency of a single categorical variable using a command from appropriate statistical software, e.g. tabulate from Stata or freq from Epi Info. Stata would give you numbers of individuals for each category together with the percentage and cumulative values. You can obtain a two-way table with two categorical variables.

Summarizing Quantitative Variables:

You can obtain a summary of a quantitative (numeric) variable. Output in Stata or SPSS for example would give you the numbers of individuals (observations), Mean, standard deviation, Median, Minimum and Maximum values.

Processing and analysis plan:

Once you have a clear idea of what you want to ask of the data, you are ready to plan the manipulation and analysis of the data. You have already identified the key variables and now need to think about how to approach other stages such as data preparation and combining data and what analysis to perform.

Avoid the temptation of throwing yourself headfirst into data manipulation. Before you do that is it is absolutely essential that you examine the raw data first. Have your codebook or data dictionary ready and take a look at all variables identified for analysis and determine the types of data. Produce simple tabulations for categorical variables and summary statistics for quantitative variables. This allows you to check data quality and make sure you have valid values for all your variables. Look for discrepancies between related variables and identify missing information as opposed to a true blank.

Data analysis:

The type of analysis you do would depend on the type of variables that you have created and plan to use. There are two main categories of variables namely the Categorical and Quantitative variables.

Categorical variables are non-numeric and can be further divided into ordinal and nominal. For ordinal variables, order of categories matters such as severity of illness (1=mild 2=moderate 3=severe) whereas for nominal order does not matter. Quantitative variables are numeric such as counts as in number of years old or measurements such as temperature and weights. Quantitative variables can be further classified as Ratio or Interval variables

Table of Procedures:

	Binary	Nominal	Ordinal	Continuous
Binary	Contingency Table	Contingency Table	Trend tests	Mann-Whitney Test
	Chi-Square Test	Chi-Square Test	Mann-Whitney Test	T test*
Nominal		Contingency Table	Kruskal-Wallis test	Kruskal-Wallis test
		Chi-Square Test		One-way ANOVA*
Ordinal			Kendall's Tau Somers D	Jonckheere-Terpstra test
Continuous				Correlation
				Linear Regression*

* Parameter tests (assume continuous variable is normally distributed)

Univariate Analysis:

For a categorical (nominal) variable such as marital status, the simple Univariate analysis would be to obtain counts and frequencies of each category. For a quantitative variable such as age, you could obtain its mean, standard deviation, and mode.

Bivariate Analysis:

For two categorical variables such as asples and rate of detection of Chlamydia, you could perform a Bivariate analysis known as Contingency table analysis. For analysis of both a Quantitative and Categorical variables you perform a different set of analysis to compare the means, medians and variance. One such analysis is the t- test to compare means of a quantitative variable such as age among negative and positive women (binary); for more than two categories (non-binary) you use analysis of variance (ANOVA). If both the variables are quantitative say while blood cell count and temperature then one can do a Regression analysis

Multivariate Analysis:

You can perform a multivariate analysis when you want to look at more than one explanatory variable with the help of statisticians. Multivariate analysis of Variance (MANOVA), Factor Analysis, Cluster Analysis, Principal Component Analysis and Multivariate Logistic Regression.

Precision of observation:

When a variable is not discrete, we need to determine the precision of our measurement. How precise do we need to be? When weighing a child on a scale, does the scale read the same over repeated measures? When weighing children on a poorly adjusted expensive scale, we might get precise results, but they could still be wrong! This will reflect poorly on the study design.

Example: Validity (Accuracy) versus Precision:

Let us assume that two people are playing darts. The aim is to throw the darts as close as possible to the bull's-eye. The aim of Player 1 is unbiased (valid), but the darts generally land in the outer regions of the board (imprecise). The aim of Player 2 is biased (invalid), but the darts cluster in a fairly narrow region on the board (precise).

Errors of estimation:

Random error (sampling error) reflects a lack of precision (e.g., wide Confidence Interval). Precision can be improved by increasing sample size, or size efficiency (i.e., maximizing amount "information" per individual; example: of selecting the same number of cases & controls).

ystematic error (bias) affects the validity of a study. A valid estimate is one that is expected to equal the true parameter value.

Various biases detract from validity.

How to Prepare Scientific Presentation Using MS Power Point Presented by Mr. Godfrey Morisa Centre for Human Resource Development,

University of Papua New Guinea

Introduction:

Microsoft PowerPoint 2003 is presentation graphics software. Using PowerPoint, you can create and display set of slides that combine text with diagrams, photos, clip art, media files and animated special effects. When you need to teach, persuade, or explain, Power Point can help you create clear, attention-getting presentations.

Exploring the PowerPoint Window

The PowerPoint window as shown in Figure 1-1, opens by default displaying a slide and three other three work areas --- an Outline, tab, a Slide tab, and an area for notes. Normal view also opens with the task pane displayed, which contains information, commands, and controls for creating or opening a presentation, displayed like links on a Wed page.

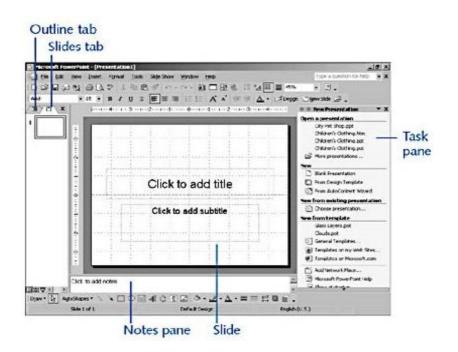


Figure 1-1: Import parts of the PowerPoint window are shown in Normal View

Elements of a Slide:

A background - Designed template comes with predesgned background.

A title - Each Slide is generally titled

Body text - Consist of contents you enter.

Placeholders - Serves as container for text and objects

Footer - Area at the bottom for specifying your name/organization.

Date & Time – Displayed at the bottom.

Slide number - Displayed by default at the bottom

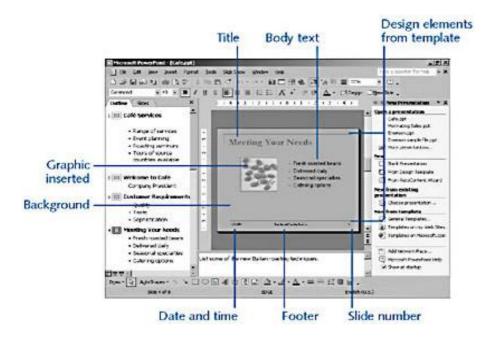


Figure 1-2. Content of a typical slide is shown is shown here.

Creating a Presentation

Starting a Presentation: There are several ways to start PowerPoint; one way is to use the start button on the task bar

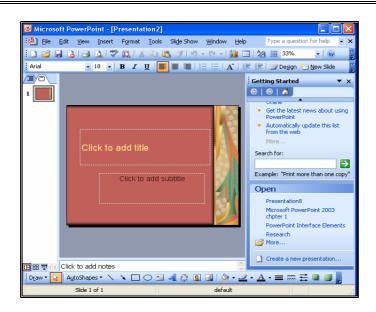
Start Microsoft PowerPoint

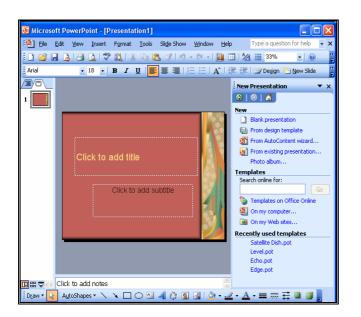
On the taskbar, click the start button; The Start menu appears. On the Start menu point to Programs; Point Microsoft Office; Click Microsoft PowerPoint icon to start PowerPoint; Click to create New Presentation; from the options given, click from Auto Contact Wizard



The PowerPoint Startup dialog box appears, giving you a choice of how to begin PowerPoint.

87





Using the AutoContent Wizard

If you have trouble preparing and writing the content of your presentation, let PowerPoint help you get started with the AutoContent Wizard, instead of using Blank Presentation & Design Template. Creating a Presentation can be much easier with the AutoContent Wizard because it saves you time by helping you to organize your presentation. It takes you time through step-bystep process and prompts you for some of the information for your presentation, including information for the *title slide*, the first slide in your presentation.

Select the AutoContent Wizard

Click the AutoContent Wizard option button

Click the OK button

Read the introduction, and then click the Next button. The second screen in the AutoContent Wizard appears, and the square next to Presentation Type on the left on the dialog box turns green to indicate that this is the current screen. presentation types quickly, the wizard organizes presentation by category.

Click the Project button; In the list box on the right, click Project Overview if it is not selected already; Click the Next button.

Choose a presentation type

First the AutoContent Wizard prompts you to select a presentation type. To help you identify



Choose a Presentation style

The AutoContent Wizard now prompts you to select the type for your presentation.

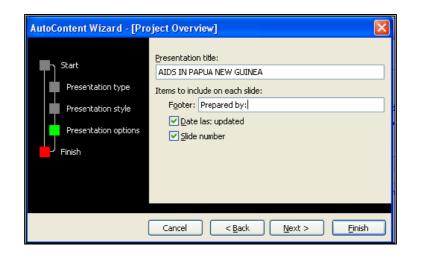
Click the On-screen Presentation option button to select that presentation type if it is not already selected; Click the Next button

Enter Presentation title slide information

The AutoContent Wizard now prompts you to enter information for the title slide and for footer information to be included in each slide.

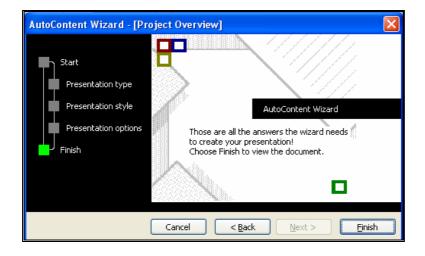
Click in the Presentation Title box, type the title of your presentation and then tab the Tab key.

In the Footer box, type the footer you want. For example; Prepared by: Make sure the Date Last Updated and the Slide Number check boxes are selected.



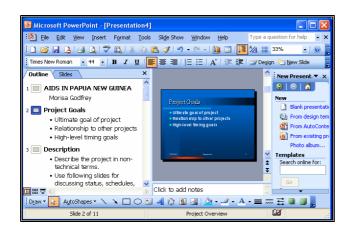
Click the Next button

Finish the AutoContent Wizard



If you want to change any of the information you previously entered, you can click the Back button. Otherwise, the AutoContent Wizard will now create your presentation. Click the finish button and the window appears with the outline slides as shown below.

90

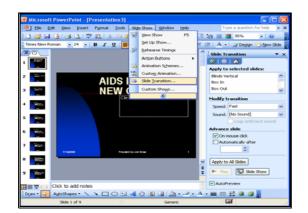


The PowerPoint Presentation appears with content provided by the AutoContent Wizard in outline form on the left and the title slide on the right. The name on the title slide is the name of the registered used. You can then change the outline by adding your text, transitions & animations to the slide.

Setting Slide Transitions

A transition is the virtual effect given to a slide as it moves on and off the screen during a slide show. How to apply a slide transition effect

Open the slide you want to apply transition to. Click Slide Show on the menu bar. Scroll down to Slide Transition and click it. From the options given choose the style you want. Select the speed and sound you want. Select on mouse click. Select Apply to All Slides. Click Play to see the preview. Click Show to present your slide show.

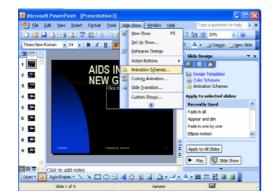


Animating Slide Text

The easiest way to apply animation effects is to use the Animation Effects toolbar. The Animation Effects toolbar contains basic effects, such as Laser Text, Drive-In, Flying, Camera, Typewriter Text, Drop-In Text, and Flash Once. Most of these have sound connected to the animation.

How to Animate Slide Show

Open the slide that you want to animate. On the Menu bar click Slide Show. Scroll down and click Animation schemes. Choose the style form the options given. Click Apply to All Slides. Click



🖲 Micro	soft PowerP	oint - [P	resentat	ion3]				_	
🕙 Ele	<u>E</u> dit ⊻jew	Insert	Format	Tools	Slig	e Show	Window	Help	-
1 🗋 💕	🔒 👌 🎒	1 🍄 🛛 🗉	à 🖺 🛷	19.	¥	¥iew Sł	how	F5	0
Times Ne	w Roman 🛛 👻	24 🔹	B =	:= A		Set Up	Show		Slide
				Ľ	٥	<u>R</u> ehear	rse Timings		•
1 🖼						Action	Buttons	•	
2 🖬					R	Animat	ion S <u>c</u> heme	s	
3 🖬				_	3	Custor	<u>n</u> Animation		
4 19		Jhat This P	<i>l</i> eans		₽	Slide <u>T</u> r	ransition		
5 19		Add as irong s	blemeni hol w yau teel or Mini			Custor	n Sho <u>w</u> s		
6 🖸		ahoui Ms lopic Summarize kes	adhit youwari				۲		^
7 😡		your autience	lo remember			Fade in a Appear a			
8							ne by one		
		Platter Al				Ellipse mo	tion .		~
9 🖬							All Slides		
					•	Play	_	de Show	
	88 9 <			1	>		•		
Draw -	AutoShap	es • 🔪	$\mathbf{X} \square ($	0	4	÷ 🛽	🔏 🖄	- 🥒 -	Α.
	Slide 8 of 9					Generic		C	ø

Reference:

Mspress-Microsoft.com [homepage on the internet] US: Microsoft Press Products, Inc.; c

Play to see the preview. Click Slide Show to Present

Presenting your Slide Show

To present your slide shows go to the Menu bar and click Slide Show

Scroll down and click View Show

1999 [cited 11th June 2009]; Available from www.mspress.microsoft.com

PAPERS PRESENTED AT THE JOINT DIVISIONAL SEMINAR SERIES: JANUARY to JULY 2009 DIVISIONS OF BASIC MEDICAL SCIENCES, HEALTH SCIENCES AND DENTISTRY

Prevalence and Determinants of Non-Adherence to Highly Active Antiretroviral Therapy among HIV/AIDS Patients in Heduru Clinic, Port Moresby General Hospital

Lisa Ijape and Victor J. Temple Division of Basic Medical Sciences, School of Medicine and Health Sciences, University of Papua New Guinea

ABSTRACT:

The adherence of patient to treatment protocol is a potent predictor of the effectiveness of Highly Active Antiretroviral Therapy (HAART). One of the major concerns with scaling up of HAART in resource-limited countries is the emergence of drug resistance HIV strains caused by non-adherence to medication, resulting from suboptimal drug levels. Very high levels of adherence to medication by people with HIV/AIDS using HAART must be maintained at all times, in order to ensure long-term efficacy of the drugs.

Currently, in Papua New Guinea, there is very limited published information on the levels of adherence and predictors of suboptimal adherence to treatment among people with HIV/AIDS using HAART.

The major aim of this research project was to assess the prevalence and determinants of non-adherence to HAART regiment among people with HIV/AIDS attending the Heduru clinic.

This was a non-intervention, prospective, cross-sectional study carried out in Heduru Clinic. The study population was selected by simple random sampling of HIV/AIDS patients receiving HAART. No patient was selected twice during the period of the study. Patients of all age groups using HAART for more than three month were eligible to participate in the study.

A pre-tested Simplified Medication Adherence Questionnaire (SMAQ) was used for data collection from consented patients. The potential non-adherence determinants were based on the criteria proposed by Morisky as modified by Knobel.

Over the four months duration of this study, signed consent were obtained from 135 of the 140 selected patients on HAART, this gives a response rate of 96.4%.

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

Twenty-three (39.0%) male respondents met the criteria for non-adherence, which gives an adherence rate of 61.0%. The number of females that met the criteria for non-adherence was 24 (31.6%), which is equivalent to an adherence rate of 68.4%.

The 61.0% and 68.4% adherence rate among the male and female respondents respectively are significantly lower than the recommended 95% adherence required for optimal clinical management and complete suppression of the HIV. The prevalence of non-adherence to HAART is very high among male and female HIV-positive patients attending the Heduru clinic in PMGH. The major determinants of non-adherence include forgetfulness, carelessness, and high frequency of missed doses.

INTRODUCTION

Current evidence indicates that, when used properly, the highly active antiretroviral therapy (HAART) significantly improve the clinical status people living with the human of immunodeficiencv virus (HIV)/ acquired immunodeficiency syndrome (AIDS) [1, 2]. Adherence to HAART treatment protocol is vital for it to be effective, to prevent resistance and other complications. Adherence rate below 95% is an independent predictor of increased viral cross-resistance, resistance. opportunistic infections, development of drug resistance, clinical failure, treatment failure, which may results in immunological failure and prolonged hospital admissions [1, 2, 3, 4, 5].

Poor adherence or non-adherence includes failure to follow drug schedules for whatever reasons, taking incorrect doses, and stopping consumption of the drugs partially or completely [1, 2, 3]. Poor adherence to treatment protocol is one of the major concerns with scaling-up the use of HAART in most resource-limited countries [1, 6, 7, 8].

The HIV/AIDS epidemic is rapidly growing in the Asia-Pacific region [1, 7, 8]. According to the 2007 estimation report on the HIV/AIDS epidemic in Papua New Guinea (PNG), from 1987 when the first case of HIV was reported, the number of HIV-positive individuals has significantly increased to over 59,500 in 2007 [8]. Recent report indicates that, if HIV transmission rates in PNG remain at their current levels, then the HIV prevalence rate will be about 6.0% by 2015; estimation that about 200,000 people in the country will be HIVpositive [9]. The guidelines for the use of HAART in PNG were developed and implemented in 2003; however, the rollout of HAART outside the National Capital District (NCD) in PNG commenced in 2006 [7, 8, 10].

The Heduru clinic in Port Moresby General Hospital (PMGH) started prescribing and dispensing HAART to people living with HIV/AIDS (PLWHA) in 2005. No published scientific data is available to indicate the prevalence rate of adherence by PLWHA receiving HAART in Heduru Clinic. In addition, no scientific data indicating the determinants or predictors of non-adherence to medication by PLWHA receiving HAART in Heduru clinic PMGH has be published.

The major aim of this study was to assess the prevalence and determinants of non-adherence to HAART regiment among HIV-positive male and female patients attending the Heduru clinic in PMGH.

SUBJECTS AND METHODS:

This was a non-intervention, prospective, crosssectional study carried out in Heduru Clinic in PMGH, which is the major general, specialist, and reference hospital in the National Capital District (NCD) and PNG. PMGH also serves as the Teaching Hospital for the School of Medicine and Health Sciences (SMHS), University of Papua New Guinea (UPNG).

The study population consisted of registered HIV-positive male and female patients that came in for their routine follow up visits at Heduru clinic in PMGH. Clinical services including dispensing of HAART are offered free to all HIVpositive patients attending the Heduru clinic. All HIV-positive patients that have been using HAART for more than three months were eligible for enrolment in the study. Selection was by simple random sampling. No patient was selected twice during the period of the study. The purpose of the study was explained to each selected patient. Those patients that verbally consented to participate were each given an informed consent form to read and sign. The total sample size of 140 was based on a design effect of one, a relative precision of 10%, confidence level (CL) of 95%, predicted non-response rate of 10% and an assumed non-adherence prevalence rate of 15%.

A structured pre-tested questionnaire was used for data collection. The questionnaire consisted of two sections. The first section, consisting of six questions, was the Simplified Medication Adherence Questionnaire (SMAQ), which is the modified version of the Morisky Scale [4, 11]. This section was used to determine nonadherence. The potential non-adherence determinants were based on the criteria proposed by Morisky as modified by Knobel et al [4, 11]. The SMAQ was considered positive when a non-adherence patient was detected. That is, when there was a positive response to any of the four qualitative questions, and when more than two doses of medications were missed over the pass week or when there was over two days of total non-medication during the past three months [4].

The second section of the questionnaire, consisting of thirteen questions, was used to obtained socio-demographic data of the respondent. To avoid bias and distortion only one interviewer administered the questionnaire throughout the study.

The SPSS version 10 and Excel MS data pack softwares were used for statistical analysis of data. Chi-square test (Fisher's exact test), ANOVA, Kruskal-Wallis tests, and Logistic regression analysis were performed. To evaluate variables associated with nonadherence, multivariate analysis was performed using logistic regression.

Ethical clearance and approval was obtained from the SMHS Research and Ethics Committee and the Medical Research Advisory Committee NDOH (MRAC No. 08/27). Request for permission was also obtained from the Chief Executive Officer and Director of Medical Services PMGH. Oral and signed informed consents were obtained from each consented patients.

RESULTS:

Over the four months duration of this study, signed consent forms were obtained from 135 of the 140 selected patients on HAART. Thus, the response rate was 96.4%.

The mean age (\pm SD) of the 135 respondents was 33.2 \pm 9.6 years, the 95% confidence interval (95% CI) was 31.6 – 34.8 years, and the age range was 18 – 57 years. Distribution of the 135 respondents according to age groups indicates that 55 (40.7%) were in the 20 – 29 years age group, followed by 45 (33.3%) in the 30 – 39 years age group, 19 (14.1%) in the 40 – 49 years age group, and 13 (9.6%) in the 50 – 59 years age group. All the respondents have been using HAART for over six months. However, 77.8% (105) of them were not aware of the type of medication that they are using.

For detailed analysis of the data, the 135 respondents were seperated according to gender. There were 59 (43.7%) males and 76

(56.3%) females. Twenty-three (39.0%) male respondents met the criteria for non-adherence, which gives an adherence rate of 61.0%. The number of females that met the criteria for non-adherence was 24 (31.6%), which is equivalent to an adherence rate of 68.4%.

Table 1 shows the descriptive statistics of the age for the male and female respondents in the non-adherence and adherence groups. In the non-adherence groups, the mean age (29.5 \pm 8.3 years) of the female respondents was significantly (p = 0.03) lower than the mean age $(34.3 \pm 9.2 \text{ years})$ of the male respondents. Distribution of the non-adherence and adherence male and female respondents into age groups is presented in Table 2. Nonadherence among male respondents was highest (43.5%) in the 20 – 29 years age group, followed by 30.4% in the 40 - 49 years age group, and 21.7% in the 30 - 39 years age group. Among the female respondents, nonadherence was 50.0% in the 20 - 29 years age group, 33.3% in the 30 - 39 years age group, and 4.2% in the 40 – 49 years age group. This indicates slight difference in the age distribution trend among the male and female respondents.

Demographic characteristics of the male and female respondents in the non-adherence and adherence groups are presented in Table 3. The result indicates that, 65.2% of non-adherence male respondents were married compared to 37.5% of the non-adherence female respondents. 56.5% of the non-adherence male respondents were employed compared to 12.5%

of the non-adherence female respondents. In both cases the differences were statistically

significant (p = 0.000).

Table 1: Descriptive statistics of the age (yrs) of male and female respondents in the adherence and nonadherence groups

	Male respondents	(n = 59)	Female respondents (n = 76)			
	Non-Adherence	Adherence	Non-Adherence	Adherence		
N (%)	b) 23 (39.0%) 36 (61.0%)		24 (31.6%)	52 (68.4%)		
Mean	34.3yrs	37.5yrs	29.5yrs	31.4yrs		
Std. Deviation	9.2	10.3	8.3	8.8		
95% Confidence	30.3 – 38.3yrs	34.0 – 41.0yrs	25.9 – 33.0yrs	29.0 – 34.0yrs		
Interval (95% CI) Median	34.0yrs	34.0yrs	27.0yrs	30.0yrs		
Interquartile Range (IQR)	25.0 – 44.0yrs	27.5 – 47.5yrs	25.0 – 32.0yrs	24.0 – 35.8yrs		

Table 2: Gender distribution of adherence and non-adherence respondents according to age groups

	Males respond	ents (n = 59)	Female respondents (n = 76)			
Age Groups (yrs)	Non-Adherence (n = 23)	Adherence (n = 36)	Non-Adherence (n = 24)	Adherence (n = 52)		
15 – 19 yrs	0	0	2 (8.3%)	1 (1.9%)		
20 – 29 yrs	10 (43.5%)	10 (27.8%)	12 (50.0%)	23 (44.2%)		
30 – 39 yrs	5 (21.7%)	12 (33.3%)	8 (33.3%)	20 (38.5%)		
40 – 49 yrs	7 (30.4%)	7 (19.4%)	1 (4.2%)	4 (7.7%)		
50 – 59 yrs	1 (4.3%)	7 (19.4%)	1 (4.2%)	4 (7.7%)		

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

	Male respondent	s (n = 59)	Female responder	its (n = 76)
Characteristics	Non-Adherence (n = 23)	Adherence (n = 36)	Non-Adherence (n = 24)	Adherence (n = 52
Marital Status	(((
Married	65.2% (15)*	50.0% (18)	37.5% (9)*	52.0% (27)
Single	17.4% (4)	33.3% (12)	33.3% (8)	11.5% (6)
Widowed	4.3% (1)	5.6% (2)	0	19.2% (10)
Separated	8.7% (2)	8.3% (3)	20.8% (5)	9.6% (5)
Divorced	4.3% (1)	2.8% (1)	8.3% (2)	7.7% (4)
	* p = 0.000			
Employment status				
Employed	56.5% (13)**	33.3% (12)	12.5% (3)**	21.2% (11)
Unemployed	21.7% (5)**	16.7% (6)	79.2% (19)**	67.3% (35)
Volunteer	0	11.1% (4)	0	5.8% (3)
Farmer	4.3% (1)	16.7% (6)	8.3% (2)	1.9% (1)
Private Business	17.4% (4)	22.2% (8)	0	1.9% (1)
Missionary	0	0	0	1.9% (1)
	** p = 0.000			
Number of times meals				
are eaten per day				
Once	0	11.1% (4)	4.2% (1)	5.8% (3)
Twice	60.9% (14)	50.0% (18)	70.8% (17)	51.9% (27)
Thrice	39.1% (9)	38.9% (2)	25.0% (6)	42.3% (22)
Living distance from				
clinic				
Near	21.7% (5)	8.3% (3)	12.5% (3)	9.6% (5)
Short distance	69.6% (16)	80.6% (29)	66.7% (16)	80.8% (42)
Very far distance	8.7% (2)	11.1% (4)	20.8% (5)	9.6% (5)
Frequency of visits to				
clinic				
Once a month	91.3% (21)	66.7% (24)	66.7% (16)	71.2% (37)
More than once a month	4.3% (1)	8.3% (3)	12.5% (3)	7.7% (4)
Every two months	4.3% (1)	25.0% (9)	20.8% (5)	21.1% (11)
Other Medications				
Yes	26.1% (6)	27.8% (10)	29.2% (7)	30.8% (16)
No	73.9% (17)	72.2% (26)	70.8% (17)	69.2% (36)
Living with whom				
Living with family	52.2% (12)	80.6% (29)	79.2% (19)	82.7% (43)
Living with wantok	34.8% (8)	8.3% (3)	16.7% (4)	9.6% (5)
Living alone	13.0% (3)	11.1% (4)	4.2% (1)	7.7% (4)

Table 3: Demographic characteristics of male and female respondents in the Non-Adherence and Adherence groups

98

Table 4: Multiple logistic regression analysis of risk factors for non-adherence male and female

respondents (SMA: Simplified Medical Adherence)

SMA Questionnaire	P-value (Pearson Chi- square)		Odds Ratio		95% CI Lower		95% CI Upper	
(Independent variables)	Males	Females	Males	Females	Males	Females	Males	Females
Do you ever Forgot to take your medicine? (Forgot)	0.005	0.046	2.35	1.75	1.28	1.02	4.3	3.05
Are you careless at times about taking your medicine? (Careless)	0.029	0.32	1.8	1.18	1.07	0.87	3.06	1.6
Some times if you feel worse, do you stop taking your medicines? (Felt worse)	0.96	0.57	1.04	2.17	0.19	0.14	5.78	33.2
Thinking about the last week, how often have you not taken your medicine? (Missed weekend dose)	0.064	0.013	3.13	3.8	0.87	1.23	11.3	11.7
Did you not take any of your medicine over the last weekend? (Missed over 2 doses last week)	0.000	0.02						
Over the past three months, how many days have you not taken any medicine at all? (Missed over 2 days in past 3 months)	0.000	0.000						

The multiple logistic regression analysis of nonadherence compared to the corresponding adherence male and female respondents is presented in Table 4. Respondents that are independently more likely to be in the nonadherence category are, males and females who forgot to take their medicines; males who are careless in taking their medicines; females who missed last weekend dose; and both males and females that missed over two doses the previous week or missed over two days in the past three months. The odds ratio is also presented for some of the risk factors.

DISCUSSION:

The guidelines for the use of HAART in PNG indicate that, ongoing counselling about the importance of adherence, recruitment of a carer in assisting with adherence, and measurement of

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

adherence are essential components of care for all HAART prescribing centres in PNG [7, 10]. The justification for this study therefore, was the lack of published information on the levels of adherence and determinants of suboptimal adherence to treatment among people living with HIV/AIDS (PLWHA) using HAART in Heduru clinic. The major focus of this study therefore, was to determine the prevalence and determinants of non-adherence to HAART among PLWHA attending the Heduru clinic in PMGH.

The 3.6% non-response rate obtained in this study is lower than the 10% predicted non-response rate used in calculating the sample size. Majority of the respondents were in the 20 – 29year and 30 – 39year age groups, which are similar to data, obtained in other studies in NCD [12] and Nigeria [13]. This indicates that the highest prevalence of HIV/AIDS is among the prime members in the affected communities. The data supports the observation that in most developing countries the HIV/AIDS epidemic is more profound and it affects the most economically productive and fertile age groups in the communities [1, 14].

The 77.8% of respondents that had no knowledge of the type of HAART that they are using indicates inadequate patients understanding and awareness of their medication and dosing. According to WHO [1,

15] adherence rate is usually higher among patients who are able to identify their medications in their own words and describe their proper dosing and administration.

The 61.0% and 68.4% adherence rate among the male and female respondents respectively are significantly lower than the recommended 95% adherence required for optimal clinical management and complete suppression of the HIV.

The very high prevalence of non-adherence among the male (39.0%) and female (31.6%) respondents in Heduru clinic should be of concern to program planners. Such a high level of nonadherence may cause decline in health of the patients, increased frequency of opportunistic infections, possible development of resistance and cross-resistance, and faster progression of the disease [1- 4, 14, 15]. In addition, it could seriously limit future use of the HAART for treatment of other infected individuals in the NCD.

To attain the over 95% adherence to treatment regimen, intensive advocacy, education and awareness campaign should be carried out among PLWHA using HAART. Every individual should be made aware that for HAART to be effective long-term and to prevent the emergence of resistant strains of HIV in the NCD, very high levels (\geq 95%) of adherence to medication must be maintained at all times [1 – 4, 10, 13].

Chi-square tests and Kruskal-Wallis tests were used compare the demographic to characteristics of the non-adherence female and male respondents. The Pearson Chi-square (p = 0.000) indicates statistically significant differences for the employment status and marital status of the non-adherence male compared to non-adherence female respondents. A similar level of significance was obtained using the one way ANOVA after post-Hoc tests (Scheffe).

No statistically significant differences (Chisquare, p > 0.05) were observed between Nonadherence Male and Female respondents for the other demographic characteristics: Number of meals per day; Living distance from clinic; Frequency of visits to Heduru clinic; Taking other medications, and Residence status.

The risk assessment of non-adherence among the male and female respondents, in the present study, was identified by the multivariate logistic regression of the six independent variables used in the Simplified Medication Adherence Questionnaire (SMAQ).

Male (p = 0.005) respondents who forgot to take their medications have a 2.35 fold risk (95% CI 1.28 - 4.3) of not adhering to their medication. Female (p = 0.046) respondents who forgot to take their medications have a 1.75 fold risk (95% CI 1.02 - 3.05) of not adhering to their medication. Our data supports the widely reported findings that forgetfulness is one of the most commonly cited reasons for non-adherence [1, 10, 13 - 15].

Male (p = 0.029) respondents who are careless at times about taking their medication have a 1.8 fold risk (95% CI 1.07 – 3.06) of not adhering to their medication. Unlike the male respondents, careless was not a risk factor for non-adherence among the female (p = 0.32) respondents in our present study.

Female (p = 0.013) respondents who missed their last weekend dose of medication have a 3.8 fold risk (95% CI 1.23 – 11.7) of not adhering to their medication. Missed weekend dose was not a risk factor for the male (p = 0.064) respondents in our present study. These findings are supported by some studies in which women cited stress of childcare as being related to missing a dose of their medication [10, 13 – 15]. Stress can interfere with proper dosing of medication regimens, and stress is said to be experienced more often and to a great degree by PLWHA in resource-limited countries [1, 14].

Missing over two doses of medication in the last two weeks was a significant determinant of nonadherence for both male (p = 0.000) and female (p = 0.02) respondents in the present study. In addition, missing over two days of medication in the past three months was also a significant determinant of non-adherence for both male (p =0.000) and female (p = 0.000) respondents. Our data supports the observation by several studies that missing doses of medicine is one of the common problems among PLWHA [1, 3, 5, 10, 13 – 15].

CONCLUSION:

The prevalence of non-adherence to HAART is very high among both male and female HIVpositive patients attending the Heduru clinic in PMGH. The major determinants of nonadherence include forgetfulness, carelessness, and high frequency of missed doses.

The need to address these and other problems in order to reduce significantly the risks of nonadherence to HAART among male and female HIV-positive patients attending Heduru clinic in PMGH cannot be overemphasized. There is an urgent need to implement the "guidelines for the use of antiretroviral therapy in PNG" together with the WHO document "Scaling-up antiretroviral therapy resource-limited in settings".

REFERENCE:

- WHO, Adherence to long term therapy evidence for action 'Chapter XII: Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome' WHO 2003
- 2. Turner BJ, Adherence to antiretroviral therapy by human immunodeficiency virus-

infected patients; J Infectious Diseases, 2002: 185 (Suppl 2): S 143 – 51

- 3. Webster RD and Barr D. Adherence to Highly Antiretroviral Therapy (HAART) Active HIV/AIDS: A among individuals with compendium of HAART Adherence Research, Nov 1997 to Nov 1999 Adherence to HIV therapy: Building a bridge to success Forum for collaborative HIV research Centre for Health Policy Research; George Washington University Medical Centre Nov. 15 & 16, 1999, WDC 2 - 18
- Knobel H, Alonso J, Casado JL, Collazos J, Gonzalez J, Ruiz I, Kindelan JM, Carmora A, Juega J, and Ocampo A. Validation of a simplified medication adherence questionnaire in a large cohort of HIVinfected patients: the GEEMA study: AIDS, 2002; 16: 605 – 613
- Sarna A, Pujari S, Sengtar AK, Garg R, Gupta I, Van Dam J. Adherence to antiretroviral therapy & its determinants amongst HIV patients in India. Indian J Med Res 127; January 2008; 28 – 36
- Castleman T, Seamon-Fosso E, Cogill B. Food, and nutrition implications of antiretroviral therapy in resource limited setting. Food and Nutrition Technical Assistance Technical Notes No. 7, Revised May 2004; 2 – 13.
- Papua New Guinea National Strategic Plan on HIV/AIDS: 2006 – 2010. National AIDS Council, PNG.

- The 2007 Estimation Report on the HIV Epidemic in Papua New Guinea. The National AIDS Council and The National Department of Health
- Papua New Guinea, Australian officials discuss PNG's HIV/AIDS research, prevention efforts The Body: The Complete HIV/AIDS Resource: 6th March 2009 www.thebody.com/content/news/art50753.h tml.
- Pantumari J, Passirem D, Esorom D, Millan J, Law G, McBride J, Cooreman E, Pathanapornpandh N, Plange NK, Tau G, Mete S, Ipai L, Lavu E, Wesselingh S, and Dakulale P. Guidelines for the use of Antiretroviral therapy in PNG. NDOH NAC AUSAID Publication, November 2003; 1 – 9. <u>www.nacs.org.pg/</u>
- Morisky DE, Green LW, Levine DM. Concurrent, and predictive validity of a selfreported measure of medication adherence; Med. Care: 1986; 24: 67 – 74.
- Ilaisa S, Temple VJ, Saweri W, Lloyd A. Nutrient, and energy intake of people living with HIV/AIDS in Port Moresby, Papua New Guinea: A 24-hour recall study. Med. Sci. Bull 2007, Vol 4; 16 – 25.

- Olowookere SA, Fatiregun AA, Akinyemi JO, Bamgboye AE, Osagbemi GK. Prevalence and determinants of non-adherence to highly active antiretroviral therapy among people living with HIV/AIDS in Ibadan, Nigeria J Infect Developing Countries, 2008; 2 (5): 369 – 372,
- 14. UNAIDS/WHO, AIDS epidemic update 2006, WHO document, Geneva 2006.
- AETC: National AIDS Education and Training Centres: National Resource Centre; Clinical Manual for Management of the HIV-Infected adult; 2005 Edition; Section 3: Antiretroviral Therapy; 1 – 9
- Shah CA, Adherence to High Activity Antiretroviral Therapy (HAART) in Pediatric Patients infected with HIV: Issues and Interventions. Indian J of Pediatrics Vol. 74, January 2007; 55 –60

A Physiological Approach to Adolescence Behavior and How to Channelize it in Right Direction

Subhra Datta

Division of Basic Medical Sciences,

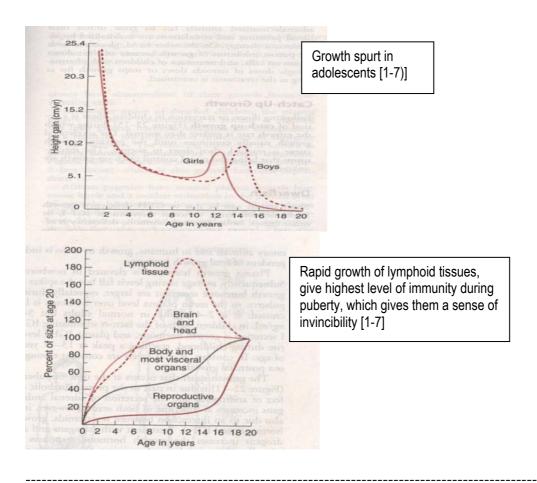
School of Medicine and Health Sciences, University of Papua New Guinea

Introduction:

Adolescence is a transition period from childhood to adulthood and also called puberty. In girls this period is 8-12 years of age (Mean 10.5 in American girls) and in boys, 9-14 years (Mean 11.5 in American boys). Adolescence age varies from different countries with different climatic and cultural conditions. It is earlier in tropical countries than in cold Scandinavian countries. Over centuries the mean age of puberty is becoming earlier.

During adolescence 5 major changes take place in an individual:

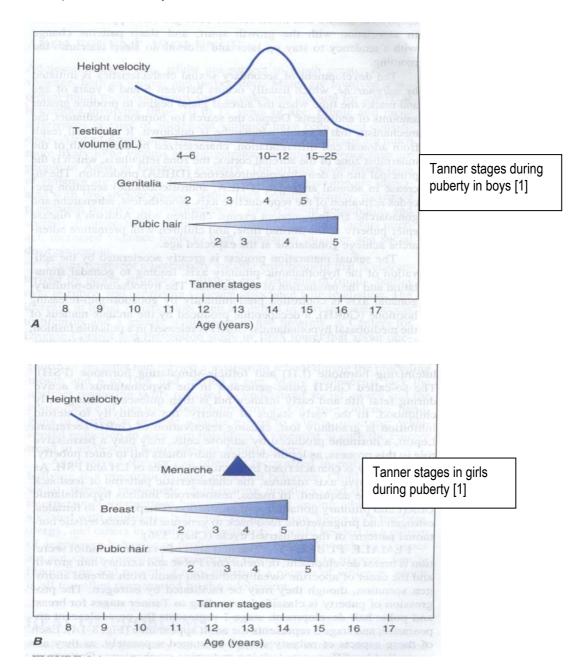
A growth spurt, Development of secondary sexual characteristics, Reproductive capability, Establishment of gender identity, Psycho-social changes in behaviou



Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

104

Development of secondary sexual characteristics



Changes in reproductive organs during adolescence [1-7]:

Before adolescence the gonads and anterior pituitary gland are capable of functioning but

hypothalamus did not release the Gonadotrophic Releasing hormone (GnRH), so both Gonadotrophic hormones (FSH and LH) were not secreted and gonads were quiescent. During childhood gonadal removal does not lead to increased level of FSH and LH level in plasma. Many factors like leptins, hormones of pineal gland etc inhibit the arcuate nucleus of hypothamus, which is the pulse generator for GnRH secretion.

During puberty the medio-basal and arcuate nucleus of hypothalamus become active and start secreting GNRH in girls in a cyclic pulsatile manner [1-]7). In the boys the release is *acyclic* in nature. Male and female Hypothalamus in these regions are significantly different morphologically and physiologically. Also there is a increased spurt of GHRH and CRH from the hypothalamus, which cause increased level of growth hormone and ACTH secretion from the anterior pituitary gland. The increased level of growth hormone is responsible for growth spurt during puberty. The increased level of ACTH leads to secretion of high level of Dihydroepiandrosterone (DHEA) & to puberche Androstenedione leading in adolescence.

Major body changes in boys during adolescence [1-7])

Under the influence of FSH and LH hormones of anterior pituitary gland, there is growth of sertoli cells and Leydig cells of testes which increase the volume of testes (10-12ml). Leydig cells secrete Testosterone. Under the influence of testosterone there is thickening of vocal cords leading to breaking of voice, increased length of penis, increased volume of prostate gland, lengthening of epididymis, and vas diferens and growth of scrotum with rugosity. There is growth of axillary and pubic hair (male pattern) with thickening of skin and coarse texture of body hair. There is increased apocrine secretion, increased muscular and bone growth. Testosterone leads to Aggressive behavior, which becomes quite common in puberty.

Major body changes in girls during adolescence:

Thelarche: Start of breast development due to ovarian estrogen secretion

Puberche: Growth of pubic and axillary hair & ↑apocrine secretion due to adrenal androgens (androstenedione & DHEA)

Menarche: Start of menstruation and menstrual cycle. Initially the menstrual cycles are irregular and anovular for a few months to 1.5 years, then normal cycle establishes with ovulation.

Reproductive capabilities during adolescence:

In boys the onset of complete spermatogenesis and production of viable sperms during puberty leads to their reproductive capabilities

In girls, the reproductive capability is only possible after normal ovulation starts, which might take even 18 months after the menarche.

Establishment of gender identity [1]:

Before puberty the gender roles are quite clear in young boys and girls. During adolescence, the gender identity should be re-established. It is quite normal in adolescence to act in a different way in reality or in fantasy. Adolescent boys and girls might experiment with cross-dressing, homosexuality or get attracted to much older men/women. In many old tribal cultures, the 'initiation rituals' in young adolescent boys to 'manhood' and girls to 'womanhood', helps in establishment of gender identity. Unfortunately, in the modern so-called civilized world, there is no such process to help the adolescent to get proper gender identity.

Behavior changes in adolescent girls [1,10]:

They become aware of their personal appearances and become interested in make-up and dresses. They like to be admired by the peer group of same sex and the opposite sex. They often have mood fluctuations with occasional emotional outbursts. They like to defy family rules and like to experiment with alcohol, drugs and sex. However, estrogen and progesterone, keep their temper normally under control.

Psychosocial changes in behavior during adolescence in boys [1, 10,11,12]

During adolescence within a few months multiple hormones act in the boys. The hormones like testosterone, adrenal androgens, growth hormone spurt all act synergistically, in the musculo-skeletal system, skin, hair, reproductive organs, immune system and most importantly on the central nervous system.

Behavior changes in boys during adolescence [1,11,12]

In boys, there is abstract thinking during adolescence. They have increased need to socialize with friends, which might lead to gang affiliation. They have a strong desire to establish an identity, independent of the family, though they still need the family whenever needed. They also desire to have full independence without taking responsibilities. At this stage of life experimentation with drugs, alcohol and sex is quite common. They start having aggressive and risk taking behaviors.

Factors that contribute violent behavior [2,11,12]

Peer pressure and the need for attention/respect, Low self-esteem, Early childhood abuse/neglect, Witnessing violence at home, in the community or in the media, Easy access to weapons in the western world, Genetic predisposition to aggressive behavior

Main reasons for violence in adolescent boys [11]

According to American Psychological Association (APA), the reasons for violence are the following:

Expression, Manipulation, Retaliation

Aggressive behavior in adolescent boys [2]:

Some adolescent boys become more aggressive than others. It is the probably the synergistic actions of both nature and nurture. Rise of testosterone definitely plays the central role. Also bad parenting, lots of violence at home, acute stress in childhood (abuse), poor education, too much exposure to violent movies and video games and growing up in poor neighbourhood with a lot of gang activities or violence contribute in aggressive behavior in adolescent boys. However, some boys have genetic predisposition to violence, like: born with an extra Y chromosome (a violent streak in many cases), decrease in serotonin production (neurotransmitter) in the brain or decrease in the enzyme Monoaminooxidase (MAO) in serotonergic neurons or polymorphism of 5HT receptors like 5HT 2AR,5HT 2CR, 5HT TPR [2,6].

Experimental proof for brain areas involved in aggression [1,2,7]:

Limbic system is responsible for our emotions and behavior [9]. So, damage or dysfunction of areas of limbic system could lead to aggressive behavior. It has been shown that removal of neocortex leads to aggressive behavior in rats, cats and monkeys (Sham rage?) [9]. Selective lesion of ventromedial nucleus of hypothalamus in normal animal, leads to aggressive behavior (Sham rage?) [2,9]. Lesion of septal nuclei with intact cerebral cortices also leads to aggressive behavior (Sham rage?) [2,4,9]. Increased activity in amygdaloid nuclei leads to aggressive personality trait and lesion of amygdala leads to placcidity. However, destruction of VMN after amygdalectomy leads to aggressive behavior Stimulation of lateral area of Hypothalamus and central grey area of midbrain also cause rage and aggressive behavior. Antonio Domassio showed a small lesion in the genu of CC at the prefrontal lobe leads to anger and aggressive behavior in rats, cats and monkeys [2,9].

Evidence of the role of neurotransmitters in violence [1,2,4]

36 criminals serving jail term for violence and murder showed decreased serotonin level in blood. The persons released from jail with low serotonin level repeated offense, like suicidal tendencies, impulsive aggression etc [2,9].

Experimental proof for the role of serotonin in aggression [2,8]

In the mice where serotonin 1B receptor has been ablated by targeted deletion, become extremely violent compared to the wild mice with intact receptor. Destruction of serotonergic neurons in mice, cats, hamster, goldfish, monkeys lead to increased aggressive behavior. Certain serotonin agonists which act on 1B serotonin receptors control these aggressions. Platelet 5HT could be a good indicator in determining the central 5HT content [2,8]. In personality disorders, it could reflect the real serotonin level in the brain. Serotonin level of the brain could decrease as a result of poor nurture and abuse. It has been observed that an abused child usually develops into an abusive adult. Lack of love, confinement, torture and sexual abuse from early childhood leads to decreased serotonin level in the brain. Long term experiments done on young monkeys and other species of animals have proved this fact. There are also other neurotransmitters for aggression. Genetic deletion of neuronal isoform of NO synthase (nNOS) leads to aggressive behavior in mice. Pharmacological blocking of this enzyme by 7Nitroindazole also augments

Pac. J. Med. Sci. (Formerly: Medical Sciences Bulletin)

aggression. But deletion of endothelial NO synthase (eNOS) decreased aggression of these animals, even when the animals became hypertensive [2,5].

The Role of family and society to channelize the behavior of the adolescents:

Always check and keep an eye on the adolescent, whether he/she is abused sexually or otherwise

Most of the sexual abuses take place at home and the perpetrator is one of the most trusted adult in the family. Any adolescent showing cruelty to animals or bullying any younger or helpless peer (so-called bullies!) might become an aggressive individual in later life. Parents and teachers must take a serious note on these simple behavior patterns in their ward. On the other hand, the victim of the bullies, suffer from severe depression and then one day turn into a violent individual doing mass shooting or take any such disproportionate actions. Teachers, parents and peers also should watch carefully these so-called extremely quiet, friendless students in the class, those who only keep to themselves. These adolescents need immediate counselling and proper psychological evaluation. Parents and teachers must take care in nurturing both these groups in a helpful way, where the violent trend could become channelized in a positive direction

How important it is to maintain discipline in adolescent behavior?

It is important to install discipline right from childhood in a positive manner. Parents, teachers must learn the skill to maintain disciplined behavior in adolescents without using force. Unlike common belief, adolescents do like and also expect discipline and some amount of control from their guardians. However, adults must know how to be firm in attitude without being too strict! There should be always direct discussion, after an adolescent behaves in an in-disciplined manner. He/she must realize that this behavior is not acceptable.

How to channelize the violent trait in behavior of adolescents?

Plenty of unconditional love, affection and constant encouragement can divert the violent nature to another direction

Such young people should be encouraged to play active sport like, rugby, football, boxing etc to channelize their energy.

A young person showing violent trend in nature could be encouraged to take up a suitable profession in later life.

He should be encouraged to make a career as a murder investigator, police detective or soldier/paramilitary personnel instead of becoming a murderer.

Instead of being a killer, he can become a good butcher.

Should a violent adolescent be controlled with strict discipline or punishment?

The answer is definitely, 'NO'. This person should be given more care and love instead of punishment. Very gently, the behavior trait should be corrected by showing better result with gentleness. A male adolescent person should not be brought up with too much stress on 'male ego'. Social attitude must change. Instead of bringing up adolescent to be a 'man', he should be encouraged to be a good human being and learn to be more caring person. Parents must keep the adolescent busy with lots of activities like sport, acting, music etc instead of joining local 'gangs'.

How to deal with quiet depressed and oppressed adolescents?

These adolescents usually have poor school performance. They withdraw from the peers, teachers and regular school activities. They are lonely and feel rejected. Sometimes they have trouble controlling anger and in girls they cry very often. Parents and teachers must watch carefully whether these adolescents are bullied physically or electronically through mobile phone messages etc. Suitable strong actions should be taken officially against the perpetrators to prevent this phenomenon.

Counselling should start urgently. Parents and teachers must give plenty of love and affection to these people to make them feel secure once again. A lot of praises and encouragement would boost their self-image, which had been battered by the bullies before.

What is the statistic of violence in PNG?

In 2002, there were 200 people brought in dead in PMGH. Nearly all were victims of murders or accidents (data obtained from Prof. Sims, Ex-Professor of Public Health Division in School of Medicine & Health Sciences, UPNG).

Reasons for the present statistics of increased violence in the world [3]: There is too much difference between rich and poor in most of the societies leading to frustrations among poor underprivileged young adolescents.

Poverty leading to breaking up of family units and lack of strong home base for an adolescent

Widespread sexual, verbal, physical and cyber abuse of the weak and the vulnerable

Decay of the moral and social fabric leading to dissatisfied adolescents

Lack of true love and more materialism in life

Lack of role models in schools, family and society

Wide spread drug abuse, because drug industry is a multi-billion dollar industry and adolescents are their huge clientele.

Summary:

Violence and aggression is a manifestation of the action of testosterone in adolescent boys.

It is a part of survival strategy in nature to maintain territory.

However in human society, in the adolescent period, it is very important to channelize the

youthful energy in sports, arts and other group activities.

However, some adolescents could be genetically violent in nature.

In case this violent adolescent is allowed to continue his behavior, he would turn out to be a menacing adult eventually.

The aggressive attitude could be controlled and tamed from an early age in life

At home and in schools discipline should be a part of bringing up process from childhood without using physical force.

The respect for the guardian/teachers should be instilled in the psyche of adolescents.

Proper career counselling in adolescents could help to channelize the violent trend in nature.

A very quiet and introvert adolescent also should be psychologically assessed and treated appropriately.

If any adolescent suffers from depression, he/she could turn into extreme violence (Bipolar manic personality).

Plenty of love and care at home and school is essential for controlling violent trend in adolescents.

There must be role models among family, school etc for adolescents to learn and emulate.

References:

- Anthony L et al, Harrison's Principles of Internal Med. Ed. Braunwald et al 15th Ed 2001.
- Datta S: Neurophysiology of aggressive behavior, Medical Scinces Bulletin, 2:22-24, 2004
- 3. David M Stoff et al: Handbook of antisocial behavior, 2009
- Davidson RJ, Putnam KL, Larson CL: Science(USA)289(5479):591-594,2000.
- Demus GE, KriegfeldLJ, Blackshaw Set al:J Neurosc19:30,1999.
- Fredrick A: Arch Neurol 61:1249-1253, 2004.
- Ganong WF: Review of Medical Physiology 23rd ed. 2008
- Goveas JS, Csemansky JG, Coccaro EF: Psychiatry Res (Ireland) 126(1):23-32, 2004
- Kandel ER, Schwartz JH, Jassel TM: Principles of Neural Science 4th ed. 2000
- Teenage brain: A work in progress http://www.nimh.nih.gov/health/publicati ons 2003
- 11. Troubled teens behavior www.balmoralfarm.ns.ca
- 12. Understanding adolescent behavior www.imdb.com/title/tt079072

History of Dentistry in Papua New Guinea

Dr. S.L. PERERA

Division of Dentistry,

School of Medicine and Health Sciences, University of Papua New Guinea

Traditional dentistry has been practiced in Papua New Guinea (PNG) from ancient times. In the few instances where pain was related to teeth a certain member eventually became adept in treatment. Even now certain tribes far away from dental facilities still resort to the use of strings and stones to extract teeth while certain medicinal plants are used to treat dental pain.

After the territory of Papua New Guinea was established under the control of Australia, a dental treatment service to relieve pain was set Treatment Teams visited mainly large up. centres such as Port Moresby, Lae, Rabaul etc. These teams comprised of 1 - 4 dental officers from Australia.

Then in 1958 Dr. Gunther, then Director Health Services, decided to start a proper dental program in PNG. Dr. J. Francon Williams, who was an assistant Director of hygiene in New Zealand was commissioned to report on the feasibility of starting a public dental service program for PNG. He conducted a large oral survey in the territory mainly on school children in Port Moresby, Eastern Highlands and the coastal areas of Madang, Morobe and Rabaul. His conclusion from the survey was that dental caries was a significant public health problem. He recommended the establishment of a school of dental service similar to the one that operated in New Zealand at that time. The program he recommended was divided into a preventive school dental service and a general maxillofacial unit as a service for adults. He also recommended the setting up of a central dental store.

The proposal was accepted and a training section for dental workers was started in 1960 at the Port Moresby General Hospital at the then Walterstrong Wing. Soon after the available facilities at the Port Moresby General Hospital were outgrown and dental training moved to the hospital animal house building. A further relocation in 1962 was made to the Papuan Apinapi complex of buildings at Lawes Road and which also saw extensions made to the nearby forestry building in 1967 to provide additional space for the dental program.

In 1963 a dental technician course was started which was followed in 1966 by a dental officers' course which as established as a modular program by Dr. D. Barmes and Dr. Sharmshula. This was the first world's dental modular

program to train dental therapists and dental officers.

In mid 1968 another change took place when the training program was moved to 6 mile. The six mile dental college lasted for more than ten years where increases in staff numbers and improvement in facilities were made.

In 1973 the Government decided that dental officers be trained at the University of Papua New Guinea. In 1976 a department of dentistry was established at Taurama and Dr. W. Deubert was appointed the Foundation Professor of Dentistry. Thus between 1976 and 1983 there were two training schools one at Taurama training dental officers and the other at 6 mile training dental therapists and dental technicians. Then in late 1982 a decision was made by the National Executive Council of the government of the day to merge all dental training and this be done at the University of Papua New Guinea. As a result, the six-mile Port Moresby dental school was closed down and a transfer of equipment and staff members to Taurama was made.

In 1984 the Gabriel Griss Building which had been completed in 1980 was formally declared open for training of dental personnel. The training program for dental officers however lasted only until 1987 when it was closed down.

Following the closure the Diploma in Dental Therapy program was transferred to the then College of Allied Health Sciences in 1988 while retaining the Gabriel Griss Memorial building facility until the program was re-transferred to the University of PNG in 1994 where it continued to offer a diploma program until 2004. A new modular program was launched in November 2003 to train dental officers and dental therapists by Professor J. M^cIntyre and Dr. S. L. Perera. These two programs are currently running smoothly. In 2008 a dental technician program leading to a diploma after three years training duration was launched.

Acknowledgement by the author

Dr. K. K. Beaga. Mr. S. Waiho, Dr. G. Maino, Dr. D. Stephana, Prof. Ian Maddocks, Mr. A. Aufe, Mr. F. Webb, Dr. Sassolan, Dr. R. Kila, Dr. A. Saweri, Dr. B. Gwale, Dr. Panghatana Mr. J. Aime, Ms. Karen Karo, Mrs. A. Afo, Mrs. R. Kila, Mr. P. Sali, Ms. Josepha Kapa, Dr. M. Apaio, Mrs. Ann D. Waiko.

Reference:

- Dr. G. N. Davis Future of Dental Service in PNG 1990, pg 1-3
- 2. Territory of PNG Dental Service Department of Public Health
- 3. University of PNG Handbook in 1995
- Dental Education in PNG UPNG Library, Waigani
- What is the Future of the Dental Services in Papua New Guinea, Nov 1986
- Let the Dental School get on with its Important National Job, Professor J. D. Jago, Feb – 1987

- Manpower Training Requirements for Dental Training and Dental Field Services – UPNG Library
- Huli Oral Health, MPH Thesis, Dr. P. L. Newell, University of Sydney
- 9. A Short History of Paua New Guinea, Professor John D. Waiko
- Its for10. A History of Dentistry in Sri Lanka, Dr. H.rvices –W.M.Coory2008

Assessment of the Costs of Medicines and Laboratory Tests in the Management of Opportunistic Infections in Patients with HIV and AIDS at Port Moresby General Hospital

Ms. Nancy Bala and Dr. Phillip G. K. Kigodi

Division of Health Sciences,

School of Medicine and Health Sciences, University of Papua New Guinea

Introduction: The HIV and AIDS Epidemic at a glance

New and cumulative annually reported HIV infections in PNG continue to show a geometric increase nationwide. Since the first 6 cases of HIV were reported in PNG in 1987, the number of HIV and AIDS cases rose to 7036 by the end of March 2003. Available statistics show that from 1995 to 1997 known cases increased by 50% annually then by about 30% per year.

In 2003, an estimated 150 new cases were reported each month and it was estimated then that 10,000 to 15,000 people lived with HIV and AIDS [1]. Both actual and predicted rural and overall national trends in the HIV epidemic from 1993 to 2012 show a sharp increase with urban trend showing just a slight slowing down for the

same period. The prevalence of HIV infection in PNG can only be estimated because no nationwide systematic assessment has been done and current information has relied on surveys from a few locations which involved a small number of population groups. Outside of Port Moresby and a few other towns, HIV prevalence has mostly been measured in blood donors, attendees of sexually transmitted infections (STI) clinics and TB populations. In addition sentinel surveillance has been done in Port Moresby, Lae and Goroka among antenatal women and sex workers, and in all these places the HIV prevalence rate was found to be higher than one per cent. The alarming increase of HIV infection has gone hand in hand with a high prevalence of other sexually transmitted infections. Effective and early treatment of STI reduces HIV risk.

HIV prevalence as a generalized fast-growing epidemic

The epidemic is fueled mainly by high levels of risky heterosexual practices which include multiple sex partners, low and inconsistent condom use, lopsided gender equity, an unwieldy number of language groups and a challenging geographical terrain as well as a rapid societal transition. HIV infection affects men and women in almost equal numbers. Known HIV-positive cases in PNG is higher than in neighbouring Thailand and Cambodia.

The number of women attending antenatal clinics in Port Moresby that were HIV positive doubled² between 1998 and 1999 to 0.3%, and rose to 1.07% for women aged 15-24 in 2003.

HIV infections have been reported in all provinces of PNG with the highest numbers being in NCD followed by Western Highlands, Morobe, Eastern Highlands and Enga. It is a generalized epidemic [2]. with new cases increasing by 30% annually since 1997 Since the majority of those infected are in the age range of 15-49 HIV Impacts on all national endeavours of economic and socio-cultural effort [3]. The single most important mode of transmission of HIV is heterosexual contact (89.8%) [3]. The 2008 STI, HIV and AIDS Six Monthly Surveillance Report, January – June, 2008 which unfortunately is also the most difficult to tackle due to all cultural taboos that surround it.

The 1st National Consensus Workshop was held in 2000 at which it was estimated that the number of people living with HIV was 10,000 to 15,000. The 2nd Consensus Workshop four years after the first consensus meeting in 2004, and at its disposal were more new data for review which included data on HIV, AIDS and STI as well as social and behavioural factors that influence the dynamics of the epidemic. The meeting revised the estimated number of people infected with HIV be 25,000 to 69,000 with a median estimate of 47,000 giving a median adult prevalence [4] of 1.7%

WHO estimated that PNG has the highest prevalence of gonorrhea (12%) and genital chlamydia (27%), and the second highest prevalence of syphilis (3.7%), the 4th highest prevalence of HIV in Asia Pacific and the highest HIV prevalence of all Pacific Island nations. Supporting this view, community based studies conducted by the PNG Institute of Medical Research of asymptomatic people in 10 provinces showed that of the total 3288 people tested, 40% (1315) were infected with at least one STI. Of those infected the prevalence of chlamydia was 13.2% (434), syphilis was 15.0% (493), gonorrhea 11.5% (378) and trichomoniasis 19.7% (648).

The prevalence of HIV was 3.4% in urban areas and 1.3% in rural areas, with an overall prevalence of 2.4%. Females showed higher levels of HIV infection in both rural and urban

areas. The presence of an STI greatly increases a person's risk of contracting and transmitting HIV.

The HIV and AIDS Epidemic at PMGH

Since mid-2001, AIDS has been the leading cause of admission and death in the medical wards at the Port Moresby General Hospital. AIDS patients occupy 70% of medical ward beds and 30% of patients with TB are HIV positive. The case fatality rate between 2000 and 2006 for those on ART declined by 25%.

Experience with Antiretroviral Therapy (ART)

The ART program started as a pilot project in February 2004, at the PMGH Heduru Clinic under the 3x5 initiative. The program has since expanded to other sites and by the end of June 2007 there were twenty-six ART sites across the country. Overall, there were 2,367 registered patients from the ART sites, of whom 1646 (70%) were on treatment.

Of the facilities offering ART service, public hospitals account for 33 per cent (n = 10) of all ART sites and are responsible for providing ART to 91 % of all patients. Faith Based Organizations (FBO) 50 % (n = 14), economic enclave sites 8% n = (2) and private hospitals 8% (n = 2). FBO, despite having the highest number of sites, cater for only 8% of all patients on ARV. Enclave sites (1.2%) and private clinics (0.6%) provide treatment on a much smaller scale. Organizations involved and their contribution in the ART Program

Opportunistic Infections Categories

At the global level opportunistic infections (OI) and other disorders common with HIV diseases have been identified and grouped into a number of broad categories⁵ as follows:

Bacterial includes and Mycobacterial Mycobacterium avium Complex (MAC, MAI), Salmonelliosis, Syphilis and Neurosyphylis, Tuberculosis (TB), Bacillary angiomatosis (Cat scratch disease).

Fungal Infections: which include Aspergillosis, Candidiasis (thrush, veast infection), Coccidioidomycosis, Cryptococcal meningitis, Histoplasmosis.

Malignancies such as Kaposi's Sarcoma and Lymphoma such as Systemic Non-Hodgkins Lymphoma (NHL,) and Primary CNS Lymphoma.

Protozoal Infections are: Cryptosporidiosis, Isosporiasis, Microsporidiosis, Pneumocystis carinii Pneumonia (PCP) and Toxoplasmosis.

Viral Infections involve Cytomegalovirus (CMV), Hepatitis, Herpes Simplex Virus (HSV, Genital Herpes), Herpes Zoster (HZV, Shingles), Human Papilloma Virus (HPV, Genital Warts, Cervical Cancer), Molluscum contagiosum, Oral Hairy Leukoplakia (OHL), Progressive Multifocal Leukoencephalopathy (PML)

Neurological Conditions are AIDS Dementia Complex (ADC) and Peripheral Neuropathy,

Other Conditions and Complications are Apthous Ulcers, Malabsorption as well as Depression, Diarrhea, Thrombocytopenia, Wasting Syndrome, Idiopathic Thrombocytopenic Purpura, Listeriosis, Pelvic Inflammatory Disease, particularly if complicated by Tubo-Ovarian Abscess Lymphoma, Burkitt's Iymphoma and Immunoblastic Lymphoma.

Statement of the Problem

In PNG more than 69,000 people are estimated to be living with HIV and AIDS. It is well established that infection with the HIV virus opens up the individual for a wide range of other infections called opportunistic infections. Despite the fact that HIV and AIDS patients use up a lot of the medicines for the treatment of opportunistic infections there are no additional funds to offset the demand placed on 'traditional' supplies of medicines. The donor community supports antiretroviral treatment and prophylaxis of the commonest OIs such as TB and oral thrush only.

The government has not set aside additional funds to meet the increasing pressure on medicines and other devices as more and more HIV and AIDS patients take medication for OIs. There is an urgent need to determine the cost of managing OIs to provide information which may be used by DOH to solicit for more funds to keep the devices and medicines inventory proportionate to demand.

Aim and Objectives

Aim of this study was to assess the cost of treatment and laboratory tests in HIV and AIDS patients with opportunistic infections at PMGH. Its objectives were to identify common OIs in HIV and AIDS patients, to calculate the cost of Medicines used to treat the OIs, to document the duration of each OIs in each patient. To list the types of Medicines used to treat the OIs and to calculate the cost of the lab tests for detection of OIs.

Methodology

The methodology used in the study was a nonintervention retrospective Quantitative and Qualitative observation survey using both closed and open ended questionnaires to collect data which included age, gender, types of opportunistic diseases, duration of treatment and type of medicines used. The study was done at PMGH Wards 4A, 4B, 7, 8 and Heduru Clinic. Records of patients used in the study were identified by numbers only in order to keep the identity of the patient.

Most of HIV and AIDS patients (70 %) were admitted in Ward 4B but after discharge their files were kept at the Heduru Clinic the data was collected from clinical notes and the medicine sheets from the patient files kept at the Heduru clinic. Additional information relating to allocation of funds for the treatment and management of HIV and AIDS was obtained from the WHO office, Health Department and the National Aids Council. A number of specialist Medical officers and sisters in charge of the various Wards were interviewed to complement the information collected.

Sampling, Study unit and Sample size:

The study population comprised AIDS patients at PMGH where adult patients aged 18 and above totalling 42 who were registered for the ART program. The selection criterion was any adult patient of either gender diagnosed with HIV and AIDS who was an inpatients or outpatient.

For out patients, data of a one year period was collected while for inpatients the data collected was for a 6 months period. The cost of treatment of OIs was calculated using a pricelist obtained from the procurement section of the Medical Supplies Branch.

Data processing and analysis

All the data were entered and analysed using a master sheet created using Microsoft Excel 2003.

Ethical consideration

Ethical clearance was issued by the Research and Publications Committee SMHS and endorsed by the National Advisory Committee. Consent from the CEO of PMGH was sought prior to commencing data collection.

All sensitive data collected was held confidential by using code names and numbers during and after the data collection and analysis.

Results and Discussion

A total of 42 patients met the criteria for inclusion in the study and data for both outpatients and inpatients were documented. For the outpatients, data for a one-year period were collected while for inpatients the data collected were for a six-month period. The data collected was used to calculate the costs of both medication and clinical Laboratory tests for OIs.

The fifteen common conditions and opportunistic infections frequently treated at the Heduru clinic are shown in figure 1; the most frequent of which included cough, malaria, fungal infections, Diarrhoea, skin infections etc. 118

30 Commonly treated conditions at Heduru clinic 24 25 20 17 Frequency 15 10 10 9 9 10 6 6 5 5 3 3 2 2 2 1 0 URTI Cough Tinea 18 PTB РСР Boils Malaria Skin infection M/Papular Herpes zoster Candidiasis HIV wasting syndrome Anal thrush Oral thrush Herpes simplex A/cheilitis Diarrhoea Otitis media **Seneral** itchiness Arthritis Sore genitalia Fungal infection Scabies Pneumonia arthritis Eye infection Oral hairy leukoplasia Anaemia E PID Opportunistic infection or condition treated

Figure 1: Common opportunistic infections and conditions treated at Heduru clinic

The main causes of patient of AIDS admission at PMGH were found to be TB, gastroenteritis, anaemia, fungal infection and malaria.

The three common prophylactic medicines dispensed at Heduru OPD clinic for outpatients during the period of study were co-trimoxazole, fluconazole and isoniazid.

Management of OIs is a new priority expenditure incurred by all health facilities in the country which is set to rise sharply as more and more demand is placed on these facilities by AIDS patients. This new expenditure is eating into the budget for 'traditional' diseases. It is imperative that in order to keep 'traditional' services at the same level the management of OIs should either be separately funded or their cost should be reflected in the annual budgets so that 'traditional' public health care delivery does not decline further.

The cost of clinical laboratory diagnosis is not supported by donor agencies. When calculating the cost of the treatment of opportunistic infections the cost of antiretroviral medicines which is provided by donor agencies were excluded.

Medicines Co	osts (Kina)	Laboratory Tests (Kina)		
Description	Category Average	Total cost	Category Average	Total cost
Outpatient	103.18	2,270.03	75.36	1,658.00
Inpatient	70.44	4,22.62	240.00	1,559.56
Both	159.33	2,071.35	40.00	119.97
Range		10.00 < K >250.00		5.00 < K >75.00

Table 1: Treatment cost and clinical laboratory diagnosis cost of Ols.

Donor funded medicines dispensed at the Heduru Clinic were Co-trimoxazole, Fluconazole and Isoniazid. The main debilitating admitting cause at the PMGH for HIV and AIDS patients was Tuberculosis.

Table 1 show the different costs whose details of calculation are shown in Table 2. The average cost for treatment of OIs for an outpatient for a one-year period was K103.18, for an inpatient the costs for a 6-months period was K70.00 and K159.33 was spent on patient who was both inpatient and out-patient.

The average cost for the Laboratory tests for an outpatient for a one-year period was K70.00; the cost for an inpatient for a 6-months period was K240.00 and was calculated to be K40.00. The calculations of these costs were based on the prices indicated in the Medical and Dental stores Catalogue (as updated) which are heavily subsidised and do thus not necessarily reflect the market costs of the items

Conclusion

A number of OIs and conditions affecting AIDS patients were treated at the Heduru clinic.

Calculations of costs to manage OIs suggest that this cost will rise steeply and order to maintain the inventory of 'traditional' public healthcare NDoH should reflect this new additional cost of medicines and laboratory reagents in its annual budget. Or request donor agencies to supply a wider range medicines and reagents to the country under the Donor support programs.

References

- 1. NDOH HIV and AIDS Estimation Report for 2007
- 2. NSP on HIV/AIDS, 2004 2008 p7-8
- NDOH, (2008). The 2008 STI, HIV and AIDS Six Monthly Surveillance Report, Jan.– June, 2008
- 4. NAC and NHASP, 2000. p 1
- 5.Opportunistic-Infections <u>www.aegis.com/default.asp?req=http://www.aegis.</u> <u>com/topics</u>

	Out patient			Inpatient			
Patient	Medication cost	Test cost	Total	Medication	Test cost	Total	Total Cost
AP	16.37	8.00	24.37				24.37
MY	19.92	8.00	27.92				27.92
LA	15.46	60.00	75.46				75.46
DI	34.77	60.00	94.77				94.77
NK	25.99	20.00	45.99				45.99
СТ	10.07	34.00	44.00				44.00
MM	9.38	30.00	39.38				39.38
CV	11.76	22.00	33.76				33.76
RV	16.24	60.00	76.24				76.24
AR	15.57	60.00	75.57				75.57
KW	6.85	62.00	68.85				68.85
AP	1.28	66.00	67.28				67.28
AM	18.44	56.00	74.44				74.44
SK	13.38	30.00	43.38				43.38
PJ	6.80	10.00	16.80				16.80
NK	22.91	20.00	42.91				42.91
RL	8.35	72.00	80.35				80.35
JK	26.87	68.00	94.87				94.87
FS	16.75	84.00	100.75				100.75
RP	17.06	66.00	83.06				83.06
RB	8.69	42.00	50.69				50.69
MH	14.78	60.00	74.78				74.78
MA				33.48	30.00	63.48	63.48
JK				3.72	30.00	33.72	33.72
DK				15.36	60.00	75.36	75.36
RY				78.34	60.00	138.34	138.34
AK				40.74	30.00	70.74	70.74
GA	07.00	00.00	407.00	10.98	30.00	40.98	40.98
PM	67.02	60.00	127.02	117.18	30.00	147.18	274.20
WJ	11.62	72.00	83.62	28.98	40.00	68.98	152.60
VL	14.98	114.00	128.98	45.30	90.00	135.30	264.28
TB	22.88	20.00	42.88	2.88	10.00	12.88	55.76
SP	23.40	52.00	75.40	45.64	30.00	75.64	151.04
WN IA	42.47 5.91	46.00 30.00	88.47 35.91	30.00 2.07	30.00 20.00	60.00 32.07	148.47 67.98
KK	9.12		35.91 43.12	2.07 52.67	20.00 30.00	32.07 82.67	67.98 125.79
MB	9.12 0.15	34.00 68.00	43.12 68.15	52.67 251.45	30.00 30.00	02.07 281.45	125.79 349.60
DW	16.03	68.00 74.00	90.33	251.45 14.22	30.00 46.00	201.45 60.22	349.60 150.55
DW	2.52	74.00 30.00	90.33 32.52	44.38	46.00 28.00	72.38	104.90
LF	2.52 18.53	30.00 32.00	32.52 50.53	44.38 10.37	28.00 30.00	72.38 40.37	104.90 90.90
MT	39.48	32.00 28.00	50.53 67.48	8.80	59.00	40.37 67.80	90.90 135.28
Total	53.40	20.00	1,336.62	0.00	33.00	422.62	2,071.35
			60.71			70.44	159.33
Average			00.71			70.44	109.00

Table 2 Details of calculation of patient treatment costs.

INSTRUCTIONS FOR AUTHORS

AIMS AND SCOPE:

Pacific Journal of Medical Sciences is a peerreviewed, multidisciplinary journal published by the School of Medicine and Health Sciences (SMHS), University of Papua New Guinea (UPNG).

The aim of The Pacific Journal of Medical Sciences is to provide the forum for researchers, medical practitioners and other professionals to record, publish, and share ideas and research findings that serve to enhance the understanding of the aetiology, symptoms, diagnosis, prevention, control and management of human disease conditions world wide.

The Pacific Journal of Medical Sciences publishes original scientific research reports, case reports, short communications, letters to the editor and reviews, representing new and significant findings in all areas of medical, biomedical and health sciences (including epidemiology, public and environmental health). Book reviews, scientific news and conference proceedings are published on special request.

EDITORIAL POLICIES:

The Pacific Journal of Medical Sciences (Pac. J. Med. Sci.) editorial policies require that:

All manuscripts accepted for publication must reflect novelty and originality of quality research and be of interest to a multidisciplinary audience. All papers submitted for publication are peer-reviewed by two anonymous reviewers

and the editor-in-chief or a designated member of the editorial board.

The editorial board may request for review articles, commentaries or short reviews on contemporary medical or biomedical issues that board considered important to the the advancement of the aims of the journal.

Original research papers should be both complete and concise; they should essentially offer conclusive results, but they should not exceed 7,500 words, including abstract, tables, figures and references.

Short communications and reports should not exceed 3500 words, including abstract, tables, figures and references. Review articles should not exceed 6,000 words, including tables, figures and references. Letter to the Editor should be brief and to the point.

On preliminary editing, all manuscripts that fail to meet the basic requirements indicated above and those that contain significant and obvious typographical errors are returned without further processing.

Manuscripts submitted will be reviewed and considered for publication only if they have not been published, simultaneously submitted or already accepted for publication in another The author responsible journal. for correspondence must show evidence of approval of all co-authors when submitting a paper for publication.

All relevant ethical approval for research involving human and animal subjects must conform to the provisions of the Declaration of Helsinki in 1995 (as revised in Edinburgh 2000).

Only research methods that comply with internationally accepted principles of humane animal experimentation are accepted for publication in The Pacific Journal of Medical Sciences. The decision to accept, revise or reject any manuscript for publication in The Pacific Journal of Medical Sciences is the responsibility of the editor-in-chief; this is done after reviewing the reports and comments from the reviewers, in consultation with members of the editorial board.

Disclaimer:

All statements and opinions expressed in any of the manuscripts published in The Pacific Journal of Medical Sciences are of the authors and coauthors, and not necessarily of the editors or members of the editorial board.

The editor-in-chief and members of the editorial board of The Pacific Journal of Medical Sciences disclaim any responsibility or liability for such material and do not guarantee or endorse any products or services mentioned in the articles, nor guarantee any claims made by the authors of the articles.

SUBMISSION OF MANUSCRIPT:

Manuscript should be written in clear and concise English and be intelligible to those that are not specialists in the particular scientific area. Manuscript that does not satisfy these requirements but is acceptable for publication in the Pacific Journal of Medical Sciences because of its essential scientific content will be returned to the authors for extensive and appropriate revision, as recommended by the reviewers and editors.

A covering letter to clarify the following should accompany any manuscript submitted for publication in the Pacific Journal of Medical Sciences: (a) That the scientific data contained in the manuscript has not been published or submitted for publication in any other journal; (b) That ethical clearance and permission for the research had been obtained from the appropriate committee(s) in the institution(s) where the work was carried out; (c) That all the authors have read and approved the content of the manuscript; (d) The name, address and email contact of the author responsible for correspondence and for communicating with others about revisions and final approval of proof of manuscript; (e) Statements quantifying the contribution of each author to the manuscript (this is a requirement in the latest quidelines of the International Committee of Medical Journal Editors).

Only electronic copy of the manuscript sent as e-mail attachment should be submitted using the approved format indicated in the appropriate sections of this document.

 Manuscript should be sent by email to any of the following:
 Kikovele@daltron.com.pg;

 templevj@upng.ac.pg;
 templevictor@gmail.com;

 amasta@upng.ac.pg;
 prem.rai@upng.ac.pg

PREPARATION OF MANUSCRIPT:

Manuscripts should be prepared on one side of A4 paper, using double-spacing. Pages are to be numbered consecutively in the bottom righthand corner. Manuscript should include the following sections: Title page, abstract and keywords, text, acknowledgements, references, tables and figures.

Style:

The Pacific Journal of Medical Sciences uses both UK and US spelling. Only one or the other should be used throughout a manuscript. SI units should be used for all measurements. Use abbreviations to avoid repetition of long technical terms: Indicate the abbreviation in parentheses when the word is used in full for the first time. Use the approved generic names of chemical substances and drugs. Do not use trade names or brand names of chemicals and drugs.

Title page:

The following should be on the title page: (a) Title of the manuscript – it should be concise and informative; (b) Short running title of not more than 40 characters (optional); (c) Name of each author (first name, middle initial and last name), including highest academic degree; (d) Name and address of institution(s) in which the work was carried out; (e) Name, postal address and email contact of the author responsible for correspondence; Source(s) of research or other types of support for the research project, if any,

Abstract and key words:

The abstract should not be more than 300 words. The following should be clearly stated in the abstract: the purpose of the study, basic procedures, main findings (specific results and statistical significance, if any), and principal conclusions. Abbreviations and references should not be included in the abstract. Not more than 8 key words should be put below the abstract. Key words are used to assist indexers in cross-indexing published articles and may be published with the abstract. Medical Subject Headings (MeSH) list of the Index Medicus should be used for selecting key words (www.nlm.nih.gov/mesh/meshhome.html).

Text:

Text of an original manuscript should be separated into the standard IMRAD format as follows: Introduction, Materials and Methods, Results, Discussion. Sections on Acknowledgements and References should be included.

Introduction: This section should: (a) summarize relevant previous work, using appropriate references, without any extensive review of the subject; (b) clearly state the purpose of the study and summarize the rational for the study or observation; (c) avoid given any data on the work being reported.

Materials and Methods: This section should: (a) clearly indicate either the sampling procedure or observational subjects; (b) give appropriate references for established techniques and

procedures; (c) new techniques and procedures and extensive modifications of existing ones should be presented in sufficient details so that other researchers can easily reproduce and evaluate them; (d) indicate appropriate quality control procedures used for laboratory methods and techniques; (e) indicate ethical procedures if either human subjects were involved [if informed consent was obtained from each subject] or if appropriate guide line for using laboratory animals were followed [see editorial policies above]; (f) indicate statistical methods used, if any.

Results: Data obtained should be presented in logical sequence in the text, tables and figures should be adequately explained to facilitate their interpretation. Avoid duplicating the results by repeating in the text all the data presented in the tables and figures. The text in the results section should only emphasize or summarize the important data.

Discussion: Major findings should be highlighted before the minor findings. All findings should be related to other relevant studies, if any, using appropriate references. Indicate the implications of the findings and their significance or limitations, including implications for future research. When warranted, propose new hypotheses with appropriate data, but be sure to clearly label them as such. The conclusions should be linked with the goals of the study and be clearly supported by evidence / data. Include recommendations, if applicable.

Acknowledgements:

The following should be acknowledged: Research or other financial grants; Material support, Contributions of Institutions, Colleagues, and other relevant participants.

References:

The Pacific Journal of Medical Sciences uses the Vancouver system of referencing. The references should be numbered, using Arabic numerals in square bracket, in the order in which they are first used in the text, tables, figures, and legends. In the reference section, list the references in the order of appearance in the text, tables, figures and legends. Abstracts, unpublished data, oral communications, and personal communications should not be included in the reference section. All references should be verified against the original documents. In the reference section, the names of all authors should be included. Avoid using "et al." in the reference section. Names of journals should be abbreviated, using the approved style indicated in Index Medicus/PubMed. References should be listed according to the examples given below:

Journal articles:

 Brander LC, Buess H, Haldimann F, Harder M, Hanggi W, Herrmann U, Lauber K, Niederer U, Zurcher T, Burgi U, Gerber H. Urinary iodine concentration during pregnancy in an area of unstable dietary iodine intake in Switzerland. J Endocrinology Invest. 2003, 26 5: 389 – 396.

Book:

 Gillett JE. The health of women in Papua New Guinea. PNGIMR: Kristen Press, 1991

Chapter in a Book.

 Chaney SG. Principles of nutrition II: Micronutrients. In: Delvin TM, editor. Textbook of Biochemistry with Clinical Correlations, 4th ed. Brisbane: Wiley-Less, 1997: 1107 – 36.

Published proceedings paper.

 Kruse-Jarres JD. Basic principles of zinc metabolism. *In:* Kruse-Jarres JD, Scholmerich J, editors. Zinc and diseases of the digestive tract. Proceedings of the International Falk workshop, Germany, 1996: 3 – 15.

Tables:

Tables should be numbered sequentially in Arabic numerals, typed double-space on separate A4 paper for each table; vertical lines should not be used to separate columns. Each table should be self-contained with a comprehensive but concise legend/heading; column headings should be brief, with units in parenthesis. All non-standard abbreviations used in tables should be explained in footnotes, using the following symbols in this

sequence: *, §, ¶, #, \$.

Illustrations:

Graphs, line drawings, bar charts, maps, etc., should be labelled as 'figures' and numbered consecutively, using Arabic numerals. All figures should be drawn using computer graphics. Legends should be brief but understandable without referring to the text. Photographs should be unmounted sharp, glossy black and white prints. Photographs should contain scale bars, not magnifications. Colour photographs are not acceptable. Figures, reproduced from another source, should be clearly indicated and appropriate references and written permission from the copyright holder must be submitted with the manuscript.

Electronic copy of manuscripts (e-mail):

When a manuscript is accepted for publication, the corresponding author will be required to send an electronic copy of the corrected or modified manuscript by email.

All email attachments should be scanned with anti-virus software before sending. Automatic software for referencing, footnotes, headers, footers, etc., should not be used during formatting.

All manuscripts should be formatted using MS WORD.

GALLEY PROOFS:

Galley proof will be sent by email to the correspondent author. Only minor corrections should be made, no major alterations to the manuscript will be accepted. Galley proof should

be returned within maximum 5 working days from the date of receipt. If any major modification is made, the manuscript will be rejected at this stage.

Correspondent author should correct all printing errors and ensure that the typesetting is accurate in the galley proof. Note that the correspondent author, not the publisher will be responsible for any such errors, should they occur in the published paper.

REPRINTS:

Reprints will not be sent to authors. One copy of the journal will be sent to the correspondent author on request only, subject to availability of funds to cover postage.

COPYRIGHT:

Manuscripts accepted for publication in The Pacific Journal of Medical Sciences become the property of the journal. Therefore, all authors will be requested to sign a transfer of copyright form before the accepted manuscript is published.

Manuscript will not be published, if all the authors (or the correspondent author, on behalf of the others) do not sign the transfer of copyright form. The copyright gives the journal the exclusive rights to reproduce, translate and distribute the article for academic purposes.

CHECKLIST FOR AUTHORS:

- Running title included;
- Abstract prepared according to instructions and include key words,
- Manuscript typed double-space on one side of A4 paper,
- References cited in superscript in text and listed according to approved style for this journal,
- □ Uniform spelling throughout the text,
- Tables and Figures on separate A4 pages,
- Covering letter written as required by this journal,
- E-mail address of corresponding author indicated