QUALITY OF HEALTH CARE IN HEALTH INSTITUTIONS IN KENYA

Principal Investigator: William M Macharia,
Co-Investigators: physician, General Surgeon, Obstetrician and Anaesthetist

Introduction

- Determination of adverse events (AEs) rates is one of the most reliable ways of assessing quality of care in health institutions. Published work has estimated AEs rate to range between 7.5-16.6% irrespective of the region of the world where studies conducted. Wilson et al estimated 42.5% (range 37-51%) of the identified events to be preventable, a finding which was in keeping with earlier studies in the Americas and Europe.
- Estimated 80% associated with disability lasting at least one month, longer hospital stay or death ranking the problem among top causes of preventable morbidity and mortality world over. Socio-economic consequences are enormous.
- There is no data available on burden and contributory factors for AEs in most developing countries, including Kenya yet the existence of the problem needs to be highlighted for any meaningful attention to be drawn.
- Action needed from governments, health care professionals and the public at large before situation can change for the better.
- Since exposure of AEs has major medico-legal and associated economic implications on health facilities and medical practitioners, research work in this field elicits much apprehension and therefore resistance.
- Though often incomplete, patients’ hospital records remain the most reliable source for AEs studies.
- A validated data collection tool methodology are now available though the former not yet tested in developing countries setting.
- In consideration of the major load contributed by HIV/AIDS to inpatient services in developing countries and recent introduction of free ARTs in Kenya. Special attention needs to be paid to AEs related to the condition considering to narrow margin between toxicity and benefit of the drugs over and above known lethal interactions with other drugs.

Research Questions

Primary:
1. What the prevalence of adverse events in Kenyan hospitals?
2. What are the major contributory factors to adverse events in Kenyan Hospitals?

Secondary:
What is the adverse events rate and contributory factors among in-patients with HIV/AIDS?

Objectives

Primary:
To determine the prevalence of AEs in health facilities in Kenya and to identify main factors contribution to their occurrence.

Secondary:
Define AEs rate and major contributory factors in patients admitted with HIV/AIDS
Study Design

This will be a cross-sectional survey to determine prevalence rates and factors associated with occurrence of adverse events among all types of diseases among inpatients and for HIV/AIDS

Methods

− Hospital selection will be performed to ensure representation of rural and urban, public and private/mission health facilities.
− Selection will performed to include rural and urban diversity as well as presumed quality of care and patient socio-economic spectrum. Most post poor are admitted to public hospitals and the rich in private hospitals. These will be assumed to be represented by selection of Kenyatta National referral hospital with a 2000 bed capacity, The Nairobi Aga Khan private hospital, one provincial hospital randomly selected from 5 eligible hospitals and one randomly selected district hospitals. Only health facilities with more than 800 admissions per year will be eligible.
− 500 hundred randomly selected patient records will be retrieved from year 2004 admissions in preliminary screening from each of the selected health facilities
− Alliance for Patient Safety data collection methodology will be used; recommends three stage record review stages – initial determines completeness of records (long in-patient experience nurses), second screening for probable adverse events and admissions with HIV/AIDS (experienced medical officers) and third stage evidence for occurrence of an adverse event (mix of specialist doctors with more than 10 years post graduation experience – engaged as co-investigators).
− Adjudication on uncertain situations will be done in consultation with sub-specialty content experts
− Definition of Adverse event will be based on fulfilment of criteria for occurrence of unintended injury or complication causing disability or death etc. and caused as a consequence of health care management. Event must also have been considered preventable in the absence of attributed harm.
− Modification of inclusion criteria and definition of events in HIV/AIDS will be clearly specified
− Reproducibility of data collection will be reinforced by thorough training of the assessors and using the same group of assessors for all the hospitals to reduce inter and intra-rater reliability. Kappa statistics for both inter and intra-rater reliability will also be computed using a randomly selected sub-sample of 10% of the records in each institution.

Outcomes

− Documentation of baseline characteristics for those include and excluded and reasons for exclusion
− Overall adverse event rate and contributory factors will be primary outcomes why similar determinations for HIV/AIDS will constitute secondary outcomes.

Sample Size

− Based on recommendation of 500 records per hospital which would need to be subjected to indepth screening for occurrence of adverse events
Study Management
- Clearly defined leadership mechanisms
- Study multi-stakeholders steering committee constituted early to ensure dialogue and consensus building. Hospital administrators, medical practitioners and Dentists Board, Kenya Medical Association and National AIDS Council will be among critical stakeholders to counter mis-understanding and guarantee smooth dissemination of findings.

Ethical consideration
- National council for science and technology clearance
- Kenyatta National Hospital ethical committee clearance
- Private hospital clearance by hospital ethical and scientific committees
- Letter of study support from Director of Medical Services to add to study credibility thus helping enhance authenticity and credibility of the study.
- Anonymous record keeping with link between cases and study numbers destroyed 4 months after the study.
- Memoranda of understanding with hospital chief executives for confidentiality guarantee.

Data Analysis
- Will use recommended WHO Patient Safety Alliance data base package and analytical methods.
- Kappa statistics for intra and inter rater reliability.
- 95% confidence intervals around the rate estimates.

Budget & Justification
To be computed but will include:
1. Salaries for reviewer nurses on full salaries for about 3 months
2. Salaries for medical officers reviewers or 1 month
3. Salary for project manager for about 4 months
4. Allowance to offset time cost for specialist reviewers based on each patient file reviewed
5. Ethical review charge of US $ 50
6. Field worker training and pre-testing (estimated at 3 days)
7. 1 lap-top and 1 desk top computer and printer
8. Local Travel expenses for reviewers and investigators
9. Per diems for co-investigators in field
10. Salary for data management for about 4 months
11. Data analysis by a biostatistician
12. Meeting costs – non alcoholic beverages and snacks
13. Telephone communications/e-mail connectivity costs and stationery
14. University administrative fee is 15% of total budget (applicable to all research grants administered through the University of Nairobi)
Dissemination
– Controlled system through the guidance of study oversight committee to reduce misunderstanding and risks of litigation – constructive rather than destructive consequences.
– Direct feed-back to all primary stakeholder groups before wider publicity
– Controlled public, professional and policy makers sensitisation.
– Scientific publication in reputable peer reviewed scientific journal to add credibility of quality.