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# **COSTS AND EFFECTS OF A MULTIFACETED INTERVENTION TO IMPROVE THE QUALITY OF CARE OF CHILDREN IN DISTRICT HOSPITALS IN KENYA**

Mini-dissertation for the degree of Master of Public Health (MPH) in Health Economics at the  
University of Cape Town

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## **Part 0: Preamble**

### **Dedication**

To my parents, my teachers, past and present, to all the special friends that continue to grace my life and to God, for making everything possible.

## Thesis Abstract

There has been increased focus in improving the quality of care provided by health systems. One of the strategies that has gained prominence as a tool for improving quality of care is the development and implementation of clinical practice guidelines (CPGs). CPGs have become commonplace in clinical settings due to the view that they can improve the quality of care provided by promoting practices of proven benefit and improving consistency in clinical practice.

The increased use of CPGs in both developed and developing countries has been, deservedly, accompanied by calls for evaluations of their efficiency. A review of literature, however, reveals that there are few economic evaluations of interventions that target change in clinical practice by promoting the uptake of CPGs. The few evaluations that are available are characterized by methodological problems. This is essentially because CPG implementation is a complex intervention.

The economic evaluation of complex CPG implementation is associated with a number of methodological challenges. These issues include challenges in defining the intervention and the counterfactual and consensus on the relevant range of costs to be included in the analysis. The greatest challenge, however, lies in how to define an appropriate measure of effectiveness to be used as the outcome in economic evaluation. This includes challenges in incorporating process measures of service quality as measures of effectiveness. Questions on which measures to use, how multiple measures might be combined, how improvements in one area might be compared with those in another and what value is associated with improvement in health worker practices are yet to be answered.

In Kenya, an intervention to improve the quality of care of children was developed and tested in district hospitals. This was a multifaceted intervention employing clinical practice guidelines, training,

supervision, feedback and facilitation, for brevity called the Emergency Triage and Treatment Plus (ETAT+) strategy. This thesis presents an economic evaluation of this complex intervention.

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University of Cape Town

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## **Part A: Study Protocol**

### **Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya**

#### **Background**

An estimated 8.8 million children die globally every year before age five (You et al., 2009, Black et al., 2010). Ninety nine percent of these deaths occur in developing countries, with fifty percent in Sub-Saharan Africa (You et al., 2009). In Kenya the under five mortality rate was 74 per 1000 children in 2008 (Kenya National Bureau of Statistics (KNBS) and ICF Macro, 2010). A series of reports by the Bellagio research group reveal that most of these deaths are due to a few treatable and preventable diseases, for which effective interventions are already available (Black et al., 2003, Jones et al., 2003, Bryce et al., 2003, Claeson et al., 2003, Victora et al., 2003). Effective provision of an essential package of interventions, at scale, is felt to be critical in achieving Millennium Development Goal 4 (MDG 4) which calls for a two thirds reduction in the under five mortality rate between 1990 and 2015 (Bryce et al., 2006, Bryce et al., 2008, Veneman, 2006). Kenya's under five mortality rate was 97 per 1000 live births in 1990 and rose to 121 per 1000 live births by 2006 (Ayieko et al., 2009). The under five mortality rate then decreased to 74 per 1000 live births by 2008; this improvement has been attributed in part to improved coverage of key child health interventions, notably immunization, distribution of insecticide treated nets (ITNs) for malaria prevention and malaria case management in health facilities (Kenya National Bureau of Statistics (KNBS) and ICF Macro, 2010). To meet the millennium development goal target however, this rate will need to reduce further to 32 per 1000 live births by 2015.

While it is generally accepted that many child survival interventions need to be implemented at the community or primary care level, delivery of case management interventions for the severely ill child largely depends on the presence of functioning rural (district) hospitals. It has been observed that if functioning well, rural (district) hospitals can make an important contribution to child survival by reducing child mortality by 44% in the areas they serve, compared to the absence of any hospital (English, 2005, Snow et al., 1994). Unfortunately, the quality of care delivered in many district hospitals

in developing countries has been found to be poor and in need of considerable improvement (English et al., 2004a, English et al., 2004b). One strategy for improving the delivery of care is the development and implementation of evidence based clinical practice guidelines (CPGs) (Irimu et al., 2008). Clinical practice guidelines are systematically developed statements to assist both practitioner and patient decisions in specific circumstances (Eccles and Mason, 2001). CPGs have become an increasingly familiar part of clinical care and are viewed as useful tools for promoting the use of beneficial interventions, making care more consistent and, on occasion, less costly (Eccles and Mason, 2001). Their use has been shown to be effective in improving quality of care and patient outcomes (Schellenberg et al., 2004, Arifeen et al., 2005, Amorim et al., 2008, Naimoli et al., 2006). Benefits have been demonstrated both for interventions targeting single conditions such as pneumonia (Menendez et al., 2002, Menendez et al., 2007, Nathwani et al., 2001, Martinez et al., 2009), hypertension (Milchak et al., 2004) and diabetes (McRae et al., 2008), or multiple interventions targeting a number of high-burden conditions; the Integrated Management for Childhood Illnesses (IMCI) is one such intervention (Schellenberg et al., 2004, Rowe et al., 2009). However, the effectiveness of clinical interventions is dependent on, among other things, their delivery strategies (Grimshaw et al., 2006, Vale et al., 2007, Prior et al., 2008, English et al., 2008). Studies in both high and low-income countries have shown that providing CPGs alone yields little effect, and that multifaceted interventions including, for example, training, feedback and supervision are more effective than single interventions (Grimshaw et al., 2006, Davis et al., 1995, English et al., 2008, Prior et al., 2008, Pariyo et al., 2005).

All interventions are associated with costs. In a resource constrained environment, we are increasingly challenged to justify resource allocation in terms of costs and effects. This has led to an expansion of the literature on cost effectiveness of health interventions in developing countries around vaccines (Akumu et al., 2007, Valencia et al., 2008), HIV/AIDS interventions (Hogan et al., 2005), insecticide treated nets (ITNS) and other malaria interventions (Guyatt et al., 2002, Wiseman et al., 2003, Goodman et al., 2006) and tuberculosis interventions (Baltussen et al., 2005). Given the need for resources to implement

clinical guidelines, it is imperative that they too be subjected to rigorous evaluation of their costs and consequences. Information on the costs and effects will also be useful in modeling the scale up of the intervention to increase access for the population in need.

Systematic reviews conducted to evaluate the effectiveness of guideline implementation have shown that most studies are of poor quality and the findings are difficult to generalize to other settings (Prior et al., 2008, Grimshaw and Russell, 1993, Grimshaw et al., 2004, Grimshaw et al., 2006, Vale et al., 2007, Hoomans et al., 2007). Economic analyses related to such studies are particularly poor. In a systematic review by Grimshaw et al, of the 235 studies evaluated, only 29.4 % reported any economic data, and overall, the methods of the economic evaluations and cost analyses were poor (Grimshaw et al., 2004). Major weaknesses included the lack of transparency in costing methodology, omission of intervention development costs and difficulty in defining appropriate effectiveness measures for complex interventions. Subsequent systematic reviews have revealed the same weaknesses (Prior et al., 2008, Hoomans et al., 2007).

These findings reveal gaps in guideline implementation evaluation methodology and underscore the need for more rigorous studies. In the area of child health interventions, the multi country evaluation (MCE) of the Integrated Management of Childhood Illnesses (IMCI) offers a suggested methodology for evaluation of the effectiveness and costs of guideline implementation (WHO, 2003). However, methodological questions that still remain unanswered include:

- What is the relevant scope of costs that should be considered in the economic evaluation of interventions to develop and implement CPGs?

- What is an appropriate measure of effectiveness for complex health interventions such as the usage of clinical guidelines where conventional measures such as mortality, DALYs or QALYs may either not suffice or may not be measurable?

This thesis therefore aims to contribute to the developing field of economic evaluation of complex interventions. Specifically it will involve the examination of the costs and consequences of a multifaceted intervention to improve the quality of care of children in district hospitals in Kenya. The work will involve the development of an explicit, comprehensive costing approach clearly identifying development costs and implementation costs. Of interest will be the costs that are considered by stakeholders to be relevant for decision making and those that form the basis for modeling scaling-up.

The work will also involve a cost effectiveness analysis, where effectiveness of the intervention is evaluated using selected process of care measures that constitute indicators of quality of care. Additionally the work will involve the modeling of scale up costs and budget impact of the intervention if implemented at a national scale.

## **Aims of the Study**

### **Broad Objective**

The broad objective of the study is to conduct a cost effectiveness analysis of a multifaceted intervention to improve the delivery of evidence based care for severely ill children in district hospitals in Kenya.

### **The Intervention**

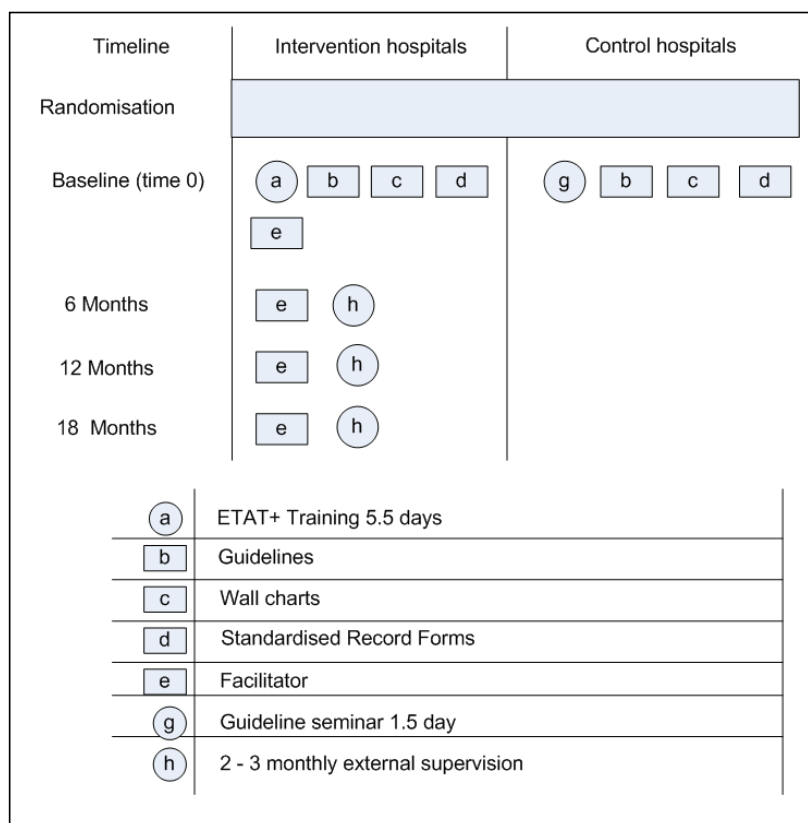
This was an 18 month hospital based, multifaceted intervention aiming to promote adherence to new, evidence-based clinical practice guidelines (CPGs) for management of seriously ill newborns and children admitted to hospitals. The clinical practice guidelines were developed or adapted from existing WHO guidance. A training course linked to the CPGs and also adapted from the existing WHO Emergency Triage, Assessment and Treatment (ETAT) course was developed. This new course included a considerable amount of new material on newborn resuscitation and the common causes of serious illness in the newborn or child and has therefore was called “Emergency Triage Assessment and Treatment Plus Admission Care” (ETAT+) (English et al., 2008, Irimu et al., 2008).

This training, conducted over 5.5 days, and augmented by provision of CPG booklets, job aids and pediatric admission records (PAR) was used to initiate the intervention. The pediatric admission record (PAR) is a structured form used by clinicians to document a sick child’s clinical information on admission. The PAR was designed to capture key symptoms for common childhood illnesses (malaria, pneumonia, diarrhea and dehydration, meningitis, malnutrition and HIV/AIDS) as well as signs and approaches to severity classification and other facility information needs (Mwakyusa et al., 2006).

This was then followed by supervision in the form of 2-3 monthly visits, reports, *ad hoc* follow up training during supervisory visits and appointment of a local facilitator supported with regular phone

calls. Detailed surveys of hospital practices were conducted pre-intervention and at 6 monthly intervals thereafter. Results were fed back to intervention hospitals in face to face meetings and by distributing written reports. In the 4 control hospitals, only CPG booklets, initial lectures in the form of a 1.5 day seminar and surveys followed by written reports were provided. These hospitals did not receive any quality improvement facilitation. The specific components of the intervention are outlined in detail elsewhere (English et al., 2008, Irimu et al., 2008) with the delivery schedule outlined in Figure 1.

**Figure 1 Delivery of the Intervention**



## **Specific Objectives**

1. To determine the total economic cost of delivering the intervention to intervention hospitals in comparison to control hospitals where a partial version of the intervention was delivered
2. To develop of a summary measure of quality of care to be used as the measure of effectiveness in the cost effectiveness analysis
3. To undertake a cost effectiveness analysis of the intervention as delivered in intervention hospitals compared to a partial version of the intervention in control hospitals
4. To model the costs of scaling up the intervention in Kenya and to determine the impact this scale up will have on the child health budget

## **Methods and Analysis**

### **Study Design**

This shall be a cost effectiveness analysis alongside a cluster randomized trial.

### **Perspective**

A provider perspective will be adopted.

### **Time Horizon**

The time horizon will be the development, implementation and follow up period of the intervention (September 2006 – April 2008).

### **Data Collection and Sample Sizes**

This cost effectiveness analysis is a sub-component of a parent study that evaluated a multifaceted intervention to improve the quality of care of children in district hospitals in Kenya. This parent study was a cluster randomized trial (cRCT) in which 8 rural district hospitals in 4 provinces in Kenya were

randomized into 4 control and 4 intervention hospitals, with the intervention hospitals receiving the full package of the interventions while the control hospitals received a partial version (Ayieko et al., 2011).

To evaluate any changes in costs and any changes in outcomes through CPG implementation, data on clinical performance and resource use were collected by clinical record review of children aged 2-59 months, admitted to these hospitals with common, acute illnesses. Data were collected through baseline cross-sectional surveys in both intervention and control hospitals, and follow-up surveys at six-monthly intervals. In total there were 6 surveys in the intervention hospitals, and 4 surveys in the control hospitals. The reason for the two additional surveys in intervention hospitals was to observe whether the intervention effects were sustained beyond the follow up period. Resource use data were collected by patient record review using patient case-record data abstraction forms (appendix 1). Data collected that are relevant to the costing component include medicines prescribed to patients and their quantities, laboratory investigations conducted, fluids administered to the patients and length of stay of patients in the hospital.

To identify clinical records for evaluation, calendar dates were randomly sampled from the 6 month period prior to a survey and only records from children admitted on these days were retrieved. The proportion of calendar dates sampled was adjusted to yield approximately 400 records per hospital per survey based on each hospital's daily admission rates. The data collected did not require personal identifiers of patients or health workers, each were identified by unique codes and hence patient and respondent confidentiality was preserved.

The time spent by intervention implementers to implement the intervention was captured by a time quantification tool (appendix 2). This tool was in the form of a questionnaire administered to the 6 core intervention implementers. These 6 intervention implementers are employees of the intervention implementing institution, the KEMRI-Wellcome trust research programme.

Start up and implementation costs were obtained from a review of accounting records kept by the KEMRI-Welcome trust. These records included resources, quantities used and their monetary costs. This was done after obtaining official permission from KEMRI administration.

### **Evaluating Costs**

Costing this guideline implementation study will follow accepted principles recommended for costing other health care interventions (Drummond, 2005). Given that a systematic review of 69 economic analyses of guideline implementation identified that guideline development costs were usually ignored while 11 reported only costs of implementation and 12 both implementation and treatment costs (Grimshaw et al., 2006) this study will take particular care to report costs of the three main stages (Vale et al., 2007):

- The development of the guidelines
- Implementation of the package of approaches used to support guideline introduction
- Treatment costs

The additional costs in the intervention hospitals, compared to the control hospitals will be determined for the intervention period of 18 months. Both the total and unit costs of the intervention will be determined. The total costs will be an aggregate of all the costs of the interventions, while the unit costs refer to the cost of a single output, such as cost per sick child treated or average cost per hospital (Conteh and Walker, 2004, Creese, 1994). This analysis will seek to measure the economic costs of the intervention.

### *Costing Approach*

In identifying the costs, an ingredients approach will be used (World Health Organization, 2003). This will seek to identify the specific resources (ingredients) used in the intervention, quantify them and to assign a financial and / or economic cost to them.

### *Sources of Cost Data and Collection*

Data abstraction tools will be developed for the collection of costs and utilization of resources. Data sources to be used will include:

- Accounting records for the project
- KEMRI-Wellcome trust salary scales and per diem rates (subsistence costs)
- Kenyan Ministry of Health salary scales and per diem rates (subsistence costs)
- Project diary and logs (dates, duration of time spent on activities and personnel involved)
- Interviews with project implementers (personnel time allocation)
- Intervention team travel logs (destinations and distances)
- Market rates for services and prices for inputs (to estimate economic costs)

### *Financial vs Economic Costs*

Financial costs differ from economic costs in that they represent the actual monetary outflow or expenditure on resources (Kumaranayake, 2000b). Financial costs therefore do not include costs that are not paid for such as donations. Where costs are paid for but at subsidized prices, financial costing reports these subsidized prices since they represent the actual monetary flow.

Economic costs on the other hand are defined in terms of the alternative uses that have been forgone by employing a resource in a particular way (Drummond, 2005). This perspective recognizes the *opportunity cost* of using resources, as these resources are then unavailable for productive use elsewhere (Kumaranayake, 2000b). This approach will therefore value donated and subsidized goods at their actual market prices. Examples of economic costs in the intervention include the opportunity cost of personnel time spent in the development and implementation of the intervention and venue costs for training since most training rooms were donated by the hospital.

### *Identifying Costs*

The intervention costs will be broadly categorized into four groups (Adam, 2004, Goodman et al., 2006):

#### *a) Development Costs*

Development costs include all resources attributed to the intervention from the time when the decision was made to develop and implement the intervention up to but excluding the initial hospital training. Development costs include the development of ETAT+ guidelines, adaptation of the guidelines, and preparation of training materials.

#### *b) Hospital Start-up Costs*

Start-up costs include initial hospital training and purchase of equipment by the hospitals to facilitate compliance with the CPGs. The opportunity costs for resources used in these activities will be evaluated. For example, the staff time used in attending meetings will be evaluated and a share of salaries will be attributed to the economic costs of the intervention.

Since the development and hospital start-up costs will be incurred before the intervention begins while the benefits are spread over a long period (more than one year), they will be treated as a **capital purchase** that provides services over time. The equipment purchased to enable CPG implementation will be annualized over the expected life of the item. Other items (e.g. initial training) will be annualized over the expected life of the intervention as a whole.

#### *c) Follow-Up Costs*

These will include all the costs incurred after the start-up period until the end of the 18 month implementation period. Activities include follow up training, supervisory visits, telephone calls, feedback meetings and onsite facilitator costs.

#### d) *Treatment Costs*

Treatment costs will be defined as the cost of provision of care to sick children from admission to discharge and will be computed as the sum of “hotel” costs, laboratory diagnosis and medicine costs. It is important to include these costs as it is likely that the implementation of CPGs will lead to changes in the costs associated with inpatient care for sick children. “Hotel” unit cost estimates will be derived from the World Health Organization, “Choosing Interventions that are Cost Effective” (WHO CHOICE) estimates (World Health Organization, 2005). The WHO CHOICE estimates represent the “hotel” component of hospital costs, excluding drugs and diagnostic tests and including other costs such as personnel, capital and food costs. Laboratory unit cost estimates will be obtained from laboratory costing data for a local district hospital in Kenya (Kilifi District Hospital). Medicine unit costs will be obtained from data on medicines prices in the Kenyan market for 2009. Utilization data on hospital length of stay, laboratory tests and medicines prescribed will be obtained from data extracted from clinical records reviewed during the study surveys.

#### *Presenting, Annualizing and Transferring Costs over Time*

Costs will be adjusted for inflation using an appropriate GDP deflator (Walker and Kumaranayake, 2002). Economic capital costs will be annualized to derive the equivalent annual economic costs of these items (Walker and Kumaranayake, 2002). A discount rate of 3% and the respective useful lives of the capital resources will be utilized to determine the annualization factors for capital resources. Costs will be presented in United States dollars (USD). Given the fluctuations in exchange rates within the time horizon, costs will first be converted from Kenyan Shillings (KES) to USD using the respective period’s mean annual exchange rate, before deflation to the base year to minimize currency fluctuation effects (Kumaranayake, 2000a).

## Evaluating Effectiveness

Others in the research group are currently involved in evaluating intervention effectiveness by measuring changes in the structure and process of hospital care for sick children. Effect sizes for changes in these measures between baseline and post implementation will be determined by calculating the difference of differences between children treated in the intervention and control hospitals. These data will be extracted from clinical records during the study surveys.

## Cost Effectiveness Analysis

Data on changes due to the intervention will be explored and literature reviewed with the aim of developing an effectiveness measure that best summarizes the range of process measures to incorporate into cost effectiveness analysis (CEA). Possible approaches include developing a patient level summary variable based on key quality indicators that represents receipt of *“appropriate or recommended care”* allowing a cost effectiveness ratio of *“cost per additional child receiving appropriate care”* to be determined (figure 2) as in recent published work (Rowe et al., 2009). While QALYs or DALYs are often used to measure and compare outcomes in CEA, the main study was not powered to measure differences in mortality or morbidity.

### Figure 2 Calculating the Incremental Cost Effectiveness Ratio

$$ICER = (C_i - C_c) / (E_i - E_c)$$

Where

$C_i$  – Total cost in intervention hospital

$C_c$  – Total cost in control hospital

$E_i$  – Total number of children receiving appropriate care under intervention conditions

$E_c$  – Total number of children receiving appropriate care under control conditions

## **Sensitivity Analysis**

Given the potential uncertainty about the values of several estimated parameters, one way sensitivity analysis will be conducted to test the robustness of the conclusions to changes in key parameters within meaningful ranges (Walker and Fox-Rushby, 2001). For example, salaries of personnel involved could vary widely depending on the cadre of personnel and whether they are employed by the government or private sector. Parameters to be subjected to sensitivity analysis will include:

- Intervention effectiveness
- Salary levels
- Hotel costs
- Development costs

## **Ethical Considerations**

The larger study, for which this analysis is a subcomponent, has already received ethical approval from the Kenya Medical Research Institute (KEMRI) ethical review board and the national ethical review board of Kenya. Ethical approval will also be sought from the University of Cape Town ethical review board. The economic analysis will not seek to collect information from patients or their families, precluding the need for informed consent. Clinical record data will be anonymized to conceal the identity of the children whose clinical records will be used. Findings of this economic analysis are likely to benefit the population of children in Kenya by influencing policymaker's decisions on resource allocation to improve the quality of care provided to children in district hospitals in Kenya.

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## **Part B: Literature Review**

### **Costs and Effects of a Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya**

#### **Introduction**

There has been increased focus in improving the quality of care provided by health systems. One of the strategies that has gained prominence as a tool for improving quality of care is the development and implementation of clinical practice guidelines (CPGs) (Irimu et al., 2008). CPGs have the potential to improve the quality of care by encouraging the adoption of interventions of proven benefit (best practice) and discouraging ineffective practice (Grimshaw et al., 2004). The increased use of CPGs in both developed and developing countries has been, rightfully, accompanied by calls for evaluations of their effectiveness and efficiency in improving quality of care. Given that quality of care interventions, like other healthcare interventions, cost money, there is a need for economic evaluations of these interventions to inform policy makers on how best to use scarce resources to maximize benefits. Approaches to conducting economic evaluations of quality improvement interventions, including CPGs, is the subject of this literature review.

An exploratory search of PubMed was done as the starting point of the literature search. This was followed by further searches in PubMed and websites of quality of care organizations based on identified key words from the exploratory search. A manual search through the references of identified studies was also conducted. Finally articles and books about the methods of economic evaluation were included.

This review is structured as follows. The first section seeks to lay out the definition and concept of quality of care and explore the use of clinical practice guidelines in improving quality of care. This is followed by an examination of the effectiveness and efficiency of clinical practice guidelines in

developed and developing countries in improving the quality of care delivered to patients. This is followed by an examination of a conceptual framework for the economic evaluation of the implementation of quality improvement interventions that incorporate clinical practice guidelines (CPGs). The final section presents a discussion of the challenges that are associated with the economic evaluation of such interventions.

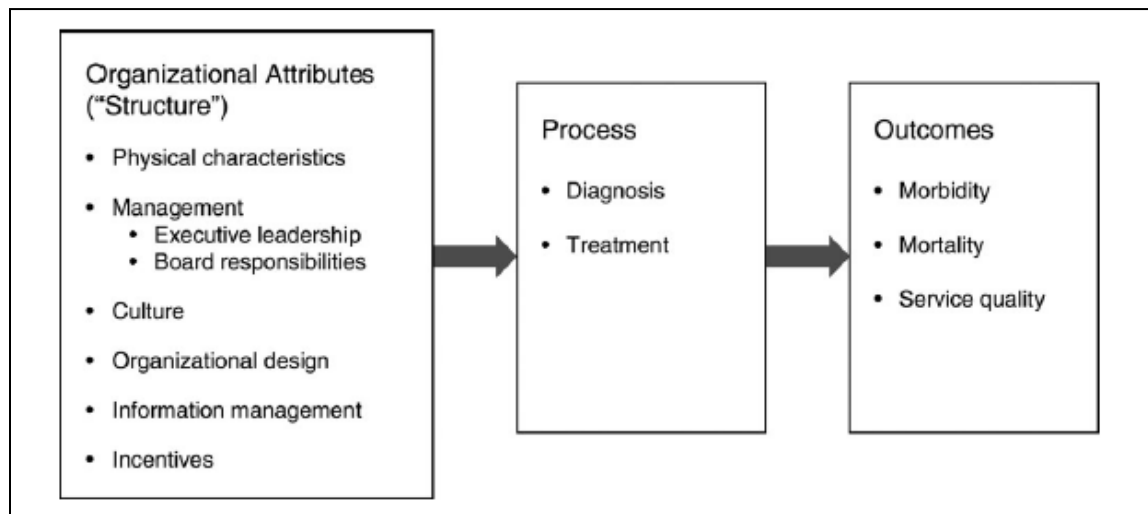
## **Quality of Care**

The international organization of medicines (IOM) has defined quality of medical care as the degree to which health services increase the *likelihood of desired health outcomes* and are *consistent with current professional knowledge* (Institute of Medicine, 1990). Desired health outcomes is emphasized in this definition, highlighting the crucial link between how care is provided and its effect on health (Institute of Medicine National Roundtable on Health Care Quality 1998). The premise is that improving quality of care *increases the likelihood* of beneficial outcomes. *Current professional knowledge* underlines the importance of adopting and appropriately using current evidence and for the potential for such practice to change with the advent of new knowledge and approaches (Institute of Medicine National Roundtable on Health Care Quality 1998).

### ***Approaches to Evaluation of Quality of Care***

The most dominant framework for the evaluation of quality of care is the one proposed by Donabedian (Donabedian, 2005). This framework proposes that quality of care should be measured in terms of the structure, process and outcomes of care, the so called “quality triad” as outlined in figure 3 (Donabedian, 2005, Donabedian, 1969) .

**Figure 3 Donabedian Triad for Quality Improvement**



The evaluation of structure involves the assessment of the availability of equipment and infrastructure needed to provide care (Donabedian, 1969, Donabedian, 2005). For the provision of care for children under five, structural aspects include the availability of medicines for management of common childhood diseases, equipment such as either oxygen cylinders or concentrators, infant warming device in the nursery, weighing scales for infants and laboratory services such as full hemogram tests, measurements of bilirubin, blood glucose test and others (Opondo et al., 2009). The focus on structure is based on the premise that a healthcare facility needs structural capacity to provide good care (Donabedian, 2005).

The evaluation of process involves an assessment of the provision of care (Donabedian, 2005, Donabedian, 1969). This is linked to the notion that a specified structural capacity can enable the provision of care of a particular quality. Process of care measures have been used to evaluate quality in child health with recent examples including the multicountry evaluation of the Integrated Management of Childhood Diseases (IMCI) (Bryce et al., 2004). Here process of care measures included child assessment, diagnosis, treatment and caretaker counseling (Pariyo et al., 2005).

The evaluation of outcomes consists of the assessment of the end results of medical care in terms of health outcomes (Donabedian, 1969, Donabedian, 2005). This includes patient outcomes such as recovery, mortality and morbidity (Donabedian, 1969, Donabedian, 2005). The extent to which desired health outcomes are achieved is the ultimate test of the assumptions for using structure and process measures to assess quality of care.

The study under evaluation in this thesis evaluates and reports quality changes in terms of process of care measures that span assessment, diagnosis and treatment (Ayieko et al., 2011). The choice of process measures as opposed to outcome measures was informed by the observation that process measures are more suitable for assessing changes in hospital care compared to outcome measures for reasons that will be discussed in a latter section of this review.

### ***Clinical Practice Guidelines***

Clinical practice guidelines (CPGs) have been defined as systematically developed statements to assist practitioner and patient decisions on appropriate health care for specific clinical circumstances (Institute of Medicine Committee on Clinical Practice Guidelines, 1992, Prior et al., 2008). CPGs are perceived to be useful in improving quality of care by promoting the use of “best practice” and have thus become common in clinical practice (Eccles and Mason, 2001).

While interest in the use of CPGs has been increasing (Grimshaw and Russell, 1993, Eccles and Mason, 2001), there has been uncertainty about whether CPGs are effective in changing professional practice in ways that would improve quality of care and health outcomes (Grimshaw and Russell, 1993). This uncertainty is coupled with the fact that the development and adoption of CPGs costs money. This has led to attempts to evaluate the effectiveness and efficiency of clinical practice guidelines, and of alternative ways of implementing these guidelines, in improving quality of care (Grimshaw and Russell, 1993, Grimshaw and Hutchinson, 1995, Grimshaw et al., 2001, Grimshaw et al., 2006, Prior et al., 2008).

### *Do Clinical Guidelines Influence Clinical Practice?*

In developed countries, the benefits of guidelines have been demonstrated for interventions targeting single conditions such as pneumonia (Menendez et al., 2002, Menendez et al., 2007, Nathwani et al., 2001, Martinez et al., 2009, Lancaster et al., 2008, Frei et al., 2006), hypertension (Milchak et al., 2004), diabetes (McRae et al., 2008) and asthma (Gazarian et al., 2001). Grimshaw and Russell undertook a systematic review of rigorous evaluations of clinical guidelines published between 1976 and 1992 (Grimshaw and Russell, 1993). Out of the 59 studies included in the review, all but 4 of them reported significant improvement in the process of care (Grimshaw and Russell, 1993). Of the 11 studies that studied patient outcomes as the primary end point, all but 2 showed significant improvement in targeted outcomes (Grimshaw and Russell, 1993).

In an updated review by Grimshaw and colleagues to include a further 32 studies up to 1994, 81 of the 87 studies that investigated process of care showed significant improvement (Grimshaw et al., 1995). Of the 17 studies with patient outcomes as the primary endpoint, 12 showed significant improvement (Grimshaw et al., 1995). A subsequent systematic review by Grimshaw and colleagues of studies published between 1966 and 1998 that included 235 studies reported that 86.6% of the studies showed improvement in quality of care (Grimshaw et al., 2006).

In developing countries, where rapid and far reaching changes are urgently required, clinical practice guidelines have been employed mostly as part of packages targeting conditions causing the greatest burden of disease; the Integrated Management for Childhood Illnesses (IMCI) is a good example (Bryce et al., 2005a, Bryce et al., 2005b, Arifeen et al., 2009).

The multi-country evaluation (MCE) of IMCI provides useful insights into the effectiveness of CPGs and related interventions in developing countries (Schellenberg et al., 2004a, Bryce et al., 2005a, El Arifeen

et al., 2004, Huicho et al., 2005b, Amaral et al., 2004). IMCI has been adopted by over 80 countries as a strategy for reducing child mortality and improving child health and development (Schellenberg et al., 2004b). This complex public health intervention incorporates training, case management (guidelines), multiple health system strengthening approaches and a community component. MCE-IMCI studies in Tanzania, Brazil, Peru, Bangladesh and Uganda reported that in all settings where case management training was implemented and where sufficient coverage of trained health workers was achieved, the quality of care improved (Amaral et al., 2004, Schellenberg et al., 2004b, El Arifeen et al., 2004, Gouws et al., 2004). The evidence from these rigorous evaluations strongly suggests that properly developed guidelines can change clinical practice and may lead to changes in patient outcome.

#### *Introducing Guidelines into Practice*

The uptake of clinical practice guidelines by health care professionals is not an automatic process. The successful implementation of these guidelines depends on a number of factors including how the guidelines were developed and how they were implemented into routine practice (Grimshaw and Russell, 1993, Grimshaw et al., 1995, Grimshaw et al., 2006). Successful clinical guideline implementation requires that health care workers change their professional behavior to adhere to the new guidelines. Factors that influence this required change in professional behavior are inherently complex (Grimshaw et al., 1995). It has been shown that passive dissemination strategies such as publications in professional journals can influence the level of health care workers awareness and knowledge of the clinical guidelines (Kosecoff, 1987). These simple strategies have however been shown to be insufficient in causing sustainable behavior change in health care workers (Grimshaw et al., 1995). More active strategies, specifically educational interventions, involving training of health care workers have been observed to be more likely to bring change in professional behavior (Grimshaw 1995). Recent experiences in implementation of IMCI in developing countries have however showed that training alone is not enough, and that multifaceted strategies, involving training, follow up supervision and feedback are required to achieve sustained change in professional practice (Pariyo et

al., 2005). Evidence is however insufficient to conclude on the relative effectiveness of different guideline implementation strategies in different contexts (Grimshaw and Russell, 1993, Grimshaw et al., 1995, Grimshaw et al., 2006, Prior et al., 2008).

### *Models of Health Worker Behavior Change*

The design of interventions to promote the uptake of clinical practice guidelines have drawn heavily on models with a basis in social and behavioral science theories. Richard Grol, in a paper in 1997 summarized the following models that guide initiatives to influence health worker behavior (Grol, 1997).

#### Educational Approaches

Educational models hold that health workers are driven to change by their inherent strive for professional competence (Grol, 1997). Thus the strategies for change focus on stimulating this motivation. Examples include promoting learning from experience, problem-based learning, small group interactive learning and local consensus processes. The aim of these strategies is to give targeted health workers the feeling that they own the change process (Grol, 1997).

#### Epidemiological Approaches

Epidemiological approaches are based on the assumption that humans are rational beings who make rational decisions (Grol, 1997). This model presupposes that if health workers are provided with evidence of “best practice”, they will be inclined to change their practice in line with this evidence. Strategies based on this theory aim to synthesize and summarize evidence of “best practice” in the form of evidence based clinical guidelines. Key issues include credibility, soundness, and validity of the guidelines (Grimshaw et al., 1995). The guideline development process should also be explicit and rigorous (Grimshaw et al., 1995).

#### Marketing Approaches

Marketing approaches emphasize the development and marketing of an attractive change proposal (practice change) which meets the needs of the targeted health workers and helps them to achieve their goals (Green et al., 1980, Rogers, 1983, Kotler and Roberto, 1989). The message of the intended change is spread through a number of channels including mass media, word of mouth, professional networks, and the use of opinion leaders. Innovation theories, communication theories, health promotion theories and social marketing theories propose such approaches (Grol, 1997).

### Behavioral Approaches

Behavioral approaches are based on classical theories of conditioning and controlling behavior (Pervin, 1970). Human behavior is seen as primarily influenced by stimuli before or after a specific action. Strategies drawing from this theory include audit and feedback, reminders, incentives and sanctions (Grol, 1997).

### Social Influence Approaches

This approach holds that change is achieved as a result of the influence of, and interactions with, social networks (Rogers, 1983). The opinions, feedback or pressure coming from significant individuals in a social network have a substantial impact on whether clinical guidelines are adopted (Grol, 1997). Strategies based on this theory include the use of opinion leaders to diffuse information across a social network, outreach visits or academic detailing by respected peers or experts, peer review in small local groups or teams, and demonstration of new performance by colleagues (Grol, 1997).

### Organizational Approaches

The focus of organizational approaches is in creating the necessary conditions for change rather than on individual performance (Berwick, 1992). Poor health worker practices are therefore seen as a system rather than individual failure. Change strategies hence focus on fixing organizational and structural factors hindering change (Grol, 1997). This school of thought is cognizant of the environmental and contextual factors that influence change.

### Coercive Approaches

Coercive approaches focus on pressure and control as a method for change (Grol, 1997). This “carrot and stick” view informs strategies such as the development of laws and regulations, licensing and accreditation, budgeting and contracting, performance based financing, complaints procedures, and legal pursuits. These strategies draw their value from the fact that health workers may be stuck in their habits and routines and hence some external pressure is needed to effect and maintain change.

### *Evidence of Cost Effectiveness*

Evidence of the cost effectiveness of alternative approaches to clinical guideline implementation is scarce, and where available, of poor quality, hardly transferable or generalizable (Prior et al., 2008, Vale et al., 2007, Grimshaw et al., 2004). A systematic review by Prior and colleagues showed that the costs and cost effectiveness of guideline implementation strategies were infrequently reported (Prior et al.,

2008). In another systematic review by Grimshaw and colleagues, of 235 studies identified, only 63 included any information on costs (Grimshaw et al., 2004). Only 3 of the studies provided evidence of cost effectiveness (Grimshaw et al., 2004). The authors concluded that the studies were of poor methodological quality and rarely considered all relevant costs and effects (Grimshaw et al., 2004).

Economic evaluations of IMCI have ranged from cost analysis, cost consequence analysis to cost effectiveness analysis. A cost analysis in Tanzania reported that IMCI was not associated with higher costs than routine child care in the four districts studied (Schellenberg et al., 2004a). Similar analysis in Brazil reported no statistically significant difference in the cost per child of caring for under-fives in IMCI municipalities (US\$ 95.00) relative to the comparison municipalities (US\$ 98.00) (Adam et al., 2009). A study in Uganda that modeled the relationship between costs of IMCI and quality reported that that on the margin, investing in IMCI training at a primary facility level can yield a significant 44.3% improvement in service quality for a modest 13.5% increase in annual facility costs (Bishai et al., 2008). In Benin, a study investigating the effectiveness and efficiency of a multifaceted implementation strategy for IMCI reported an incremental cost-effectiveness ratio of US\$ 5.30 (95% CI 3.96, 6.93) per additional child receiving appropriate care comparing no IMCI to IMCI plus study supports (Rowe et al., 2009).

## **Economic Evaluation in Health Care**

Economic evaluation is a technique developed to provide a framework for decision making when choices have to be made between several courses of action (Drummond, 2005, Fox-Rushby, 2005). It has been defined as the comparative analysis of alternative courses of action in terms of both costs and consequences (Drummond, 2005). In the context of healthcare, the alternative courses of action to be compared are health care interventions.

The necessity to make choices is occasioned by the fact that health care resources are always scarce, whereas healthcare needs are unlimited (Drummond, 2005, Fox-Rushby, 2005, Gold, 1996). These choices are made on the basis of many criteria some of which are explicit while others are implicit. Economic evaluation seeks to make explicit one set of criteria that may be useful in deciding among different uses of scarce resources (Drummond, 2005).

### ***Types of Economic Evaluations***

There are different types of economic evaluation methodologies, characterized by the type of efficiency question (allocative or technical) they seek to answer and the measurement of consequences. In health care, a particular allocation of resources is defined to be allocatively efficient if it increases health outcomes in comparison to competing uses of these resources within the health sector. More narrowly, an allocation of resources is technically efficient if it increases health outcomes in comparison to alternative choices to respond to a particular need (e.g. to treat childhood illnesses). Whereas all forms of economic evaluation measure and present costs in monetary units, there are differences in the measurement of consequences (Drummond, 2005). These different methodologies are briefly outlined below.

### ***Cost Benefit Analysis***

In cost benefit analysis (CBA), benefits and costs are both valued in monetary terms (Fox-Rushby, 2005, Drummond, 2005). This enables the analyst to make direct comparison of a programme's incremental costs and consequences in the same units of measurements (monetary) (Drummond, 2005). An advantage of this method of analysis is that it allows for comparisons to be made across programmes and sectors beyond health (Fox-Rushby, 2005). A CBA therefore answers the question of allocative efficiency of resources not just within the health sector, but also beyond. Comparisons can for example

be made between interventions in the health sector and in the transport sector given that costs and effects of both interventions are presented in monetary terms. The results of a CBA are presented in a benefit to cost ratio. A ratio greater than 1 is favorable since it shows that the programme's incremental benefits are greater than its incremental costs (Drummond, 2005).

### *Cost Utility Analysis*

Cost utility analysis is a form of evaluation that is useful in evaluating interventions where both the quantity as well as the quality of life is considered important (Drummond, 2005). Examples include chronic diseases such as arthritis and cancer, where interest lies not just in improving survival, but also in the quality of life of patients with the disease. In cost utility analysis the incremental cost of the programme is compared to the incremental health improvement attributable to the programme (Drummond, 2005). The health improvement is measured in quality adjusted life years (QALYs) or a variant such as the disability adjusted life year (DALYs) (Drummond, 2005, Fox-Rushby, 2005). The results are usually expressed as incremental cost per QALY gained or per DALY averted. The QALY and DALY are generic measures of health outcomes and can be obtained for different health care conditions. Interventions targeting different health conditions can therefore be compared in terms of their costs and effects. CUA can therefore answer questions of allocative efficiency *within* the health sector.

### *Cost Effectiveness Analysis*

In cost effectiveness analysis (CEA), the incremental cost of a programme is compared to the incremental health effects of the programme, where the health effects are measured in natural units related to the objective of the programme (Drummond, 2005, Fox-Rushby, 2005). Examples of outcomes measures include improvement in blood pressure in mm hg, cases of disease averted or lives saved. The results are expressed in incremental cost effectiveness ratios (ICER) as the incremental cost per additional unit of effect (Drummond, 2005). Since the unit of effect measurement in CEA is unique to

the specific health intervention being evaluated, the results of CEA cannot be compared with evaluations of programmes targeting different health conditions. CEA therefore is designed to answer technical efficiency questions within specific health programmes or interventions.

#### *Cost Minimization Analysis*

When two alternative interventions are assumed to yield equivalent benefits, only costs are compared (Fox-Rushby, 2005). The rational choice in this case is to select the alternative with the least cost. This form of analysis is referred to as a cost minimization analysis (Fox-Rushby, 2005) and is a subset of CEA. In selecting between two blood pressure lowering drugs for example, if the effectiveness of both drugs in lowering blood pressure and their safety profile is equivalent, a comparison of the costs of the two will lead to the selection of the cheaper alternative. Like CEA, CMA will answer technical efficiency questions within specific health programmes.

#### *Cost Consequence Analysis*

In cost consequence analysis (CCA), health and non-health outcomes are identified and quantified, and are presented separately alongside the costs of the intervention (Fox-Rushby, 2005). This method was developed partly because of the difficulties of valuing health and non health benefits and partly because for certain interventions, decision makers find a single ratio (ICER) or amount (as in CBA), impenetrable (Fox-Rushby, 2005).

#### ***Why Conduct Economic Evaluations?***

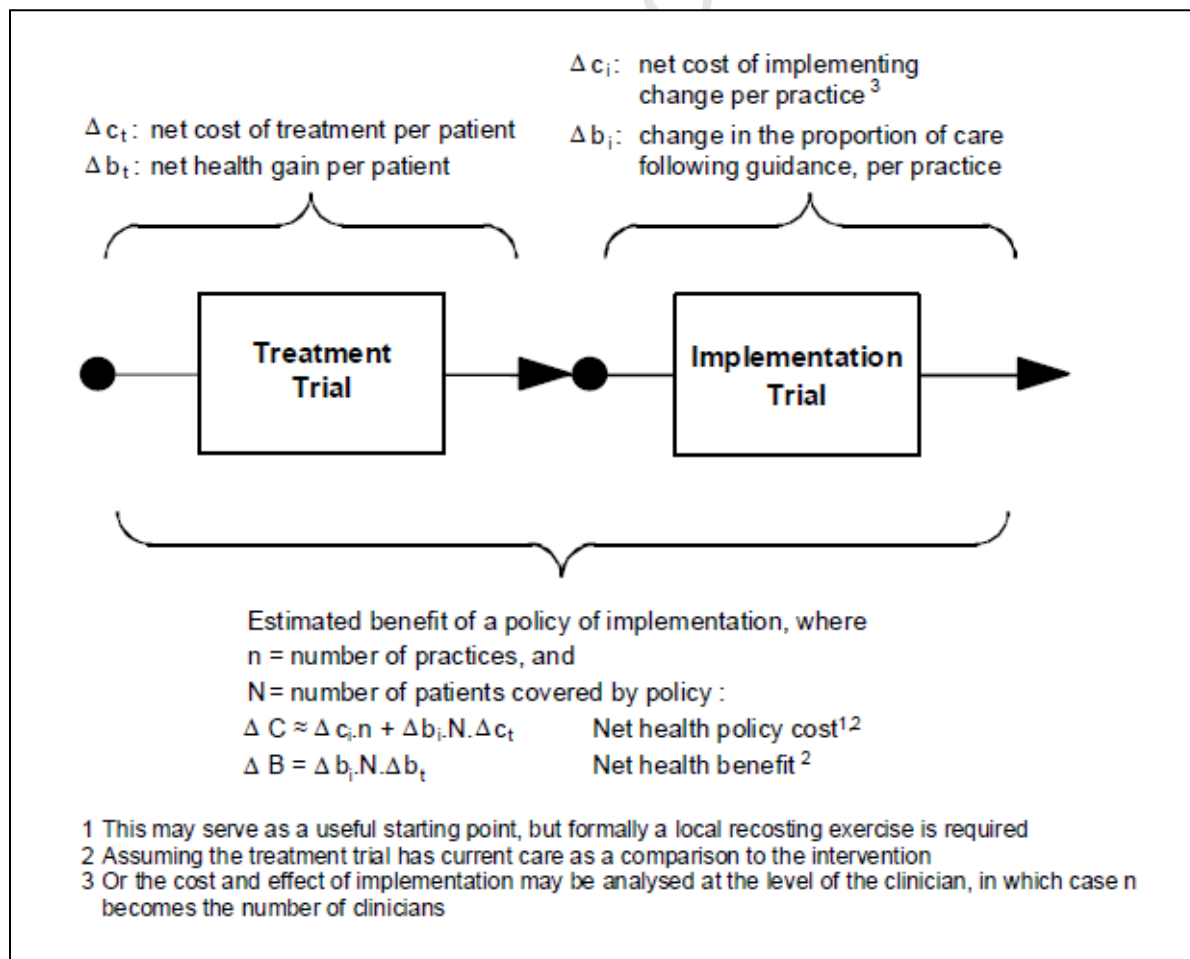
Based on the assumption that health systems have fixed budgets and competing needs, health resources should be allocated across interventions in such a way that the most health is generated with the available budget. By analyzing the efficiency of interventions, economic evaluations offer a framework for priority setting within health care. For example, Bobadilla et al showed that a reallocation

of 50% of the health budget from interventions that are less cost effective to those that are more cost effective could result in a 64 % increase in years of life saved in the East African region (Bobadilla, 1994 ).

**Framework for Economic Evaluation of Quality Improvement Interventions**

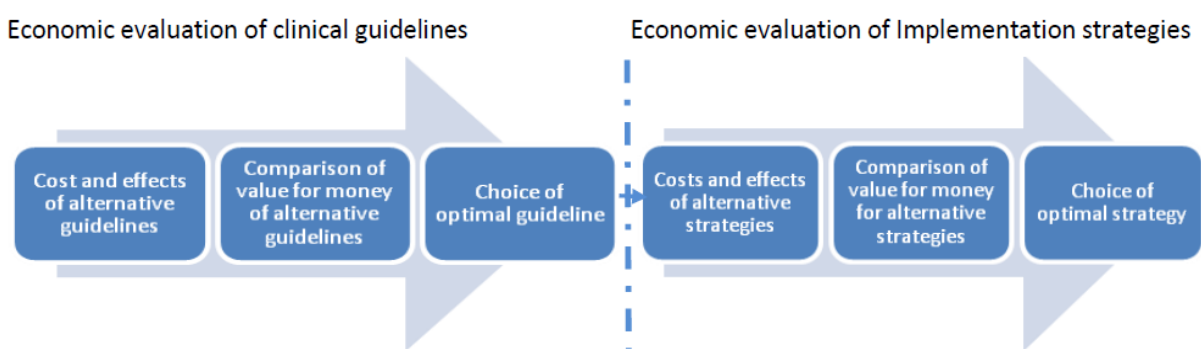
Quality improvement interventions have been conceptualized as comprised of two components (figure 4). The treatments considered to be “best practice”, and the strategies to achieve appropriate adoption of these “best practices” (Freemantle et al., 1999, Mason et al., 2001, Severens, 2003, Hoomans et al., 2009b). Their evaluation has therefore been seen as a two part evaluation; the evaluation of the “recommended treatment” and the evaluation of the CPG implementation strategy (Severens, 2003, Mason et al., 2001). Both phases are associated with benefits and costs and are thus subject to economic evaluation.

**Figure 4 Evaluating Quality of Care improvement interventions(Freemantle et al., 1999).**



Some have argued that economic evaluation should only be done on guidelines that recommend treatments that have already been proven to be cost effective (Sculpher, 2000, Mason et al., 2001, Gandjour and Lauterbach, 2003, Gandjour and Lauterbach, 2005). Proponents of this view contend that interventions to implement CPGs cannot be good value for money unless the ‘good practice’ outlined in the CPGs is cost effective (Sculpher, 2000). For this school of thought, the evaluation of quality improvement interventions that employ CPGs should be done sequentially; treatment cost effectiveness should first be established, either by trials or modeling exercises, thereafter followed by CPG implementation cost effectiveness (Sculpher, 2000, Mason et al., 2001, Gandjour and Lauterbach, 2005). This allows for the selection of the most efficient implementation strategy for practices that are already proven cost effective (Freemantle et al., 1999, Sculpher, 2000). Thus the CPG implementation evaluation measures the change in resources required to implement the CPGs (e.g. training, development of manuals etc) and the health worker behaviour change achieved. These findings are combined with the effectiveness estimates and costs from trials, which have previously assessed treatments (Freemantle et al., 1999). This is outlined in figure 5.

**Figure 5 Sequential Evaluation of Quality Improvement Interventions (Hoomans et al., 2009b).**

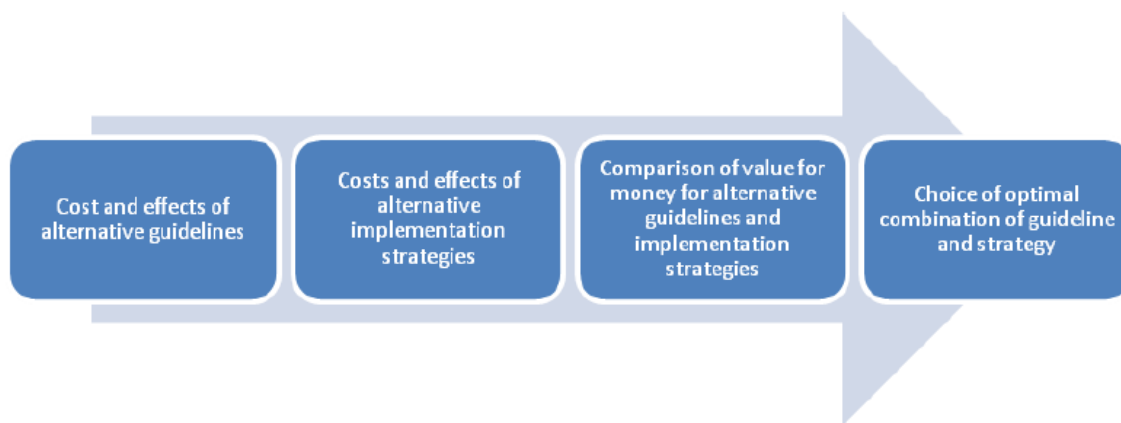


An alternative approach that considers decisions about guidelines and their implementation strategies simultaneously has also been proposed (Hoomans et al., 2009a, Hoomans et al., 2009b). In this approach, decisions about which CPG and what implementation strategy to adopt are made

simultaneously (Hoomans et al., 2009b). This decision is based on overall estimates of the cost effectiveness of changing clinical practice, for different combinations of CPG and their implementation strategies (Hoomans et al., 2009b). Hoomans and colleagues have demonstrated that the choice to use either a sequential vs. a simultaneous approach affects the choice of guidelines and the implementation strategies adopted and argue that, in most cases, an integral approach results in more efficient resource utilization (Hoomans et al., 2009b). This is outlined in figure 6.

**Figure 6 Simultaneous Evaluation of Quality Improvement interventions(Hoomans et al., 2009b).**

**Economic evaluation of clinical practice change**



Regardless of which approach is adopted, it is apparent that estimates are required of the costs and effects of all guidelines and of all implementation strategies under consideration.

***Measuring Effects***

Traditionally, generic measures such as quality adjusted life years (QALYs) and disability adjusted life years (DALYs) have been recommended for inclusion in cost utility analysis (Weinstein et al., 1996, Murray, 1994). The QALY assigns a weight between 0 (for death) and 1 (for full health) to each state of health and multiplies that by the number of years the health state lasts (Sassi, 2006). The DALY is a measure derived by adding the years of life lost due to disease (YLL) and the years of life lived with disability (YLD) (Murray, 1994, Anand and Hanson, 1997, Fox-Rushby and Hanson, 2001). YLL is the difference between a person's life expectancy assuming full health and the age a person dies

prematurely due to disease. The YLD is calculated by assigning disability weights to health states between 0 (for full health) and 1 (for death) and multiplying this by the number of years the health state lasts (Robberstad, 2005). QALYs and DALYs are hence composite measures of health outcomes (mortality and morbidity). These generic measures are useful in economic evaluations due to their ability to enable potentially greater comparability across interventions.

Evaluators of quality improvement strategies have however preferred intermediate or process measures over health outcome measures (Mason et al., 2001). This is due to the difficulties associated with measuring outcome measures which will be outlined in the next section which discusses the challenges in the economic evaluation of quality improvement interventions. An example of a process measure is the proportion for whom prescribed care follows guideline recommendations (Mason et al., 2001). In a systematic review of the effectiveness and efficiency of guideline dissemination and implementation strategies, only 5 of the 63 studies identified attempted to use patient outcomes as their primary end point (Grimshaw et al., 2004). The rest of the studies used process measures.

Process indicators as proxies for quality of care (and therefore clinical outcomes) have already been used in evaluations of child health interventions including IMCI. One approach has been to develop a set of sick child assessment tasks that are considered important and to use this set to construct a continuous guideline adherence indicator on a scale of 1 to 100 (Schellenberg et al., 2004a, Chopra et al., 2005, Gouws et al., 2005, Rowe et al., 2009, Bishai et al., 2008, El Arifeen et al., 2004). The index of integrated child management developed by the WHO and used in the MCE studies is an example (Gouws et al., 2005, Bishai et al., 2008). A second process indicator used is a dichotomous measure of appropriate treatment (Rowe et al., 2009, Bryce et al., 2005a). This measure is developed by identifying key tasks considered critical in the management of specific diseases and scoring treatment events as either *appropriate* or *not appropriate* depending on whether all disease specific tasks are completed or not (Rowe et al., 2009, Gouws et al., 2005).

## **Challenges in the Economic Evaluation of Quality Improvement Interventions**

For simple (single) interventions such as Insecticide treated nets (ITNs) or malaria chemoprophylaxis, tracing costs and identifying outcomes is conceptually relatively easy, although it requires considerable effort and attention in practice. The (apparent) generalizability of results reported in terms of standard units such as the cost per DALY averted is also a major advantage in supporting decision making.

Complex interventions however, present a set of challenges to economic evaluation (Shiell et al., 2008). The following discussion is based on the premise that multifaceted quality improvement strategies that incorporate clinical practice guidelines are complex, and are therefore plagued by evaluative challenges associated with complex interventions. Complex interventions in health care comprise a varied number of separate intervention elements which are all hypothesized to be essential to effectiveness (May et al., 2007, Shiell et al., 2008, Craig et al., 2008, Rickles et al., 2007, Shepperd et al., 2009). Examples include adaptation of treatment guidelines and whole community educational interventions (Medical Research Council, 2000). Their multiple components may act both independently and interdependently (Craig et al., 2008, Shiell et al., 2008, Rickles et al., 2007, Shepperd et al., 2009) and complex systems have several defining characteristics (Shiell et al., 2008, Rickles et al., 2007, Shepperd et al., 2009), including being:

- Self organizing
- Sensitive to initial conditions
- Likely to undergo non-linear phase transitions
- Often have emergent properties : Properties of the system that are not reducible to or predictable from individual components and therefore require a holistic rather than a reductionist approach to their assessment
- Subject to interaction and feedback effects

Compared to narrower clinical interventions, complex interventions are associated with a broader range of costs and benefits. These interventions also present difficulties in attribution, given that the causal chains between the intervention and effects are often long and complex and often subject to environmental effect modification and confounding (Victora et al., 2004, Weatherly et al., 2009). These characteristics present special challenges to the process of evaluating the economic efficiency of such interventions (Shiell et al., 2008) that are largely methodological with respect to determining costs but also conceptual when considering outcomes. These challenges will be discussed in the following sections.

### ***Defining the Intervention***

For an intervention to be appropriately evaluated, it should be accurately and comprehensively described (Drummond, 2005). With complex interventions, it is more difficult to draw boundaries around the intervention (Shiell et al., 2008, Shepperd et al., 2009). Reviews of nearly 1,000 behavior change studies found that interventions were defined satisfactorily in only 5% to 30% of the experimental studies (Dane and Schneider, 1998, Michie et al., 2009, Gresham et al., 1993). An appropriate intervention description should include information on the setting where the intervention is delivered, the target population, the time frame, a description of intervention components, the frequency of delivery and the extent of coverage of the target population (World Health Organization, 2003).

### ***Defining the Counterfactual***

Economic evaluation involves comparing an intervention to an alternative (Drummond, 2005, Gold, 1996, Fox-Rushby, 2005). Choosing relevant alternatives to compare with quality improvement interventions requires care and a range of potential alternatives may be appropriate (Freemantle et al., 1999). Possible options include “no care”, an alternative package of care or standard care (Freemantle et al., 1999). There is lack of consensus on the appropriate comparator when evaluating quality of care

interventions. Whereas standard care has been considered appropriate, it can sometimes be as complex as the intervention and change over time (Campbell et al., 2000). It is also considered unethical to withhold a potentially beneficial intervention from health facilities, with the implication that it may not be possible to use randomized study designs. Alternative approaches have included comparing an implementation strategy with a control group which may receive no formal intervention, but be passively exposed to the same material as a means of evaluating the added benefits of a more active approach (Nzinga et al., 2009, English et al., 2009).

### **Analyzing Costs**

The range of costs to be considered when evaluating clinical guideline implementation interventions is often broad (Grimshaw et al., 2004). Systematic reviews of economic evaluations of alternative approaches to guideline implementation reveal variability in inclusion of different categories of costs (Vale et al., 2007, Prior et al., 2008). One notable feature is the omission of development costs that include the opportunity cost of time spent on guideline development and stakeholder meetings, among others (Adam, 2004). Where new guidelines are developed, as in our study in Kenya, these costs are often significant. Their exclusion may thus underestimate the true resource requirements of the intervention. Consensus is needed on how development costs should be included in such interventions.

Development costs are once off, have benefits spanning beyond a year, and are often treated as capital costs and thus annualized (Adam, 2004). However, unlike conventional capital costs, estimating the useful life of these costs is subject to uncertainty and variation. Factors that increase uncertainty include uncertainties about the useful life of guidelines (before they become outdated) and the useful life of any training programmes particularly given the high turnover of trained healthcare workers in developing countries (Huicho et al., 2005a). Estimates of the useful life of clinical guideline have varied from 3 to 10 years in evaluations (Shekelle et al., 2001a, Shekelle et al., 2001b). Suggestions have been to include review dates when developing clinical guidelines (Shekelle et al., 2001a, Shekelle et al., 2001b).

### ***Evaluating Effectiveness***

It has been argued that composite measures of effectiveness such as QALYs and DALYs are unsuitable in evaluating complex interventions, with examples from palliative care (Normand, 2009) and mental health (Chisholm et al., 1997). This is because complex interventions often have a range of benefits beyond health outcomes which are inadequately captured by the reductionist nature of QALYs (Normand, 2009) and DALYs (Sayers and Fliedner, 1997). For example, multifaceted quality improvement intervention such as IMCI would arguably result in changes in clinical case management due to adoption of evidence based practice, health worker motivation due to training and skills improvement, health system improvements such as improved availability of medicines and equipment among many others. Whereas these changes may result in better clinical outcomes, this relationship is non-linear. How can the full range of these benefits be captured within a DALY or a QALY?

More relevant to developing countries, calculation of the DALY requires estimates of changes in mortality and morbidity (Anand and Hanson, 1997, Murray, 1994). While this is possible for individually randomized controlled trials of specific interventions, there are challenges to be overcome in measuring these in complex interventions which will be described briefly.

### ***Outcomes vs. Process Measures***

The promotion of clinical guidelines is premised on the supposition that evidence-based patient care is on the causal pathway to better health outcomes (English et al., 2008). Such clinical outcomes are commonly assessed with measures such as mortality, disease status, functional ability, and quality of life (Davies and Crombie, 1995). However, outcome measures such as these may be difficult to interpret in the context of complex interventions which often have facilities, teams or even entire populations rather than the individual patient as the unit of intervention (Davies and Crombie, 1995). Hospital outcomes, for example, especially those assessed through routine reporting systems, may be influenced

by inadequate or poorly applied definitions, data quality, patient case-mix, clinical quality of care, unrecognized contextual or temporal confounding and chance (Lilford et al., 2004). Given that the study context is often real-life, it is much harder to control for possible confounders and effect modifiers compared to classical experimental RCT. Indeed the resources required for studies to demonstrate “statistically significant” reductions in mortality that are credibly free from bias, residual or unrecognized confounding are often enormous (English et al., 2008). Because of this, it is hard to base evaluations on such outcomes and as a result there is little evidence of the effectiveness of quality improvement initiatives (Schouten et al., 2008). These challenges perhaps explain, in part, why the IMCI evaluation studies in Tanzania (Schellenberg et al., 2004b), Bangladesh (Arifeen et al., 2009) and Peru (Huicho et al., 2005b) were unable to demonstrate significant reduction in mortality despite evidence of improvement in process measures.

In the absence of definitive clinical outcomes data, increased use is being made of process measures as quality metrics to gauge intervention success (Hoomans et al., 2007, Prior et al., 2008, Grimshaw et al., 2006, Grimshaw et al., 2004, Vale et al., 2007). Process measures are favored over outcome measures because they can be measured more reliably, validly and are more sensitive to differences in one desirable endpoint, the quality of care (Freemantle et al., 1999, Davies and Crombie, 1995, Grimshaw et al., 2004, Mant, 2001, Mant and Hicks, 1995, Mant and Hicks, 1996, Donabedian, 2005). Thus if components of clinical guidelines such as the recommended drugs have been shown elsewhere to improve outcomes, then process indicators that reflect the degree to which such best practice care is provided are themselves valid and appropriate end points (English et al., 2008). Despite the attractions of measuring process, these measures are valuable indicators of quality only when the processes in question are well supported by research evidence (Davies and Crombie, 1995). Process measures are associated with limitations, some of which are described below.

### *Multiplicity of Process Measures*

It will be immediately clear that a large number of processes of care measures are possible. The WHO index of integrated child assessment for example is constructed from 14 process indicators while the IMCI disease specific indicators for appropriate treatment vary in number (Gouws et al., 2005). This has prompted attempts to derive summary measures from process measures. A common approach to the selection of process measures to include in such summaries has been the use of a panel of experts to group related process measures based on perceived face validity (Gouws et al., 2005). This approach, while useful was found to lead to measures that meet face but not content or construct validity (Gouws et al., 2005).

An alternative approach has been to employ statistical methods like principle components analysis (PCA) to assign indicators to appropriate groups that satisfy both face, content and construct validity (Gouws et al., 2005). PCA is a data reduction method that identifies coherent subsets of variables, called principal components, each of which might be argued to represent a particular construct (Kleinbaum, 1998). The first principal component (PC) is the weighted linear combination of index items that explains the greatest variation in the original data (Gouws et al., 2005). The second PC explains the greatest proportion of remaining variation. Successive PCs explain as much of the remaining variance in the data as possible. All PC's are linear combinations of items and are uncorrelated with each other (Kleinbaum, 1998).

Whereas PCA may allow for summary measures of process of care across individual variables to be created, the scoring approach derived from one study dataset cannot necessarily be applied to data from different contexts. Indeed it is quite likely that the same approach applied to an alternative study would yield different components and thus calculate summary process indices differently even if exactly the same primary data are collected.

### *Variability of Process Measures*

Relevant process measures may also often vary across and perhaps even within programmes. For example IMCI is adapted prior to implementation to meet the needs of a specific country (Schellenberg et al., 2004a, Huicho et al., 2005b). In some settings care of children with malaria is of major interest, in others there is no malaria (Victora et al., 2005). Even within a programme different sites will have different patient populations, paediatric admissions in some hospitals being dominated by severe malaria while in others severe pneumonia is the predominant problem (English et al., 2009). This variability makes it difficult to compare results of evaluations across settings.

Questions about which process measures to use, how they might be combined, whether weighting for importance or prevalence is required and how to incorporate them into a generalizable summary measure useful for comparative economic evaluation are still to be answered.

### **Conclusion**

Whereas complex, “package of care” interventions that rely heavily on clinical practice guidelines are perceived to be effective in improving quality of care in low income settings, there is need for further work to develop appropriate methods for their economic evaluation. In particular, there is need for clearer standardization and thinking on intervention definition and choice of comparator. Evaluators should pay special attention to development costs and especially the opportunity costs of time spent in guideline development since these costs are difficult to capture. There is also need for methodological work to develop appropriate effectiveness measures for quality of care interventions.

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## Part C: Journal Manuscript

### A Multifaceted Intervention to Improve the Quality of Care of Children in District Hospitals in Kenya: A Cost Effectiveness Analysis

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## **Abstract**

### **Background**

More than 8.8 million children die globally before they reach the age of five. In Kenya, the under five mortality rate was 74 per 1000 children in 2008. To improve care for seriously ill children, a multifaceted approach employing guidelines, training, supervision, feedback and facilitation was developed, for brevity called the Emergency Triage and Treatment Plus (ETAT+). We assessed the costs and efficiency of the implementation of the ETAT+ strategy in district hospitals in Kenya.

### **Methods**

A cost effectiveness analysis from the provider's perspective was conducted alongside a cluster randomized study that compared the implementation of ETAT+ in four district hospitals in Kenya to four control district hospitals receiving a partial version of the intervention between 2006 and 2008. Effectiveness of the intervention was measured using 14 process measures that capture improvements in quality of care and span the assessment, diagnosis and treatment on admission of children under five. Economic costs were estimated through interviews with implementers of the intervention, accounting and clinical record reviews. An annual discount rate of 3% was used and one way sensitivity analyses were used to assess uncertainty. Incremental cost effectiveness ratios (ICERs) were defined as the cost per percentage improvement in quality of care.

### **Findings**

The cost per child admission was US\$ 54.74 in intervention hospitals compared to US\$ 31.06 in control hospitals, while quality of care as measured by the 14 process measures was 25.01% higher in intervention hospitals than in the control hospitals. These results suggest an additional cost of US\$ 0.78 to achieve a percentage improvement in quality of care. The estimated annual costs of scaling up the intervention to all district hospitals in Kenya was US\$ 3,6 million which is 0.60 % of the annual child health budget in Kenya.

## **Interpretation**

The implementation of ETAT+ as a multifaceted intervention yields significant improvements in quality of care but at a higher cost. The costs of scaling up the intervention appear affordable, with a very low budget impact. The decision to scale up ETAT+ has the potential to significantly improve the quality of care delivered in district hospitals in Kenya, with minimal additional spending.

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## Background

An estimated 8.8 million children die globally every year before the age of five [1, 2]. Ninety nine percent of these deaths occur in developing countries; fifty percent in Sub-Saharan Africa [1]. Most of these deaths are due to a few treatable and preventable diseases, for which effective interventions are already available [3, 4]. In 2000, United Nations (UN) member states adopted the Millennium Development Goals (MDGs). MDG 4 focuses on reducing the under five mortality rate by two thirds between 1990 and 2015. Kenya's under five mortality rate was 97 per 1000 live births in 1990 and rose to 121 per 1000 live births by 2006 [5]. The under five mortality rate then decreased to 74 per 1000 live births by 2008, an improvement that has been attributed in part to increased coverage of key childhood interventions such as immunization, insecticide treated nets (ITNs) for malaria prevention and malaria case management [6]. To meet the millennium development goal however, this rate has to be reduced further by more than 50% from the current rate to 32 per 1000 live births by 2015. There is therefore need for increased child survival initiatives to accelerate progress towards this target.

While it is generally accepted that many child survival interventions need to be implemented at the community or primary care level, delivery of case management interventions for the severely ill child largely depends on the presence of functioning rural (district) hospitals. It has been observed that if functioning well, rural (district) hospitals can make an important contribution to child survival by reducing child mortality by 44% in the areas they serve, compared to the absence of any hospital [7, 8]. Unfortunately, the quality of care delivered in many district hospitals in developing countries has been found to be poor and in need of considerable improvement [9, 10]. Assessments of these facilities showed that they are characterized by unreliable availability of essential supplies such as drugs and equipment required for provision of child health and offer inappropriate care that is often not based on evidence [9].

One strategy for improving the delivery of care is the development and implementation of evidence based clinical practice guidelines (CPGs) [11]. CPGs are hypothesized to improve the quality of care by promoting the adoption of practices with proven benefit (best practice) and discouraging the use of ineffective practices [12]. It has also been shown that providing CPGs alone yields little effect, and that multifaceted interventions including, for example, training, feedback and supervision are more effective than single interventions [13-15].

To improve the quality of care for seriously ill children on admission, a multifaceted approach employing clinical practice guidelines, health worker training, follow up supervision, feedback and facilitation was developed, for brevity called the Emergency Triage and Treatment Plus (ETAT+) strategy [11, 16]. In a resource constrained environment, we are increasingly challenged to justify resource allocation in terms of costs and effects. Given the need for resources to implement clinical guideline based practice, it is imperative that they too be subjected to rigorous evaluation of their costs and consequences. Information on the costs and effects will also be useful in modeling the scale-up of the intervention to increase access for the population in need. The aim of this research was to analyze and present the total economic costs of the ETAT+ strategy, assess the efficiency of the intervention in comparison with passive guideline dissemination in district hospitals in Kenya, and model the costs of scaling up the intervention to a national level.

## **Methods**

### **Study Design**

This was a cost effectiveness analysis alongside a cluster randomized controlled trial (cRCT). The time horizon selected was 18 months (September 2006 – April 2008), which was the period during which the intervention was implemented and evaluated. Costing took a provider's perspective. While this is often considered narrow [17, 18], for the purpose of this analysis, we considered it sufficient in encompassing the relevant range of costs and effects that are of interest to the targeted policy maker in informing

budgeting and planning for scale-up of the intervention in Kenya. To account for differential timing and time preference, we discounted costs using a 3% annual discount rate [19]. One way sensitivity analysis was used to assess uncertainty around hotel costs estimates, development costs, effectiveness estimates and staff salaries. Costs are valued and presented in 2009 US\$ while effects are measured in terms of process indicators of quality of care that included measures of child assessment, diagnosis classification and treatment on admission.

### **Data Collection and Sample Sizes**

In this cRCT, 8 rural district hospitals in 4 provinces in Kenya were randomized into 4 control and 4 intervention hospitals, with the intervention hospitals receiving the full package of the interventions while the control hospitals received a partial version [20]. Data on clinical performance and resource use were collected by conducting reviews of the clinical records of children aged 2-59 months, admitted to these hospitals with common, acute illnesses. These data were collected at baseline and at six-monthly intervals in follow up surveys. In total, 6 survey rounds were completed in intervention hospitals and 4 in control hospitals. The 2 extra surveys in intervention hospitals were conducted to assess whether the intervention effects were sustained in the post follow up period. Approximately 400 clinical records (admissions) were sampled per facility per survey. In total, clinical performance indicators were extracted from 1130 and 1005 clinical records at baseline and 1158 and 1157 at 18 months post implementation in the intervention and control hospitals respectively. Resource use data were collected from 6199 and 5115 clinical records for intervention and control hospitals respectively.

### **The Intervention**

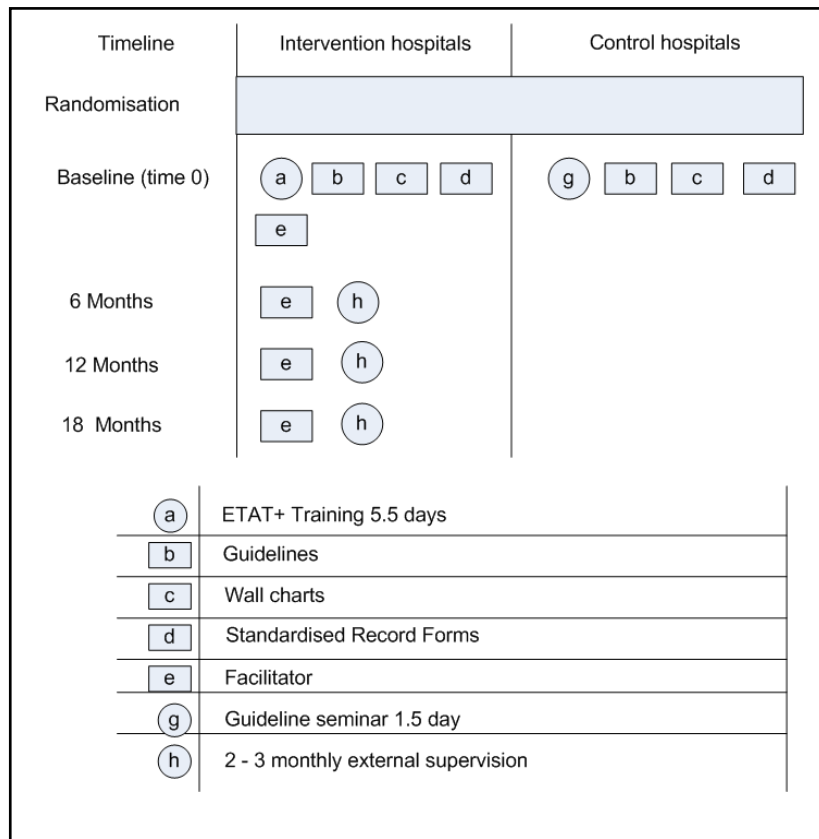
This was a package of care intervention that was delivered in the form of clinical practice guidelines (CPGs) dissemination, health worker training, job aids, follow up supervision and local (health facility) facilitation by a non-physician (nurse or diploma level) clinician. The role of the local facilitator was to offer supervisory and on-site problem solving support to the facilities in implementing the intervention.

The CPGs were developed and adopted from existing World Health Organization (WHO) case management guidelines for common pediatric conditions. This includes guidelines for emergency pediatric care, malaria, pneumonia, asthma, diarrhea and dehydration, meningitis, malnutrition, HIV/AIDs and neonatal care. The training course was developed by adopting the existing WHO Emergency Triage, Assessment and Treatment (ETAT) course with the addition of new material on newborn resuscitation and common causes of serious illness in the newborn or child. This new training was given the name “Emergency Triage Assessment and Treatment Plus Admission Care (ETAT+)”. The aim of the intervention was to promote adherence to evidence based clinical practice guidelines (CPG) for the management of seriously ill children under five admitted to hospitals.

In intervention hospitals, the intervention was delivered over 18 months as a combination of the ETAT+ training to health care workers conducted over 5.5 days, dissemination of CPG booklets, job aids and pediatric admission record (PAR) forms. The pediatric admission record (PAR) is a structured form used by clinicians to document a sick child’s clinical information on admission. The PAR was designed to capture key symptoms for common childhood illnesses (malaria, pneumonia, diarrhea and dehydration, meningitis, malnutrition and HIV/AIDS) as well as signs and approaches to severity classification and other facility information needs [21]. This was followed by 2-3 monthly supervisory visits and ad hoc follow-up trainings and appointment of a local facilitator in each facility that was supported by regular phone calls. Results and feedback reports of the surveys conducted in the facilities were disseminated in face to face meetings in intervention hospitals.

In the control hospitals a partial version of the intervention was delivered in the form of CPG booklet distribution, a 1.5 day seminar and survey report feedback. Control hospitals did not receive any follow up supervisory support and/or local facilitation. The delivery schedule for the intervention is outlined in Figure 7.

**Figure 7 Delivery of the Intervention**



### Evaluating Costs

An ingredients approach was used to measure costs. The costs collected included those incurred in development, implementation and treatment on admission of sick children in intervention and control hospitals. The latter are important to include as the use of CPGs may lead to changes in clinical practice with associated changes in the use of resources to treat sick children. Costs were collected using clinical and accounting record reviews and interviews with those involved in the implementation of the intervention. Development costs were collected for 2005-2006, annualized assuming a useful life of 4 years, and inflated to 2009 values using GDP deflators [18, 22]. Costs of ETAT+ initial training and capital costs incurred during the follow up period were collected between 2006 and 2008 and annualized over 2.5 years to reflect the annual costs of child care in the hospital. Costs were summed across all categories to obtain the total cost per hospital and per admission in intervention and control hospitals.

### ***Guideline Development Costs***

Development costs included costs incurred in the development of ETAT+ guidelines, adaptation of the guidelines and training materials. Data sources for this information included accounting records, researcher's log books and interviews with persons involved with these activities. The opportunity cost of time spent on these activities was estimated as the proportion of salaries of persons carrying out the activities based on the time allocated to the activity. Economic costs for tradable items were estimated from market prices. Development costs were annualized over 4 years which was considered to be the useful life of the clinical guidelines and associated development costs.

### ***Guideline Implementation Costs***

Guideline implementation costs included the costs of initial ETAT+ training of health workers, follow up training, supervisory visits and phone calls, feedback meetings and onsite local facilitator costs. The opportunity costs of resources used in these activities were evaluated. For example, the opportunity cost of staff time used in attending training and meetings were estimated as the proportion of salaries of persons attending the trainings based on the time allocated to the activity. The costs of the initial training were considered to be capital costs given that the effects of the training were expected to be realized over a period of more than one year. These costs were annualized over a useful life of 2.5 years, which was the length of time over which the training effects were seen to be sustained, based on the two additional surveys at 6 months intervals in intervention hospitals. Follow up activities and supervision were considered to be recurrent costs.

### ***Treatment Costs***

Treatment costs were collected because it was anticipated that the intervention would result in changes in these costs. Treatment costs were computed as the sum of "hotel", medicines and laboratory costs per admission. Per day "Hotel" costs were derived from the World Health Organization, "Choosing Interventions that are Cost Effective" (WHO CHOICE) estimates and recent work on economic burden of

inpatient care in Kenya [5, 23]. The WHO CHOICE estimates represent the “hotel” component of hospital costs, excluding drugs and diagnostic tests and including other costs such as personnel, capital and food costs [24]. Medicine unit costs were derived from 2009 market prices while unit costs of diagnostic tests were derived from laboratory costing estimates from a local district hospital, Kilifi District hospital. Utilization data for patient length of stay in hospital, medicines and laboratory tests were collected from patient clinical records. Given the skewed nature of cost data, treatment costs are presented in both means (and confidence intervals) and medians (and interquartile ranges).

### ***Presenting, Annualizing and Transferring Costs over Time***

Costs were adjusted for inflation using GDP deflators for Kenya [25]. Given the fluctuations in exchange rates within the time horizon, costs were first converted from Kenyan Shillings (KES) to USD using the respective periods’ mean annual exchange rates, before inflation to the base year to minimize currency fluctuation effects [26].

### **Evaluating Effectiveness**

We used process indicators of quality of care to estimate the effectiveness of the intervention. This is in line with the Donabedian framework which proposes that quality of care can be measured by assessing either the structure, process or outcomes of care [27]. In total there are 14 indicators that span three broad areas: assessment of a severely ill child, therapeutic care and supportive care on admission. These indicators cover the diseases that result in 60% of inpatient deaths in children under 5 in Kenya. These measures were selected based on feasibility and one or more of: a clear, logical link to patient outcomes; a clear and proximate link to the intervention; requirement for minimal resource inputs; or, objectivity of the assessment(s) (English et al 2008). For any one child, 3-7 indicators would apply depending on diagnosis and severity of disease. We defined dichotomous variables for process errors e.g. wrong drug dose or intravenous fluid prescriptions, undocumented age, weight and temperature

and a continuous variable (range 0-1) to summarize assessment tasks to an aggregate assessment score for each child.

The effectiveness of the intervention was obtained by comparing the intervention and control hospitals at survey 4 using a two-stage method. In the first stage, logistic or linear regression analyses were conducted for each of the 14 process measures adjusting for hospital-level covariates (all-cause paediatric mortality, malaria transmission, and size) and gender, illness outcome (alive or died) at the patient-level. The observed events were then subtracted from predicted events in the regressions to obtain a residual for each cluster. The cluster residuals were then compared in the second stage using a t-test [20].

For purposes of the cost effectiveness analysis, the measure of effect was the mean of the adjusted differences between control and intervention hospitals at 18 months which represents the mean percentage improvement in the 14 process of care indicators in intervention compared to control hospitals. The summary measure of effectiveness (mean percentage improvement in process measures/quality of care) was computed as outlined in figure 8:

**Figure 8 Computation of the Summary Measure of Effectiveness**

$$Q = \sum_{i=1}^{14} E_i / n$$

Where:

Q: Mean percentage improvement in process of care

$E_i$ : Adjusted difference of each process of care between control and intervention hospitals at 18 months

N: Number of processes of care

## Assessing Efficiency

The incremental cost effectiveness ratio (ICER) was defined as the incremental cost per percentage improvement in quality of care. This is the ratio of the difference in admission cost per child between intervention and control hospitals, and the difference in percentage improvement in process measures of quality between control and intervention hospitals (figure 9). The ICER thus represents the additional cost per percentage improvement in quality of care.

### Figure 9 Calculating the Incremental Cost Effectiveness Ratio

$$ICER = (C_i - C_c) / (E_i - E_c)$$

Where

$C_i$  – Child admission costs in intervention hospital

$C_c$  – Child admission costs in control hospital

$E_i$  – Percentage improvement in process measures of quality in intervention hospitals

$E_c$  – Percentage improvement in process measures of quality in control hospitals

## Total Costs of Scale Up

Kenya has 121 district hospital facilities spread around the country with an estimated annual pediatric admission of 2000 per facility, hence an estimated annual total pediatric admission of 242,000. We estimated cost of scaling up this multifaceted quality of care intervention with the assumption that development costs do not change with scale up, training costs vary as a function of the number of facilities while other implementation costs vary as a function of the number of pediatric admissions. We assumed that the intervention would reach all relevant hospitals when at scale.

## Sensitivity Analysis

One way sensitivity analysis was used to assess uncertainty around estimates for effectiveness, “hotel” costs, development costs and staff salaries. Intervention effectiveness was varied between 3.54% and 52.10%. This represents the range of process of care improvements between intervention and control

hospitals across the 14 process measures, with 3.54 % being the smallest reported improvement (Proportion of gentamicin prescriptions with daily dose greater than 10mg/kg) and 52.10% the greatest reported improvement (Proportion of malaria episodes with a severity classification). “Hotel” unit cost estimates used in the base case were the WHO-CHOICE estimate for district hospitals in Kenya, inflated to 2009 to give US\$ 6.96 per day [28], while the estimate used for the sensitivity analysis was from a Kenyan study inflated to 2009 to give US\$ 15.05 per day (Nganda et al 2003). We considered scenarios where the development cost was not included in the analysis and a scenario where the full development cost was included. We also considered a scenario where the salaries of the intervention implementers (based on salary scales of a non government organization that implemented the intervention) included in the base case analysis were replaced with local government salaries which are significantly lower. We also include an analysis of a hypothetical status quo scenario where costs are incurred for guideline development and dissemination but there is no training or follow up supervisory activities. This status quo scenario reflects the case in most developing countries.

## **Results**

### **Intervention Costs**

Total intervention costs and admission costs per child in intervention and control hospitals are presented in table 1. Development and ETAT+ training costs were 15.98 % and 7.84% respectively, of total intervention costs in intervention hospitals. An average of 32 health workers underwent the initial ETAT+ training at a cost of US\$ 8069.32 per intervention hospital and hence the training cost per health worker was US\$ 252.16. Follow up activities (follow up training, supervision and local facilitator costs) were 19.89 % of total intervention costs in intervention hospitals. The annual costs of a local facilitator per health facility were US\$ 5,697.87 which was 5.62% of total intervention costs in intervention hospitals.

**Table 1 Summary of Intervention Costs**

<u>COST ITEMS</u>	INTERVENTION HOSPITALS		AS % OF TOTAL INTERVENTION COSTS	CONTROL HOSPITALS		AS % OF TOTAL INTERVENTION COSTS
	COST PER HOSPITAL US\$	COST PER PATIENT* US\$		COST PER HOSPITAL US\$	COST PER PATIENT US\$	
<b><u>START-UP COSTS</u></b>						
DEVELOPMENT COSTS	16,227.46	8.11	15.98	9,898.29	4.95	15.93
TRAINING MATERIAL COSTS	692.92	0.35	0.69	0.00	0.00	0.00
<b>TOTAL START-UP COSTS</b>	<b>16,920.39</b>	<b>8.46</b>	<b>16.67</b>	<b>9,898.29</b>	<b>4.95</b>	<b>15.93</b>
<b><u>IMPLEMENTATION COSTS</u></b>						
INITIAL TRAINING	8,069.32	4.03	7.94	2,017.33	1.01	3.25
<b><u>FOLLOW UP ACTIVITIES</u></b>						
FOLLOW UP TRAININGS	4,348.05	2.17	4.28	0.00	0.00	0.00
LOCAL FACILITATOR COSTS	5,697.87	2.85	5.62	0.00	0.00	0.00
SUPERVISION COSTS	10,135.50	5.07	9.99	0.00	0.00	0.00
<b>TOTAL FOLLOW UP COSTS</b>	<b>20,181.42</b>	<b>10.09</b>	<b>19.89</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>TOTAL IMPLEMENTATION COSTS</b>	<b>28,250.73</b>	<b>14.13</b>	<b>27.85</b>	<b>2,017.33</b>	<b>1.01</b>	<b>3.25</b>
<b>START-UP &amp; IMPLEMENTATION</b>	<b>45,171.11</b>	<b>22.59</b>	<b>44.52</b>	<b>11,915.62</b>	<b>5.96</b>	<b>19.19</b>
<b><u>TREATMENT COST</u></b>	<b>56,304.79</b>	<b>28.15</b>	<b>55.48</b>	<b>50,202.30</b>	<b>25.10</b>	<b>80.81</b>
<b><u>TOTAL INTERVENTION COSTS</u></b>	<b>101,475.90</b>	<b>50.74</b>		<b>62,117.92</b>	<b>31.06</b>	

\*Obtained by dividing the total cost per hospital by the estimated number of annual admissions for children under five per hospital (2000).

### Treatment Costs

An ordinary linear (OLS) regression of treatment costs revealed that costs did not significantly vary with child diagnosis, hospital and time (three six monthly intervals between baseline and follow up at 18 months). We therefore pooled treatment costs across surveys and diagnosis within each study arm (intervention hospitals and control hospitals) to increase sample sizes. We however also present costs in their disaggregated form. Treatment costs per admission episode in intervention and control facilities are presented in table 2. "Hotel" costs were the key driver of treatment costs and contributed between 73.18 % and 79.98 % of treatment costs. Admission treatment costs for specific diagnosis are presented in table 3 while average lengths of stay in hospital are presented in table 4.

**Table 2 Treatment Costs per Admission**

COST ITEMS	INTERVENTION HOSPITALS				CONTROL HOSPITALS			
	N	MEDIAN COST US\$(IQR)	MEAN COST US\$ (95%CI)	AS A % OF TREATMENT COSTS	n	MEDIAN COST US\$(IQR)	MEAN COST US\$ (95%CI)	AS A % OF TREATMENT COSTS
HOTEL COSTS	4,963	18.64 (9.55-23.88)	22.54 (21.99-23.09)	73.18 %	4,460	14.33 (9.55-23.88)	20.90 (20.36-21.44)	79.98 %
DRUG COSTS	5,514	1.68 (0.72-3.00)	2.51 (2.43-2.59)	8.15 %	4,460	1.11 (0.43-2.29)	1.80 (1.73-1.86)	6.89 %
LAB COSTS	6,199	3.36 (0.00-3.36)	5.63 (5.52-5.75)	18.28 %	5,115	3.36 (0.00-3.36)	3.33 (3.23-3.44)	12.74 %
TREATMENT COSTS	5,678	22.47 (14.33-32.78)	28.15 (27.61-28.70)		4,691	19.25 (13.01-29.04)	25.10 (24.56-25.65)	

**Table 3 Admission Treatment Costs per Diagnosis**

DIAGNOSIS	N	INTERVENTION HOSPITALS		CONTROL HOSPITALS		
		MEDIAN LOS* (IQR)	MEAN LOS (95% CI)	N	MEDIAN LOS (IQR)	MEAN LOS (95% CI)
MALARIA	956	3(2-5)	3.89 (3.62-4.17)	1029	2(2-4)	3.26 (3.08-3.44)
PNEUMONIA	508	4(2-5)	4.32 (3.94-4.53)	634	4(2-6)	4.50 (4.18-4.81)
DIARRHEA & DEHYDRATION	221	3(2-5)	3.71 (3.31-4.11)	225	3(2-5)	4.33 (3.87-4.81)
PNEUMONIA & MALARIA	1175	3(2-5)	3.96 (3.78-4.13)	719	3(2-5)	4.00 (3.73-4.29)
PNEUMONIA & DIARRHEA	70	3(2-5)	4.49 (3.57-5.40)	77	4(2-6)	4.70 (3.79-5.61)
MALARIA & DIARRHEA	396	3(2-5)	3.70 (3.38-4.01)	354	3(2-5)	3.68 (3.39-3.97)
MALARIA & PNEUMONIA & DIARRHEA/DEHYDRATION	188	4(2-5)	4.19 (3.75-4.62)	80	4(2-5)	4.34 (3.52-5.15)
POOLED AGGREGATE	5241	3(2-5)	4.27 (4.16-4.37)	4628	3(2-5)	4.02 (3.92-4.13)

**Table 4 Average Length of Stay in District Hospitals**

DIAGNOSIS	N	INTERVENTION HOSPITALS		CONTROL HOSPITALS		
		MEDIAN LOS* (IQR)	MEAN LOS (95% CI)	N	MEDIAN LOS (IQR)	MEAN LOS (95% CI)
MALARIA	956	3(2-5)	3.89 (3.62-4.17)	1029	2(2-4)	3.26 (3.08-3.44)
PNEUMONIA	508	4(2-5)	4.32 (3.94-4.53)	634	4(2-6)	4.50 (4.18-4.81)
DIARRHEA & DEHYDRATION	221	3(2-5)	3.71 (3.31-4.11)	225	3(2-5)	4.33 (3.87-4.81)
PNEUMONIA & MALARIA	1175	3(2-5)	3.96 (3.78-4.13)	719	3(2-5)	4.00 (3.73-4.29)
PNEUMONIA & DIARRHEA	70	3(2-5)	4.49 (3.57-5.40)	77	4(2-6)	4.70 (3.79-5.61)
MALARIA & DIARRHEA	396	3(2-5)	3.70 (3.38-4.01)	354	3(2-5)	3.68 (3.39-3.97)
MALARIA & PNEUMONIA & DIARRHEA/DEHYDRATION	188	4(2-5)	4.19 (3.75-4.62)	80	4(2-5)	4.34 (3.52-5.15)
POOLED AGGREGATE	5241	3(2-5)	4.27 (4.16-4.37)	4628	3(2-5)	4.02 (3.92-4.13)

\*LOS-Length of stay

### **Changes in Process of Care Measures**

The mean of the adjusted difference in difference in changes in the 14 process measures between control and intervention hospitals was 25.01%. The findings of performance changes across all process measures in both control and intervention hospitals are presented in table 5.

**Table 5 Average Performance in Control and Intervention Hospitals at Baseline and 18 Months Follow-up and Adjusted Difference (95%CI) at 18 Months**

INDICATOR OF QUALITY OF CARE	INTERVENTION		CONTROL		ADJUSTED DIFFERENCE BETWEEN GROUPS AT 18 MONTHS* (%)	95%CI		P VALUE
	<u>SURVEY 1</u>	<u>SURVEY 4</u>	<u>SURVEY 1</u>	<u>SURVEY 4</u>				
<b>PROCESS INDICATORS</b>								
CHILD'S WEIGHT DOCUMENTED	59.30	84.50	21.00	63.20	22.80	-4.05	49.70	0.080
CHILD'S TEMPERATURE DOCUMENTED	11.90	71.90	25.10	46.60	26.50	-4.49	57.50	0.080
AVERAGE ASSESSMENT SCORE	24.00	94.00	32.00	65.00	29.00	5.00	54.00	0.030
PROPORTION OF PNEUMONIA EPISODES WITH A SEVERITY CLASSIFICATION	9.29	95.10	14.70	57.00	38.57	9.87	67.30	0.017
PROPORTION OF GENTAMICIN PRESCRIPTIONS WITH ONCE DAILY DOSE	1.85	89.20	3.54	74.40	17.05	8.04	26.10	0.004
PROPORTION OF GENTAMICIN PRESCRIPTIONS WITH DAILY DOSE <4MG/KG	24.90	2.16	23.40	8.99	6.77	-11.90	-1.59	0.019
PROPORTION OF GENTAMICIN PRESCRIPTIONS WITH DAILY DOSE >=10MG/KG	3.78	6.25	7.15	9.82	3.54	-11.10	4.00	0.294
PROPORTION WITH ADEQUATE OXYGEN PRESCRIPTIONS	0.00	37.00	0.00	2.31	35.10	7.32	62.80	0.021
PROPORTION OF MALARIA EPISODES WITH A SEVERITY CLASSIFICATION	10.10	92.50	2.48	41.10	52.10	26.20	78.00	0.003
PROPORTION OF SEVERE MALARIA WITH QUININE LOADING	4.20	91.90	14.80	66.70	26.30	-3.66	56.30	0.075
PROPORTION OF SEVERE MALARIA WITH TWICE DAILY QUININE MAINTENANCE DOSE	0.39	87.80	9.95	45.70	42.60	25.10	60.20	0.001
PROPORTION OF SEVERE MALARIA WITH QUININE DAILY DOSE >=40MG/KG	7.33	1.02	14.10	7.46	6.53	-12.90	-0.20	0.045
PROPORTION OF DEHYDRATION EPISODES WITH A SEVERITY CLASSIFICATION	52.40	98.30	60.50	84.80	14.40	4.27	24.60	0.013
CORRECT INTRAVENOUS FLUID PRESCRIPTION	7.32	67.20	15.00	40.60	29.90	10.90	48.90	0.008
<b>MEAN CHANGE IN QUALITY OF CARE</b>	<b>13.79</b>	<b>58.98</b>	<b>15.15</b>	<b>39.24</b>	<b>25.01</b>			

\* Adjusted difference between intervention arms obtained from linear or logistic regression analysis of hospital summary data adjusting for child's sex, illness outcome and hospital factors (size, malaria endemicity, HIV prevalence)

## Incremental Costs, Effects and Cost Effectiveness Analysis

The incremental cost per admission in intervention hospitals compared to control hospitals was US\$ 19.68 .The incremental cost per percentage improvement in quality of care was US\$ 0.78 per child admission. These results are presented in table 6.

**Table 6 Cost Effectiveness Analysis**

STRATEGY	MEAN ADMISSION COSTS PER CHILD US \$	INCREMENTAL COST US \$	EFFECTS(% CHANGE IN QUALITY OF CARE)	INCREMENTAL EFFECTS (% CHANGE IN QUALITY OF CARE)	(ICER)
PARTIAL INTERVENTION	31.06		24.09		
FULL INTERVENTION	50.74	19.68	45.20	25.01	0.78

## Estimated Costs of Scale-Up and Budget Impact

For an estimated coverage of 121 district hospitals and 242,000 annual under 5 admissions, the estimated costs of scale-up were found to be US\$ 3,633,123.45. This is estimated to be equivalent to 0.60 % of the 2010 annual budget for provision of care to children under 5 in Kenya (Table 7).

**Table 7 Total Costs of Scale-Up**

DESCRIPTION	FULL INVENTION US\$	PARTIAL INTERVENTION US\$	STATUS QUO** US\$
NO OF DISTRICT HOSPITALS	121	121	121
ESTIMATED ANNUAL PEDIATRIC ADMISSION DISTRICT HOSPITALS IN KENYA	242,000	242,000	242,000
COSTS OF NATIONAL SCALE UP	3,633,123.45	321,186.32	79,186.32
BUDGETED COSTS FOR PROVISION OF UNDER 5 CHILD HEALTH SERVICES IN KENYA IN 2010*	572,000,000.00	572,000,000.00	572,000,000.00
IMPACT OF SCALING UP ETAT+ ON THE ANNUAL CHILD HEALTH BUDGET	0.60%	0.06	0.02

\*Estimates of annual costs (2010) of provision of care to children under five derived from the Kenya national health sector strategic plan 2 (NHSSP II)

\*\*The status quo scenario assumes that CPG are developed and disseminated without any training or follow up activities as is common in developing countries

## Sensitivity Analysis

The ICERs were found to vary between US\$ 0.38 and US\$ 5.56 per percentage improvement in quality of care, with one way sensitivity analysis. Scale up costs varied from US\$ 2,635,833.65 to US\$ 3,633,123.45 (Table 8).

**Table 8 Sensitivity Analysis**

ONE-WAY SENSITIVITY TEST	ICER	SCALE UP COSTS US\$
BASE CASE	0.78	3,633,123.45
LOW EFFECTIVENESS ESTIMATE (3.54%)	5.56	3,633,123.45
HIGH EFFECTIVENESS ESTIMATE (52.10%)	0.38	3,633,123.45
DEVELOPMENT COSTS – OMISSION OF DEVELOPMENT COSTS	0.66	3,503,303.73
HOTEL COSTS – USE OF A HIGHER HOTEL COST ESTIMATE FROM A LOCAL STUDY	0.89	3,633,123.45
SALARIES – USE OF MINISTRY OF HEALTH LOCAL SALARY RATES	0.66	2,635,833.65

## Findings of Incorporating a Hypothetical Status Quo Alternative

The incremental cost effectiveness ratio (ICER) of the partial intervention (in control hospitals) compared to a hypothetical status quo alternative was US\$ 0.05 per percentage improvement in quality of care as shown in table 9.

**Table 9 Cost Effectiveness Analysis with Hypothetical Status Quo Option as the Base Case Comparator**

STRATEGY	MEAN ADMISSION COSTS PER CHILD (US \$)	INCREMENTAL COST (US \$)	EFFECTS (% CHANGE IN QUALITY OF CARE)	INCREMENTAL EFFECTS (% CHANGE IN QUALITY OF CARE)	(ICER)
STATUS QUO	30.42		10.00		
PARTIAL INTERVENTION	31.06	0.64	24.09	14.09	0.05
FULL INTERVENTION	50.74	19.68	45.20	25.01	0.78

## Discussion

This analysis compares the costs and effects of a guideline based intervention aimed at improving the quality of care of children in district hospitals in Kenya. In analyzing the costs, we included the costs of developing clinical guidelines which are often left out in such analysis (Grimshaw et al 2004). Development costs are comprised mainly of the opportunity cost of time spent in designing the intervention, and of synthesizing and compiling evidence that formed the basis of the clinical guidelines. These costs, in intervention hospitals, also included costs of training ETAT+ instructors and pilot training of ETAT+, making them higher compared to control hospitals. Our analysis revealed that development costs formed 15.98 % of the overall intervention costs. This finding suggests that these items should be included in future analyses as they are important cost drivers. On average, 32 health workers were trained in each intervention hospital hence the training cost per health worker is US\$ 252.16. This cost is significantly lower than health worker training costs for similar interventions such as IMCI where the reported median cost was US\$ 633 [29] and malaria case management training with an estimated cost of US\$ 1266 [30]. One strategy that was used to contain training costs was not paying allowances to participants of the training in contrast to common practice in developing country settings.

One of the unique components of this intervention was the appointment of a local facilitator in intervention hospitals. This was a non-physician (diploma level clinician or nurse) health worker whose role was to offer supervisory and on-site problem solving support to the facilities in implementing the intervention. The annual cost of this facilitator per facility was US\$ 5,697.87. The local facilitator worked at the facility for the entire intervention period. This provided continuity and helped to keep the “quality agenda” on the table. This was considered important as it was observed that staff turnover is often significant in health facilities in Kenya. Indeed only 26 % of the health workers initially trained in intervention hospitals were still in the hospitals providing paediatric care at the time of our major endpoint (survey 4) [20]. Thus of a total 109 clinical staff responsible for paediatric admission events sampled at survey 4 from intervention hospitals only 9 (8.30 %) had received any specific formal or even

*ad hoc* training [20]. Such turnover resulted from staff transfers to other hospitals, internal staff rotation between clinical departments, scheduled rotation of clinical staff linked to training requirements (internships) and, where there were staff shortages, reallocation of clinical staff away from paediatric and newborn areas [31]. In such settings, an intervention that involves only a one-off training without follow up and efforts to institutionalize best practice is unlikely to have a sustained effect. This highlights the fact that in order to achieve sustained and meaningful change in professional practice, interventions must aim at changing organizational culture, over and above changing individual health worker professional practice. The fact that this intervention was shown to have a sustained effect even when almost all the health workers trained had left strongly suggests that a change in organizational culture was achieved.

Treatment costs were found to be higher in intervention hospitals compared to control hospitals, with the disaggregated analysis indicating that this was driven by higher costs for malaria admissions in intervention hospitals. Hotel costs were found to be between 73.18 % and 79.98 % of total treatment cost suggesting that the length of stay in hospital is the main driver of treatment costs. Interventions that would result in significant reductions in hospital length of stay will therefore be expected to be cost saving. We have assumed that the WHO CHOICE hotel cost estimates are a reasonable proxy for hotel costs for district hospitals in Kenya. However, by using this cost for all hospitals, we are in effect assuming that there are no major differences in the intensity of staffing per patient. This assumption was justified in that we did not expect that our intervention would require different levels of health worker input within the different hospital settings. However, we acknowledge this as a potential shortcoming to this research.

If one were to consider that the process of caring for a sick child involves a number of critical steps, including correctly assessing the child on presentation, making the right diagnosis which includes a severity classification, and selecting and administering the right therapy appropriately (right drug, dose,

frequency), then the intervention can be seen to have improved the process, and hence quality, of care across these key steps. Child assessment for example improved by 29.00 % (95 % CI 5.00-54.00) and the proportion of children with a severity classification improved by 38.57 % (95 % CI 9.87-67.30) and 52.10 % (95% CI 26.20-78.00) for children with pneumonia and malaria respectively. Prescription and administration of appropriate therapies was also seen to improve as demonstrated by a 35.10 % (95 % CI 7.32-62.80) improvement in adequate oxygen prescriptions, 42.60 % (95 % CI 25.10-60.20) improvement in children receiving twice daily quinine maintenance and 29.90% (95 % CI 10.90-48.90) improvement in intravenous fluid prescriptions. These processes of care were specified in the clinical guidelines which were disseminated in both the control and intervention hospitals and hence both groups of hospitals had the opportunity to implement them. There is strong evidence therefore for substantial improvements in quality of care as a result of the intervention. An argument can therefore be made that dissemination of clinical guidelines passively is not enough, and that more proactive follow up and supervisory support is required in order to ensure significant and sustained uptake of clinical guidelines. This is consistent with similar observations made in the implementation of IMCI in Uganda where training alone was found to be insufficient to change health worker practice [13].

To assess efficiency, we defined the Incremental cost effectiveness ratio (ICER) as the cost per percentage improvement in quality of care as measured from the mean of the 14 process of care measures in control and intervention hospitals. The incremental cost per child admission in the intervention hospitals compared to the control hospitals was 19.68 US\$ while the incremental effects (percentage improvement in quality of care) was 25.01 %. It is clear therefore that the more effective strategy is also more expensive. Our findings suggest an additional cost of US\$ 0.78 per child admitted to achieve a percentage improvement in quality of care. Adopting the ETAT+ strategy therefore results in improvements in quality of care of sick children but at an additional cost, which will require increasing the current budget for child health or reallocating resources from other activities to meet the budgetary requirements of ETAT+.

Also of importance is assessing the costs of scaling up, which provides insights into the feasibility of implementation of ETAT+ on a national scale. Kenya has 121 district hospitals with an estimated annual under five admission of 2000 per facility. The intervention at scale is therefore targeted at an estimated 242,000 under five admissions per annum. We estimated that it would require US\$ 3,633,123.45 to scale up the intervention to a national level. In modeling costs of scale up, we assumed that 100 % coverage of the intervention will be achieved. This is admittedly overly optimistic as in reality, 100 % coverage of interventions is rarely achieved. While scaling up could result in significant economies of scale, larger economies of scale are expected to be achieved with efficient scale up strategies. Activities such as supervision and follow up could for example be tied to already existing district level supervisory activities resulting in shared costs with other activities.

The Kenyan ministry of medical services estimates that it spends US\$ 572,000,000.00 on the provision of care to children under five [32]. Scaling up the ETAT+ intervention nationally is therefore estimated to require 0.60 % on the child health budget. This means that in order to scale up the intervention, either the child health budget will have to be increased by 0.60 % or allocations to one or a group of activities within the budget will have to be reduced by an amount equivalent to the cost of scale up. With a 0.60 % impact on Kenya's annual child budget, the impact of ETAT+ scale up on the national budget is *a fortiori* much lower. Scaling up ETAT+ nationally is hence arguably an affordable investment with expected significant improvements in quality of care provided to children in district hospitals.

Testing the sensitivity of this analysis to changes in effectiveness leads to wide variations in the ICER (US\$ 0.38 to US\$ 5.56 per percentage improvement in quality of care). This suggests that the efficiency of the intervention is sensitive to the effectiveness of the intervention. When intervention implementer's salaries are replaced by local government salaries, the ICER is reduced by 15.00 % and more relevantly, the scale up costs are reduced by 27.00 % which also suggests that staff salaries are a

significant variable in the efficiency and costs of the intervention. When WHO CHOICE hotel costs were substituted with costs from a local study, the ICER increased by 13.00 %.

We considered a hypothetical “status quo” where guidelines are developed and passively disseminated, and compared this to the partial intervention in control hospitals and full intervention in intervention hospitals. The status quo represents a scenario, which is common in developing countries, where clinical practice guidelines are developed and passively disseminated. No form of training or follow activities is undertaken. Indeed this is a generous description as experience in Kenya shows that for a long time clinical guidelines for management of sick children were available but no strategies were put in place for their distribution. The ICER of the partial intervention compared to the hypothetical status quo scenario was US\$ 0.05 per percentage improvement in quality of care. This finding implies that the partial intervention as delivered in control hospitals is more efficient than the full intervention as delivered in intervention hospitals, which has an ICER of US\$ 0.78 per percentage improvement in quality of care. This finding is due to the fact that the partial intervention is being compared to a costly but highly ineffective alternative (status quo), making the incremental costs between the partial intervention and status quo scenario minimal while the incremental effects between the two are large. This highlights the fact that ICERs of interventions in economic evaluations are influenced by what the intervention is being compared with and thus should always be interpreted within this context.

It has been observed that the economic evaluation of complex package of care interventions is associated with challenges in defining an appropriate effectiveness measure [33]. While conventionally, CEA's have used outcome indicators such as life years gained or generic measures such as QALYs and DALYs, it has been observed that these measures are often not sensitive to changes occasioned by complex interventions and do not capture the broad range of benefits that would potentially accrue from such interventions. These measures would also require estimates of changes in health outcomes

(mortality and morbidity) which, for complex interventions, are difficult to assess due to the complex causal chains between intervention and outcomes and the potential for residual and unrecognized confounding. Designing studies to measure these “hard” outcomes will also require large sample sizes that are expensive and rarely feasible in developing countries. In this analysis, we defined the effectiveness of the intervention as changes in process of care measures, in line with the Donabedian framework for quality measurement that considers quality as a triad of structure, process and outcome [27]. This approach has been used elsewhere in the evaluation of guideline based quality of care interventions [15, 34]. Process of care measures have been used to measure adherence to CPGs as the main endpoint for CPG implementation [35]. Others have extended this approach by defining measures of *appropriate care* based on observed or documented clinician practices [36]. A major limitation of this approach is that it fails to clearly bring out the value of the intervention to the patients and by extension to decision makers. There is need for a more explicit link between process measures and health outcomes. One suggestion would be to model treatment outcomes from intermediate outcomes like *appropriate care*. This could for example be achieved by using structured elicitation techniques like Delphi exercises to obtain expert opinions on, for instance, the difference in risk of death if a child with complicated malaria receives “*appropriate care*” compared with the same child receiving “*inappropriate care*”. More importantly, given that this and similar complex quality of care interventions are designed to target improvements over a range of benefits beyond clinical outcomes, perhaps a method of valuing these interventions that encompasses more than health outcomes is more appropriate. Exploring the utility of process of care by for example eliciting society’s preferences for the spectrum of process attributes of such interventions and the value they place on improvements in process of care will be key in informing decisions to adopt quality of care interventions.

Should the intervention be scaled up? The decision on whether or not to adopt ETAT+ in Kenya should be informed not only by efficiency assessments, but also other criteria such as the costs of scale up and budgetary implications of the strategy, and its contribution to equity among other criteria. In

considering affordability, the total cost of the intervention at scale is seen to have a low impact (0.60 %) on the annual child health budget and therefore can be argued to be affordable. Component costs, such as ETAT+ training are also seen to be relatively more affordable compared to similar health worker training initiatives like IMCI, malaria and HIV case management.

Improving the delivery of evidence based care for common childhood diseases responsible for the greatest mortality is likely to contribute to improved child survival. This intervention has been shown to significantly improve the quality of care for admitted children in district hospitals. Given that children are an especially vulnerable group in society, interventions that target improvement in their survival can be argued to contribute to improving equity in health in the population. The fact that this intervention targets diseases responsible for the highest number of deaths in children under five means that investing in the scaling up of ETAT+ is likely to result in the greatest health gains among children under five and hence improved technical efficiency. Promoting strategies to improve delivery of care for children in Kenya is expected to improve child survival and hence accelerate progress towards achieving millennium development goal (MDG) 4. There is therefore a strong case for the scaling up of the ETAT+ intervention in Kenya.

A major limitation of this study is the use of process of care as measures of outcome in economic analysis. The use of a process of care summary measure to assess the efficiency of the intervention, rather than generic outcome measures such as the DALY and QALY, presents challenges in the interpretation of the ICER and commenting on the cost effectiveness of the intervention. Because these measures are unique to this intervention, it is not possible to compare the results from this intervention to other cost-effectiveness or cost-utility studies. This points to the need for methodological development work for appropriate effectiveness measures for quality of care interventions, where health outcome changes cannot be demonstrated. The summary measure was also computed with the assumption that all process measures, across categories and diagnosis, are of equal weight, which is

debatable. It is more likely that different processes vary in relative importance and significance in the care of the sick child. Another limitation of this study is that a provider perspective has been used. It has been argued that this is a narrow view and that a societal perspective would be more encompassing [18, 28]. These limitations notwithstanding, this analysis presents findings that at best lay out to decision makers the costs of the intervention, the expected improvements in process of care and the budgetary implications of the intervention at scale. It can also be looked at as a partial analysis that would inform a broader modeling of the value for money of the intervention. Further work will include modeling the linkages between process improvements and health outcomes, and determining the utility of processes of care. This will involve developing an effectiveness measure that captures changes beyond clinical outcomes and encompassing process (of care) utility.

## **Conclusion**

This analysis has shown that adopting the ETAT+ strategy is more effective in improving quality of care compared to a partial version of the intervention that did not include the full training, follow up and supervisory support. These additional supports including a local facilitator are seen to lead to a sustained improvement in quality of care in intervention facilities. This work has also highlighted the methodological challenges in the economic evaluation of complex interventions, specifically quality of care interventions, where outcomes are multiple and demonstrating health outcomes is not always possible. There is therefore need for further work in developing better approaches to economic analysis of such interventions, and specifically in developing more appropriate effectiveness measures for such analyses.

Concerning methodological extensions to this work, we have proposed the modeling of health outcomes from process of care measures, which would allow the analysis and presentation of economic evaluation of this and similar interventions in terms of incremental cost per QALY gained or DALY averted. Another

suggestion is to investigate and establish the value society places on quality improvement and their preferences for technical process of care. Determining the existence and magnitude of “process of care utility” of this and similar interventions will perhaps provide a better basis for assessing the value for money for such interventions. These results are likely to be generalizable only to low income countries with similar district health characteristics, child burden of disease, and comparable quality of delivery of pediatric care in hospitals as Kenya.

### **List of Abbreviations Used**

1. KEMRI –Kenya Medical Research Institute
2. WHO – World Health Organization
3. ETAT+ - Emergency Triage and Treatment Plus
4. IMCI – Integrated Management of Childhood Illness
5. CPGs – Clinical Practice Guidelines
6. cRCT – Cluster Randomized Trial

### **Competing Interests**

There are no conflicts of interest.

### **Authors Contributions**

The idea for the study and its design were conceived by all authors, E Barasa was responsible for data analyses and preparation of the initial draft manuscript. All authors reviewed the draft manuscript and provided input to preparation of and approval for the final version of the report.

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## Part D: Policy Brief

### Improving the Quality of Care of Children in District Hospitals in Kenya: Costs and Effects of the Emergency Triage and Treatment Plus (ETAT+)

#### Introduction

In the year 2000 UN member states adopted the Millennium Development Goals (MDGs) among them MDG 4 which calls for a two thirds reduction in the number of children dying before the age of five between 1991 and 2015. In Kenya, the number of children dying before age five was 97 per 1000 children born in 1990 and by 2006 had risen to 121 per 1000 children born (Ayieko et al., 2009). This number then substantially decreased to 74 per 1000 children born by 2008 (Kenya National Bureau of Statistics (KNBS) and ICF Macro, 2010). Most of these child deaths are caused by few treatable and preventable diseases, mainly pneumonia, diarrheal diseases, malnutrition and malaria for which proven and affordable interventions are available (Jones et al., 2003). These deaths are still unacceptably high and to achieve the MDG target, will need to reduce by more than 50 % to 32 per 1000 children born by 2015. There is therefore a need to enhance efforts to improve child survival in Kenya.



#### **Box 1: Key Findings and Recommendations**

- ❖ ETAT+ was shown to improve the quality of care children admitted in hospitals by 25.01 %
- ❖ The total cost of scaling up ETAT+ is estimated to be US\$ 3,633,123.45
- ❖ This cost is estimated to be only 0.60 % of annual child health budget in Kenya
- ❖ ETAT+ is effective, affordable and should there be scaled up to all district hospitals in Kenya

The district hospital has been considered a critical avenue for the delivery of child saving interventions. It has been suggested that improving their performance would reduce child mortality by 3-30 % in the areas they serve (English et al., 2004). It has however been shown that the quality of care delivered in these hospitals in Kenya is poor (English et al., 2004). Assessments of these facilities have revealed that often they do not have essential supplies such as drugs and equipment and the care for admitted children is not based on current knowledge and evidence.

One strategy for improving quality of care is promoting the use of clinical guidelines that are based on current evidence. Clinical guidelines improve quality of care by promoting the use of

## Box 2: Package of Interventions Developed and Delivered to Intervention Hospitals

1. Evidence based clinical guidelines for management of pediatric conditions, developed with the Kenyan ministry of medical services and other key stakeholders
2. Job aids: Clinical guideline booklets, drug dosing, fluid and feed charts, structured pediatric admission forms
3. A 5.5 day health worker training on an extended version of the WHO ETAT training in line with developed CPG (ETAT+)
4. Follow up supervisory support through visits every 2-3 months
5. Appointment of a local facilitator (Clinical officer or nurse) in each facility to provide onsite supervisory and problem solving support
6. Regular hospital performance assessment and feedback every 6 months

practices of proven benefit and discouraging ineffective and outdated practices. To improve the quality of care of children admitted in district hospitals in Kenya, clinical guidelines for the provision of care to admitted children were developed and implemented in selected district hospitals. The implementation of this guideline was accompanied by 5.5 days of training for health workers, job aids and follow up supervision. A local facilitator was also appointed in the hospital to provide on-site supervision. This intervention was for brevity called the Emergency Triage and Treatment Plus (ETAT+) strategy. We present here the findings of an assessment of the costs and consequences the ETAT+ strategy.

### Research Objective

This research assessed the costs and consequences of implementing the ETAT+ strategy in district hospitals in Kenya. This was compared with partial implementation of the clinical guidelines, involving only guideline

dissemination and a short seminar (1.5 days). The research also looks at the costs of scaling up the intervention and the impact this scaling up will have on the child health budget in Kenya.

### Methods

The intervention was delivered over 18 months (September 2005- April 2008) in 4 district hospitals in Kenya. The partial version of the intervention was delivered to 4 other district hospital for comparison. The costs of the intervention were obtained as the sum of the costs of developing and implementing the intervention as well as treating admitted children. The major outcome of the intervention was quality of care delivered to children admitted in hospital. We estimated the costs that would be required to scale up the intervention to all the 121 district hospitals in Kenya and looked at the impact of this cost on the annual child health budget.

### Findings

- ❖ The total cost of the intervention for each intervention hospital was US\$ 101,475.90

which translates to a cost of US\$ 50.74 per child admitted

- ❖ The cost of ETAT+ training per health care worker was found to be US\$ 252.16 while the annual cost of a local facilitator per hospital was US\$ 5,697.87
- ❖ The intervention resulted in a 25.01% improvement in quality of care
- ❖ The estimated cost of scaling up the intervention to all 121 district hospitals in Kenya is US\$ 3,633,123.45
- ❖ This cost of scaling up is estimated to be 0.60 % of the child health budget for Kenya; The estimated budget for provision of child health services in Kenya for 2010 is US\$ 572,000,000.00 (MOH, 2005).

### **What Do These Finding Mean?**

It was observed that the intervention resulted in significant improvements in the quality of care of sick children admitted in hospital. For instance, the assessment of children by the clinician on admission improved by 29.00 % while the correct prescription and administration of medicines was also seen to improve as demonstrated by a 35.10 % improvement in adequate oxygen prescriptions, 42.60 % improvement in children receiving twice daily quinine maintenance dose and 29.90

% improvement in intravenous fluid prescriptions.

Experience in the implementation of the Integrated Management of Childhood Illnesses (IMC) revealed that that disseminating clinical guidelines passively is not enough (Pariyo et al., 2005). It was shown that training health workers should be augmented by follow up and supervision for there to be a sustained effect. This research demonstrated this to be true in Kenya and highlighted the importance of support and supervision of health workers in implementing clinical guidelines.

A unique addition to this intervention was the appointment of a non-physician local facilitator in each facility. This was a diploma level clinician (clinical officer) or nurse whose role was to offer on-site supervision and problem solving support. This was considered important given that the turnover of health workers in public health facilities is high in Kenya. Indeed it was observed that only 26 % of health workers originally trained in hospitals were still present after 18 months. The facilitator offered continuity by helping to keep the “quality agenda” on the table. This served to develop and institutionalize a quality culture that resulted in a sustained improvement in quality of care despite the high staff turnover.

Scaling up the ETAT+ strategy to all district hospitals in Kenya will require only a 0.60 %

increase in the annual child health budget. ETAT+ at scale is therefore highly affordable and results in only a minimal addition to the child health budget. At a cost of US\$ 252.16 per health worker, the health worker training is cheaper than similar trainings like Integrated Management of Childhood Illnesses (IMCI) (US\$633) (Rowe et al., 2008) and malaria case management (US\$ 1266) (MOMS and MOPHS, 2010). When this affordability is considered together with the potential improvements in quality of care for children in hospitals, ETAT+ is arguably very good value for money and should be scaled up.

This intervention also targets child survival and hence is likely to improve equity in health in Kenya. Children are a vulnerable group in the population and bear the brunt of diseases of high burden such as malaria and pneumonia. The ETAT+ strategy targets diseases of high burden children that are responsible for more than 60% of childhood deaths. This includes malaria, pneumonia, diarrhea and dehydration, malnutrition and neonatal care. Investing in the intervention will hence lead to greater gains in health improvement among children and hence improve allocation of child health resources.

## **Policy Recommendation**

### **Scale up of ETAT+**

We recommend that the government and development partners prioritize the delivery of evidence based clinical guidelines for admitted

children in hospitals as a key strategy to improve child survival. In line with this, resources should be committed for the scaling up of pediatric guideline dissemination, ETAT+ training, and sustainable structures, including human resources, put in place for the supervision and support of quality of care activities.

### **Monitoring of Quality of Care**

As part of the improvements in the national health management information system (HMIS), quality of care should be integrated in the monitoring and reporting of hospitals. This can be achieved by developing and incorporating quality of care parameters and including them as part of the routine data collected and reported by facilities. This will however only be useful if systems are in place to appropriately analyze and feedback and act on the findings of such monitoring initiatives.

### **Institutionalizing Quality of Care**

To assure sustainability of quality of care improvements, the government needs to take concrete steps to institutionalize the quality of care agenda in public hospitals. This can be done by recognizing quality as an important performance indicator for facilities and developing responsibility and accountability structures in the public hospitals to assure quality. One way to achieve this would be to create the position of a “quality manager” within hospitals. The role of this person would

be to direct and support quality initiatives within the hospitals. Our findings showed that this is an affordable and effective strategy to supporting quality initiatives.

With the adoption of performance contracting in the public health sector in Kenya, another strategy for institutionalizing quality of care is for the government to integrate provision of quality of care as part of performance targets for health workers. Quality of care should also be included as part of the performance evaluation of facilities. This should however be done transparently and with significant involvement of front line health workers and facility representatives. This will avoid perceptions of bias, unfairness and eventual loss of motivation of health workers. As discussions continue about introducing performance based financing of health facilities in Kenya, quality of care should be incorporated as a key performance benchmark.

#### **Incorporate ETAT+ Into Pre-service Training**

To ensure sustainability and improved intervention coverage, ETAT+ training should be included as part of the curriculum during the training for non degree (clinical officers and nurses) and degree level (medical student at undergraduate and master's level) clinicians. This will also in the long term reduce the costs of in-service training of health workers.

#### **Managing Staff Turnover**

While we cannot belabor the need for government to retain health workers in the

public sector, special recommendations need to be made here for the government and perhaps more relevantly, public hospital managers to put in place strategies to minimize inter departmental staff turnover within public hospitals. While the government and development partners spend significant amounts of resources on in-service training of health workers, high staff turnover significantly reduces the effectiveness of this investment. Specifically for child health a policy for cultivating health worker specialization should be adopted. Clinicians and nurses who have been trained to provide care for sick children for example, should be retained in pediatric departments to continue providing this care.

#### **Conclusion**

The ETAT+ strategy has been shown to significantly improve the quality of care of children in district hospitals in Kenya. Our findings show that scaling up the strategy nationally is very affordable while the potential benefits that could accrue are significant. A decision by the government of Kenya to invest in the adoption of ETAT+ on a national scale will therefore provide great value for money. This will no doubt go a long way in improving child survival in Kenya and accelerate progress towards achieving MDG 4 targets.

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## Part E: Appendices

### Appendix 1: Clinical Record Data Abstraction Tool

Survey No.	Quest. Type	P	Quest. No.
<i>Prospective Paediatric Data Abstraction Form – Age over 7 days</i>			
Survey No.		Quest. Type	P
Hosp ID.		Quest. No.	
Name (First, Last)	Triage Category Em / Pr / NU / E		
Date	/ / 200	Wt (kg)	Age yrs mths days
Sex	M / F / E	Temp (°C)	Vaccines M'sles Y / N / E DTP/Penta x / E
Did the admitting clinician use a Paediatric Admission Record form during admission?			Y / N
<b>History</b>		<b>Examination</b>	
Length of illness	days		
Fever	Y N E	<b>Airway</b>	Clear Stridor Needs active support to open F
Cough	Y N E	<b>Breathing</b>	Respiratory Rate /min / E
Cough > 3 weeks	Y N E		Central Cyanosis Y N E
Difficulty breathing	Y N E		Indrawing Y N E
Fill for babies aged < 2 months			Grunting Y N E
Abnormal movements / behaviour	Y N E		Acidotic breathing Y N E
High pitched cry	Y N E		Wheeze Y N E
Apnoeas	Y N E		Crackles Y N E
Pus + cellulitis, umbilicus	Y N E	<b>Circulation</b>	Pulse Weak Normal /min
			Cap Refill X <2 2 3 >3 E
			Pallor / Anaemia 0 + ++ E
Diarrhoea	Y N E	<b>Dehydration</b>	Sunken eyes Y N E
Diarrhoea > 14d	Y N E		Skin pinch (sec) 0 1 2 E
		<b>Disability</b>	AVPU A V P U I
Convulsions	Y N E		Can drink / breastfeed? Y N E
Partial / focal fts?	Y N E		Bulging fontanelle Y N E
			Stiff neck Y N E
Vomits everything	Y N E	<b>General / Nutrition</b>	Jaundice 0 + ++ E
Difficulty feeding	Y N E		Visible severe wasting Y N E
			Oedema of Kwashiorkor Y N E

### Admission Diagnoses

A. In this section, please record the diagnoses of the first admitting clinician ONLY. Please enter clinician code.

Clinician code (clinician 1)

<b>Malaria</b>	<input type="checkbox"/> Severe <input type="checkbox"/> Non-sev <input type="checkbox"/> No classif'n	<b>Anaemia</b>	<input type="checkbox"/> Sev <input type="checkbox"/> Non sev <input type="checkbox"/> No classif'n
<b>Pneumonia</b>	<input type="checkbox"/> V. Sev classif'n <input type="checkbox"/> Sev <input type="checkbox"/> Non-sev <input type="checkbox"/> No	<b>Meningitis</b>	<input type="checkbox"/>
<b>Diarrhoea</b>	<input type="checkbox"/> Non-bloody <input type="checkbox"/> Bloody	<b>Neonatal sepsis</b>	<input type="checkbox"/>
<b>Dehydration</b>	<input type="checkbox"/> Sev <input type="checkbox"/> Some <input type="checkbox"/> No classif'n	<b>Birth asphyxia</b>	<input type="checkbox"/>
<b>HIV / AIDS</b>	<input type="checkbox"/> Known <input type="checkbox"/> Possible	<b>Prematurity / VLBW</b>	<input type="checkbox"/>
<b>Malnutrition</b>	<input type="checkbox"/> Kwashi classif'n <input type="checkbox"/> Marasm <input type="checkbox"/> M. Kwashi <input type="checkbox"/> No	<b>Newborn RDS</b>	<input type="checkbox"/>
<b>Other 1</b>			
<b>Other 2</b>			
<b>B. Was the child seen again on admission by a clinician other than clinician 1? Yes/ No. – If yes give Clinician 2 code</b>			<b>If No, skip this section</b>
			<input type="text"/> <input type="text"/>
<b>Did clinician 2 change the diagnoses in any way? Yes/ No. If yes please record clinician 2's diagnoses</b>			<b>If No, skip this section</b>
			<input type="checkbox"/>
<b>Malaria</b>	<input type="checkbox"/> Severe <input type="checkbox"/> Non sev <input type="checkbox"/> No classif'n	<b>Anaemia</b>	<input type="checkbox"/> Sev <input type="checkbox"/> Non-sev <input type="checkbox"/> No classif'n
<b>Pneumonia</b>	<input type="checkbox"/> V. Sev <input type="checkbox"/> Sev <input type="checkbox"/> Non-sev <input type="checkbox"/> No classif'n	<b>Meningitis</b>	<input type="checkbox"/>
<b>Diarrhoea</b>	<input type="checkbox"/> Non-bloody <input type="checkbox"/> Bloody	<b>Neonatal sepsis</b>	<input type="checkbox"/>
<b>Dehydration</b>	<input type="checkbox"/> Sev <input type="checkbox"/> Some <input type="checkbox"/> No classif'n	<b>Birth asphyxia</b>	<input type="checkbox"/>
<b>HIV / AIDS</b>	<input type="checkbox"/> Known <input type="checkbox"/> Possible	<b>Prematurity / VLBW</b>	<input type="checkbox"/>
<b>Malnutrition</b>	<input type="checkbox"/> Kwashi <input type="checkbox"/> Marasm <input type="checkbox"/> M Kwashi <input type="checkbox"/> No classif'n	<b>Newborn RDS</b>	<input type="checkbox"/>
<b>Other 1</b>			
<b>Other 2</b>			

**Investigations ordered by clinician 1 – Record only the first of each type**

	Ordered?	Result available – time after admission					Result (give units)
Malaria Slide	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	Pos / Neg
Hb / HCT / PCV	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	
Glucose	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	
HIV test	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	Pos / Neg
Cross Match (Time sample sent)	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	
Chest Xray	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	
Lumbar Punct. (Time to microscopy result)	Y / N	No information on result	Same day	Next day	2 or more days later	Result but no time / date	
Other tests	1) _____, 2) _____, 3) _____ Result: _____ Result: _____ Result: _____						

**Please record ALL the new investigations ordered by ANY clinician during the IP stay**

	Ordered by Clinician 2 on admission	Total Number Ordered eg. 0,1, 2 etc	Total Number with results eg. 0, 1, 2 etc	Record significant results
Malaria Slide	Y / N			
Hb / HCT / PCV	Y / N			
Glucose	Y / N			
HIV test	Y / N			
Cross Match	Y / N			
Chest Xray	Y / N			
Lumbar Punct.	Y / N			
Other 1, name	Y / N			
Other 2, name	Y / N			

**Oxygen and Blood Transfusion – Record data only about the immediate admission events**

	<b>Ordered?</b>	<b>Ordered by:</b>				
<b>Oxygen</b>	Y / N / E	<input type="checkbox"/> Clinician 1 <input type="checkbox"/> Clinician 2 <input type="checkbox"/> Other				
		<b>Describe how prescribed (flow rate, device)</b>				
		<input type="checkbox"/> No detail	Flow rate =	<input type="checkbox"/> Ncath / <input type="checkbox"/> NP / <input type="checkbox"/> mask / <input type="checkbox"/> Oth		
<b>Describe actual administration</b>		<input type="checkbox"/> Correctly regulated <input type="checkbox"/> Inadequately regulated <input type="checkbox"/> Not given				
<b>Transfusion</b>	Y / N / E	<b>Ordered by:</b>				
		<input type="checkbox"/> Clinician 1 <input type="checkbox"/> Clinician 2 <input type="checkbox"/> Other				
		<b>Estimate time taken from order to start of blood infusion</b>				
		< 4 hrs	4 - 12 hrs	12-24 hrs	> 24 hrs	Ordered but not given
		Volume of Blood (mls)				
		Duration prescribed (hrs)				
		Frusemide dose			mg	
<i>If answer to transfusion No or E (empty of data) then proceed to next section</i>						

**Treatment – Record only the initial treatment prescribed for the admission episode by the clinician who attended to the child first (Clinician 1)**

	Was drug prescribed?	Was drug available to be given?	Drug prescription				
			Route	Dose	Units	Freq	Days
<b>Antibiotics</b>							
Penicillin	Yes / No	Yes / No	iv / im		mg / iu		
Gentamicin	Yes / No	Yes / No	iv / im		mg		
Chloramphen'l	Yes / No	Yes / No	iv / im		mg		
Amoxil	Yes / No	Yes / No	po		mg / mls / tabs		
Septin	Yes / No	Yes / No	po		mg / mls / tabs		
Metronidazole	Yes / No	Yes / No	iv / po		mg / mls / tabs		
<b>Antimalarials</b>							
Quinine (Load)	Yes / No	Yes / No	iv / im		mg	stat	
Quinine (Maint)	Yes / No	Yes / No	iv / im / po		mg		
Co-artem	Yes / No	Yes / No	po		tabs		
<b>Supportive Care</b>							
Paracetamol	Yes / No	Yes / No	im / po		mg / mls / tabs		
Diazepam	Yes / No	Yes / No	iv / im / po		mg	stat / pm	

**Was the initial treatment reviewed during the admission episode? Yes / No (If no, please skip this section)**

**Treatment – Record all the treatment prescribed for the admission episode by clinician 2**

	Was drug prescribed?	Was drug available to be given?	Drug prescription				
			Route	Dose	Units	Freq	Days
<b>Antibiotics</b>							
Penicillin	Yes / No	Yes / No	iv / im		mg / iu		
Gentamicin	Yes / No	Yes / No	iv / im		mg		
Chloramphenol	Yes / No	Yes / No	iv / im		mg		
Amoxil	Yes / No	Yes / No	po		mg / mls / tabs		
Seprin	Yes / No	Yes / No	po		mg / mls / tabs		
Metronidazole	Yes / No	Yes / No	iv / po		mg / mls / tabs		
<b>Antimalarials</b>							
Quinine (Load)	Yes / No	Yes / No	iv / im		mg	stat	
Quinine (Maint)	Yes / No	Yes / No	iv / im / po		mg		
Co-artem	Yes / No	Yes / No	po		tabs		
<b>Supportive Care</b>							
Paracetamol	Yes / No	Yes / No	im / po		mg / mls / tabs		
Diazepam	Yes / No	Yes / No	iv / im / po		mg	stat / prn	

**Other drugs- Please record any other drugs prescribed by either clinician 1 or clinician 2 ON ADMISSION**

Drug Name	Clinician Number	Route	Dose	Units	Freq	Days
1.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
2.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
3.	1 / 2 / 1 & 2	iv / im / po / ihl / top / F		mg / mls / tabs / F		
4.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
5.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
6.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
7.	1 / 2 / 1 & 2	iv / im / po / ihl / top / F		mg / mls / tabs / F		
8.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
9.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
10.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
11.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
12.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
13.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		
14.	1 / 2 / 1 & 2	iv / im / po / ihl / top / E		mg / mls / tabs / E		

**Other drugs- Please record ALL additional drugs prescribed by any clinician AT ANY TIME during the inpatient stay and indicate the number of days ACTUALLY given.**

Drug Name	Route	Dose	Units	Freq	Days ACTUALLY given
1.					
2.					
3.					
4.					
5.					
6.					
7.					
8.					
9.					
10.					
11.					
12.					
13.					
14.					

<b>Did the child have a prescription for fluids to treat dehydration.</b>		Yes / No	<i>If No, then skip this section, if yes continue in part A.</i>	
<b>A. Was the child given fluids using iv route?</b>		Yes / No	<i>If No, skip to part B, if yes continue</i>	
<b>Fluid prescribed</b>	<b>Fluid prescription for Step 1 and 2 (up to 6 hours)</b>			
	Step 1 / Step 2 plan used	Total Volume	Time (hrs)	
Ring / NSal / HS Darr / Other	Yes / No			
<b>B. Was the child given fluids using oral or ng route?</b>		Yes / No	<i>If No, skip to part C, if yes continue</i>	
<b>Fluid prescribed</b>	<b>Fluid prescription for first 4 hours</b>			
	Ng tube used	Total Volume	Time (hrs)	
ORS / Ring / NSal / HSD / Other	Yes / No			
<b>Was the child classified as malnourished?</b>		Yes / No	<i>If No, then skip this section, if yes continue.</i>	
<b>Feed prescribed</b>	<b>Feed prescription for first 24 hours</b>			
	Route	Feed Vol	Freq / 24hrs	
F75 / Sp Milk / HPD / Other / None	ngt / po	mls / E	E /	
<b>Supportive Care Received throughout admission.</b>				
<b>Total number of days (round to nearest 0.5) receiving</b>	<b>Days</b>	<b>Amount received (check chart)</b>		
iv fluids				
Ngt / special foods		≥80%	60-80%	<60%
Oxygen				

**Discharge Treatment – Record only the treatment prescribed to be taken away**

	Was drug prescribed?	Drug prescription				
		Route	Dose	Units	Freq	Days
<b>Antibiotics</b>						
Amoxil	Yes / No	po		mg / ml / tabs		
Seprin	Yes / No	po		mg / ml / tabs		
Metronidazole	Yes / No	po		mg / ml / tabs		
<b>Antimalarials</b>						
Quinine (Maint)	Yes / No	po		mg		
Co-artem	Yes / No	po		tabs		
<b>Supportive Care</b>						
Paracetamol	Yes / No	im / po		mg / ml / tabs		
<b>Other discharge drugs</b>						
		Route	Dose	Units	Freq	Days
1						
2						
3						
4						
5						
6						
7						
8						
9						
<b>Discharge Information</b>						
Non-admission wt		Date recorded		Source of wt	<input type="checkbox"/> Nursing notes <input type="checkbox"/> Medical notes	
Discharge Date		2 0 0	Outcome	Alive / Dead / Refer'd / Absc'd		
Follow Up	Not arranged	Hospital	Disp/ H. Contro			

## Appendix 2: Intervention Implementers Time Quantification Tool

### RESEARCHER TIME QUANTIFICATION TOOL

#### Instructions

1. Please indicate as accurately as possible the approximate time spent by you on each other study activities detailed in the table
2. You should try to give both the time in hours spent on each activity and the spread of days over which you were involved in the activity in brackets table

Name: \_\_\_\_\_

Activity	Details	Description of role	Time on activity in hours and (days)							
			I11 Hemdebey	I12 Kerugoya	I13 Kissi	I14 Kihai	I15 Busia	I16 Isiolo	I17 Kakamega	I18 Nyalumuru
STUDY PLANNING	Protocol development(ETAT)									
	Protocol adaptation meeting									
	Consultative meetings with stakeholders									
	Child health week									
	WT pilot									
	Thika pilot									
	KNH pilot									
	KMTC pilot									
	Previsit to intervention hospitals									
STUDY ACTIVITY										
TRAINING										
Initial training	Planning and travel									
	Facilitation and training									
First follow up training	Planning and travel									
	Training and facilitation									
Second follow up	Planning and travel									

## Appendix 3: Ethics Approval Letter



UNIVERSITY OF CAPE TOWN

Health Sciences Faculty  
Faculty of Health Sciences Research Ethics Committee  
Room E52-24 Groote Schuur Hospital Old Main Building  
Observatory 7925  
Telephone [021] 406 6338 • Facsimile [021] 406 6411  
e-mail: sumayah.ariefdien@uct.ac.za

08 October 2010

HREC REF: 471/2010

**Dr E Barasa**  
Health Economics Unit  
School of Public Health & Family Medicine  
Falmouth Annex  
Medical Campus

Dear Dr Barasa,

**PROJECT TITLE: COSTS AND EFFECTS OF A MULTIFACETED INTERVENTION TO IMPROVE THE QUALITY OF CARE OF CHILDREN IN DISTRICT HOSPITALS IN KENYA**

Thank you for submitting your study to the Health Science Faculty Research Ethics Committee for review

It is a pleasure to inform you that the Ethics Committee has **formally approved** the above-mentioned study.

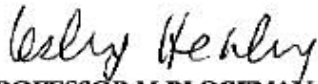
**Approval is granted for one year till the 15 October 2011.**

Please submit a progress form, using the standardised Annual Report Form (FHS016), if the study continues beyond the approval period. Please submit a Standard Closure form (FHS010) if the study is completed within the approval period.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

**Please quote the REC. REF in all your correspondence.**

Yours sincerely



**PROFESSOR M. BLOCKMAN**  
**CHAIRPERSON, HSF HUMAN ETHICS**

pp

Federal Wide Assurance Number: FWA00001637.  
Institutional Review Board (IRB) number: IRB00001938

This serves to confirm that the University of Cape Town Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

The Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

## Appendix 4: Journal Instructions for Authors

**Journal: BMC Health Services Research**

### Manuscript sections for Research articles

Manuscripts for Research articles submitted to *BMC Health Services Research* should be divided into the following sections:

- Title page
- Abstract
- Background
- Methods
- Results
- Discussion
- Conclusions
- List of abbreviations used (if any)
- Competing interests
- Authors' contributions
- Authors' information (if any)
- Acknowledgements and Funding
- References
- Figure legends (if any)
- Tables and captions (if any)
- Description of additional data files (if any)

## **Title page**

This should list the title of the article. The title should include the study design, for example:

**A versus B in the treatment of C: a randomized controlled trial**

**X is a risk factor for Y: a case control study**

The full names, institutional addresses, and e-mail addresses for all authors must be included on the title page. The corresponding author should also be indicated.

## **Abstract**

The abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract; **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number, e.g. **Trial registration:** Current Controlled Trials ISRCTN73824458. Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the CONSORT extension for abstracts.

## **Background**

The background section should be written from the standpoint of researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a very brief statement of what is being reported in the article.

## **Methods**

This should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate.

## **Results and Discussion**

The Results and Discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The results and discussion sections may also be broken into subsections with short, informative headings.

## **Conclusions**

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

## **List of abbreviations**

If abbreviations are used in the text, either they should be defined in the text where first used, or a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

## **Competing interests**

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors should disclose any financial competing interests but also any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

#### *Financial competing interests*

- In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.
- Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.
- Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.
- Do you have any other financial competing interests? If so, please specify.

#### *Non-financial competing interests*

Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

If you are unsure as to whether you or one of your co-authors has a competing interest, please discuss it with the editorial office.

## **Authors' contributions**

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

An "author" is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; and 3) have given final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

## **Authors' information**

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies,

or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

### **Acknowledgements and Funding**

Please acknowledge anyone who contributed towards the study by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include their source(s) of funding. Please also acknowledge anyone who contributed materials essential for the study.

The role of a medical writer must be included in the acknowledgements section, including their source(s) of funding.

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements.

Please list the source(s) of funding for the study, for each author, and for the manuscript preparation in the acknowledgements section. Authors must describe the role of the funding body, if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

### **References**

All references must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Reference citations should not appear in titles or headings. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal

communications should not be included in the reference list, but may be included in the text and referred to as "unpublished data", "unpublished observations", or "personal communications" giving the names of the involved researchers. Notes/footnotes are not allowed. Obtaining permission to quote personal communications and unpublished data from the cited author(s) is the responsibility of the author. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should contain all named authors, regardless of how many there are.

### **Preparing tables**

Each table should be numbered in sequence using Arabic numerals (i.e. Table 1, 2, 3 etc.). Tables should also have a title that summarizes the whole table, maximum 15 words. Detailed legends may then follow, but should be concise.

Smaller tables considered to be integral to the manuscript can be pasted into the document text file. These will be typeset and displayed in the final published form of the article. Such tables should be formatted using the 'Table object' in a word processing program to ensure that columns of data are kept aligned when the file is sent electronically for review; this will not always be the case if columns are generated by simply using tabs to separate text. Commas should not be used to indicate numerical values. Color and shading should not be used.

Larger datasets can be uploaded separately as additional files. Additional files will not be displayed in the final, published form of the article, but a link will be provided to the files as supplied by the author.

Tabular data provided as additional files can be uploaded as an Excel spreadsheet (.xls) or comma separated values (.csv). As with all files, please use the standard file extensions.

## Appendix 5: Plagiarism Declaration

1. I know that plagiarism is wrong. Plagiarism is to use another's work and pretend that it is one's own.
2. I have used the .....**Harvard style for the protocol, literature review and policy brief and biomed central style for the journal manuscript**... convention for citation and referencing. Each contribution to, and quotation in, this thesis from the work(s) of other people has been attributed, and has been cited and referenced.
3. This **mini-dissertation** is my own work.
4. I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.
5. I acknowledge that copying someone else's assignment or essay, or part of it, is wrong, and declare that this is my own work.

Name and student Number: **BARASA W. EDWINE BRSEDW001**

Signed by candidate

Signature: \_\_\_\_\_

Date: 11/03/2011\_\_\_\_\_