The Impact of Health Systems Research in Supporting In-Patient Paediatric Services in Kenya's Primary Referral Hospitals.



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Thesis submitted in fulfillment of the requirements of the Degree of **Doctor of Science**

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P2. DECLARATION

dune

This thesis represents my original work and has not been presented in any other University.

Signed

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This thesis has been submitted with my permission as the supervisor nominated by the evaluation committee

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P3. DEDICATIONS

There are indeed many persons, courses for or to which I dedicate this most likely to be final thesis to come out of me in my present life. I am not even sure in which order they should appear.

- My late parents, Mama Teresia and Papa Domasus whose patient molding oversaw the successes of my early life from conception to late childhood at a time when well below 50% of children saw their fifth birthday in that community.
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P7	LIST OF ABBREVIATIONS	
AIDS	Acquired Immune Deficiency Syndrome	
BB	Building Blocks	
CIN	Clinical Information Network	
CPG	Clinical Practice Guidelines	
CSF	Cerebro-Spinal-Fluid	
DH	District Hospital	
DHS	District Hospital Survey	
DHSG	District Hospital Survey Group	
ETAT	Emergency Triage and Treatment	
ETAT+	Emergency Triage and Treatment plus	
HIS	Health Information Systems	
HIV	Human Immune Virus	
HR	Human Resources	
HRH	Human Resources for Health	
HS	Health Systems	
HS-BB	Health Systems-Building Blocks	
HSDNEG	Health Services that Deliver for New-borns Expert Group	
HSM&EF	Health Sector Monitoring and Evaluation Framework	
HSR	Health Systems Research	
KEMRI	Kenya Medical Research Institute	
KEMRI-WT	Kenya Medical Research Institute-Wellcome Trust	

KENITAG	Kenya National Immunization Technical Advisory Group
KHSA	Kenya Health System Assessment
LHS	Learning Health Systems
LIC	Low Income Countries
LMIC	Lower Middle-Income Countries
MDG	Millennium Development Goals
МОН	Ministry of Health
NAR	New-born Admission Record
NESI	Network for Education Supporting Immunization
PAR	Paediatric Admission Record
PRIME-K	Partnership for Innovative Medical Education-Kenya
REDcap	Research Electronic Data Capture
SAM	Severe Acute Malnutrition
SIRCLE	Health Services Implementation Research and Clinical Excellence
SDG	Sustainable Development Goals
UNICEF	United Nations International Children's Education Fund
WHO	World Health Organization
WT	Welcome Trust

P8. LIST OF PUBLICATIONS CONTRIBUTING TO THE THESIS

S. No.	Ref. No.	Title	Webpage [Journal]
1	7	Assessment of in-patient paediatric	https://pubmed.ncbi.nlm.nih.gov/15194254/
		care in first referral level hospitals in	[Lancet 2004]
		thirteen districts in Kenya	
2	8	Delivery of paediatric care at the	https://pubmed.ncbi.nlm.nih.gov/15519635/
		first-referral level in Kenya	[Lancet. 2004]
3	11	Health systems research in a low-	https://pubmed.ncbi.nlm.nih.gov/18495913/
		income country: easier said than	[Arch of dis of child. 2008]
		done	
4	12	Improving documentation of clinical	https://pubmed.ncbi.nlm.nih.gov/27398232/
		care within a clinical information	[BMJ Glob Health. 2016]
		network: an essential initial step in	
		efforts to understand and improve	
		care in Kenyan hospitals	
5	13	Building Learning Health Systems to	
		Accelerate Research and Improve	https://pubmed.ncbi.nlm.nih.gov/27070913/
		Outcomes of Clinical Care in LMICs	[Plos Med. 2016]
6	14	What do we think we are doing?	https://pubmed.ncbi.nlm.nih.gov/28153020/
		How might a Clinical Information	[Res Policy Syst. 2017]
		Network be promoting	
		implementation of recommended	
		paediatric care practices in Kenyan	
		hospitals?	
7	15	Developing and introducing	https://pubmed.ncbi.nlm.nih.gov/28584069/
		evidence based clinical practice	[Arch of dis of child. 2008]
		guidelines for serious illnesses in	
		Kenya	

8	16	Developing guidelines in low-	https://pubmed.ncbi.nlm.nih.gov/28584069/
		income and middle-income	[Arch of Dis of Child. 2017]
		countries: lessons from Kenya.	
9	17	Lessons from a Health Policy and	https://pubmed.ncbi.nlm.nih.gov/32133169/
		Systems Research programme	[BMJ Global Health 2020]
		exploring the quality and coverage	
		of new-born care in Kenya	
10	18	Developing a seasonal influenza	https://pubmed.ncbi.nlm.nih.gov/30502070/
		vaccine recommendation in Kenva:	[Vaccine 37. 2019]
		Process and challenges faced by	
		the National Immunization	
		Technical Advisory Group (NITAG)	
11	10	Implementation of a structured	https://pubmed.pcbi.plm.pib.gov/16857044/
11	19	nondictric admission record for	IBMC Int Health and Human
		paediatric admission record for	Pights 20061
		district hospitals in Kenya	
12	20	A Multifaceted Intervention to	https://pubmed.ncbi.nlm.nih.gov/21483/12/
		Implement Guidelines and Improve	[PLOS Medicine. 2011]
		Admission Paediatric Care in	
		Kenyan District Hospitals	
13	21	Effect of enhancing audit and	https://pubmed.ncbi.nlm.nih.gov/30832678/
		feedback on uptake of childhood	[Implementation Science. 2019]
		pneumonia treatment policy in	
		hospitals that are part of a clinical	
		network.	
14	22	Quality of hospital care for sick new-	https://pubmed.ncbi.nlm.nih.gov/22078071/
		borns and severely malnourished	[BMC Health Serv. Research. 2011]
		children in Kenya.	
15	23	Evaluation of a training DVD on	https://pubmed.ncbi.nlm.nih.gov/26996797/
		Pneumococcal Conjugate vaccine	[Education for Health. 2016]
		for Kenyan EPI HCWs. Education	
		for Health	

16	24	Assessment of neonatal care in	https://pubmed.ncbi.nlm.nih.gov/25138104/
		clinical training facilities in Kenya	[Arch of Dis of Child. 2015]
17	25	Evaluating the level of adherence to	https://pubmed.ncbi.nlm.nih.gov/25237411/
		Ministry of Health guidelines in the management of Severe Acute Malnutrition at Garissa Provincial General Hospital.	[Pan African Medical Journal; 2014]
18	26	Adherence to Pneumonia	https://pubmed.ncbi.nlm.nih.gov/26862631/
		Guidelines for Children 2 – 59 Months at Garissa Provincial General Hospital.	[East African Medical Journal 2014]
19	27	Moving towards routine evaluation	https://pubmed.ncbi.nlm.nih.gov/25822492/
		of quality of in-patient pediatric care	[PLoS One. 2015]
20	20	Are beenitele prepared to support	
20	20	Are nospitals prepared to support	nttps://pubmed.ncbi.nim.nin.gov/19695001/
		new-born survival? -an evaluation of	[I rop Med Internal. Health, 2009]
		eight first-referral level hospitals in Kenva	
21	20	What conceity exists to provide	https://pubmed.pcbi.plm.pib.gov/29702700/
21	29		
		essential in-patient care to small	
		and sick new-borns in a high	
		mortality urban setting?	
22	30	Effective coverage of essential in-	https://pubmed.ncbi.nlm.nih.gov/29783977/
		patient care for small and sick new-	[BMC Med. 2018]
		borns in a high mortality urban	
		setting.	
23	31	Adoption of recommended practices	https://pubmed.ncbi.nlm.nih.gov/24482351/
		and basic technologies in a low-	[Arch of Dis of Child Online. 2014]
		income setting	

24	32	Effect of new-born resuscitation	https://pubmed.ncbi.nlm.nih.gov/18270586/
		training on health worker practices	[PloS ONE.2008]
		in Pumwani Hospital Kenya	
25	33	Appropriateness of clinical severity	https://pubmed.ncbi.nlm.nih.gov/29241618/
		classification of new WHO	[Lancet Glob Health. 2018]
		childhood pneumonia guidance	
26	34	Improving skills and institutional	https://pubmed.ncbi.nlm.nih.gov/29179872/
		capacity to strengthen adolescent	[Papillomavirus Research, 2017]
		immunisation programmes and	
		health systems in African countries	
		through HPV vaccine introduction	
27	76	Characteristics of admissions and	https://pubmed.ncbi.nlm.nih.gov/26662925/
		variations in the use of basic	[Arch of Dis of Child. 2015]
		investigations, treatments and	
		outcomes in Kenyan hospitals	
28	77	Delivery outcomes and patterns of	https://pubmed.ncbi.nlm.nih.gov/25841436/
		morbidity and mortality for neonatal	[Journal of Tropical Ped. 2015]
		admissions in five Kenyan hospitals	
29	78	The paediatrician workforce and its	https://pubmed.ncbi.nlm.nih.gov/32554508/
		role in addressing neonatal, child	[Arch of Dis of Child. 2020]
		and adolescent healthcare in Kenya	
30	79	Variation in and risk factors for	https://pubmed.ncbi.nlm.nih.gov/28381208/
		paediatric in-patient all-cause	[BMC Pediatrics. 2017]
		mortality in a low-income setting:	
		data from an emerging Clinical	
		Information Network	

P9. THEME AND SUB-THEME DISTRIBUTION OF THE PUBLICATIONS

Figure 1 provides descriptions of the papers central to the thesis granulated to HSR subthemes. Predominant study designs within each sub-theme are also indicated. The basis for categorization is included in the second segment.



This thesis aims to interrogate the place of HSR in enhancing care of sick children in Kenya using work done and reported by the author within his main research network, the District Hospital Survey Group (DHSG) inaugurated in 2001 which transitioned to the Clinical Information Network (CIN) in 2013. Some additional papers from other research groups involving the author are included because they were within the realm of care of sick children. Three papers focused on preventive components of HSR in relation to child health are also included though they. The other contributing research groups were the Health Services Implementation Research and Clinical Excellence (SIRCLE), Health Services that Deliver for New-borns Expert Group (HSDNEG), Partnership for Innovative Medica Education-Kenya, (PRIME-K), Kenya National Immunization Advisory Group (KENITAG) and the Network for Education Supporting Immunization (NESI). Some of the commentaries on methodologies came after the relevant research and publications they refer to. Such commentaries are, therefore, the author's interpretations of what was done with attempts to fit the methods into existing practices from literature. After the inaugural survey, all the subsequent publications from the DHSG were derived from routinely captured data. This platform later evolved into the Clinical Information Network (CIN) which manages collection, storage and synthesis of pre-determined routine clinical information on a safe electronic platform. The network ushered in an unparalleled opportunity of using routine data for policy mainstreaming and enhancement of quality of care based on locally obtained evidence.

P10. AUTHOR'S CONTRIBUTION TO THE WORK

This thesis represents a synthesis of work which may seem unrelated at casual glance but brings together extensive work from four major research groups with an overarching theme of Health Systems Research (HSR) for enhancement of child health in Kenya. There are a few additional papers from three smaller groups whose research output falls in the same sphere. The author was central in all these groups in various capacities as explained below.

The organization of the thesis streamlined the publications into four sub-themes of HSR. These are Management, Implementation, Delivery and Improvement Sciences. In-depth evaluation of the publications was made to advice categorization into these sub-themes years after the event. The author, therefore, assigned relevant papers into this thematic space many years after the events.

The District Hospital Survey Group (DHSG) was a collaboration between Kenya Medical Research Institute-Wellcome Trust (KEMRI-WT), University of Oxford, Department of Paediatrics and Child Health University of Nairobi (DOP&CH-UON), Department of Child Health and Paediatrics, Moi University and Ministry of Health (MOH) Kenya. The author was one of the founders of this group representing the DOP &CH-UON. He was a core member of the team which developed the five papers produced by this group participating in all the key stages of research and manuscript preparation. The DHSG transitioned into Clinical Information Network (CIN) whose main collaborators were, again KEMRI-WT (funder), DOP & CH-UON, MOH and Kenya Paediatric Association (KPA). The author is the focal person for DOP & CH as well as KPA.

The author was Co-Principal Investigator for the Health Services Implementation Research and Clinical Excellence (SIRCLE) project funded by the Consortium for National Health Research. This was also a collaboration between KEMRI-WT, DOP & CH-UON and MOH part of the funding was managed at the UON. The author was directly involved at all levels of research and manuscript development of the seven publications produced by this group.

The Health Services that Deliver for New-borns Expert Group (HSDNEG) was formed as an offshoot of the CIN primarily to evaluate relevant health care services within Nairobi County which had among the worst survival profiles in the country. The author was a member of this group and provided advisory for the development and subsequent publication of two highly rated papers. During this same period, the author was National Chair of the Kenya National Immunization Technical Advisory Group (KENITAG) and the Network for Education Supporting Immunization (NESI), a group based in Belgium. These two organizations published 1 and 2 papers respectively within themes of HSR. The author provided leadership in the entire processes leading to these publications. Two other papers contributing to this thesis products of a large National Institutes of Health-USA (NIH) funded project at the UON, the Maternal New-born and Child Health Linked Project. Two publications from this project involved the author at all levels of research and manuscript preparation.

In summary twenty-six of the 30 papers constituting this thesis emanated from work in which the author was key in all stages of research and manuscript preparation participating in his individual capacity as a resource leader.

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The author was also bearing the mantle of faculty member and representative of the Department of Paediatrics and Child Health, University of Nairobi. The outputs of this work in health policy enhancement and improvement of quality of care for admitted children in Kenya has been outstanding. The practice guidelines developed through this work are presently being used in other countries in the region.

The author firmly contends that his contribution to these works warrant recognition as a major shareholder of its originality. It speaks of his contribution to child health locally and beyond. The position of the UON as a source of research leaders capable of sustaining high level collaborative networks was amplified by the authors effort.

SUMMARY

S1. BACKGROUND

At the beginning of the 21st century Kenya's childhood mortality¹ was 115/1000 live births, more than the global average of seventy-five at that time². It was speculated that achieving the two-thirds reduction (from the 1990 level) envisaged by the Millennium Development Goal (MDG) 4³ would have to address curative and preventive measures in rationally proportionate measure. It was also strongly considered that success in accomplishing the MDG 4 would require improved health care provision in the subnational referral facilities which, in Low and Lower Middle-Income Countries (L and LMIC), carried the largest burdens of admitted children with life-threatening illnesses. In Kenya these were the then District (DH), renamed County Hospitals (CH) after devolution of health care in 2013. Available evidence also suggested that improving health care to scale would need an integrated systems' approach looking at health as a broad interdisciplinary program rather than isolated dispensation of vertical interventions. Care of children admitted in these hospitals, therefore, needed to function within the philosophy of Health Systems (HS) which consists of "all organizations, people and actions whose primary intent is to promote, restore or maintain health"⁴. This HS framework itself is further granulated down to six components called Building Blocks (BB)⁵. These are Governance and Leadership, Human Resources for Health, Service Delivery, Medical Products and Technologies, Health Financing and Health Information Systems.

The work constituting this thesis aimed to establish the levels of preparedness of the DHs for provision of care to children admitted with life threatening illnesses through the lens of HS-BB, follow this up with research driven interventions and confirm value of such interventions by tracing change in HS performance indicators using a second performance evaluation. The interventions towards improving HS performance supporting in-patient care was undertaken using Health Systems Research (HSR) platform which is, itself, granulated into sub-themes known as; management, implementation, delivery, improvement and operational science research⁶. These formed the basis for the intervention studies.

S.2 AIMS, OBJECTIVES AND RATIONALE

S.2.1 Aims and Objectives

The overall aim was to initiate a culture of Health Systems Research as a tool for enhancement of better child health and survival. The specific objectives sort to describe the performance indicators of HS supporting in-patient care of children admitted in primary referral hospitals, undertake interventional studies within the auspices of health systems research in response to any gaps found and finish with a post intervention performance indicator evaluation with a desire to estimate impact of such interventions.

S.2.2 Rationale

At the turn of the century, it was clear that Kenya was way off the path for attaining the newly set Millennium Development Goal (MDG) prescribing a 66.7% reduction of child deaths by the year 2015 with the 1990 level as the base¹.

The country had reported consistent increase of under five-year deaths from 1990 according to respective Kenya Demographic and Health Surveys (KDHS)¹ despite contralateral improvement for both Africa and the World during the same period. It was, hence, imperative for Kenya to do more than most for achievement of the MDG number 4. It was also obvious that efforts directed to hospital care of severely ill children were necessary to complement the more popular preventive strategies. Reports indicated that most sick children seeking in-patient care ended up in the primary referral hospitals though little was known about the quality of care provided in these facilities. It was, therefore, deliberately decided to survey a representative sample of these facilities for purposes of describing their HS performance^{7,8}. This survey revealed several gaps in performance of all the 6 HS-BB whose repair was deemed essential for improving the quality of their in-patient care. This undertaking would need elaborate interventional studies using the Health Systems Research (HSR) platform.

S.3 METHODS

S.3.1 Designs

Cross-sectional designs were used for pre- and post-intervention surveys as well as other studies describing processes and outcomes undertaken during the intervening period.

A Cluster randomised trial where individual hospitals were assigned into intervention and control groups was used for the principal implementation and several smaller sub-studies.

Other comparative designs used included parallel group (testing more than one intervention) and simple (testing one intervention).

Focused group discussions and key informant interviews were employed when engaging key stakeholders, administrators and senior clinicians.

S.3.2 Populations

- 1. Children from 0 days to 15 years for clinical data.
- 2. Health care workers for key-informant-interviews.
- 3. Care givers for quantitative interviews on infrastructure and care expectations

S.3.3 Data Management Tool

This was a web-based data capture and synthesis software using pre-determined variables entered onto the Research Electronic Data Capture (REDcap)⁹ platform. The tool is a robust online engine for data transfer and sharing. The data was then quality validated by another software known as R: Language and Environment for Statistical computing¹⁰ and then transferred to the master store at Kenya Medical Research Institute -Welcome Trust (KEMRI-WT).

S.3.4 Interventions

The multifaceted cocktail included; regular performance assessments, feedback (verbal and written), training (based on WHO ETAT), dissemination of CPGs and job aids, regular supervisory visits, on-site problem-solving sessions and introductory seminar on the CPGs. A smaller intervention package had audit and feedback as the only components. Phased policy development platform involving multi-stakeholder engagement, collection of data for population health and policy analysis and development of concise briefs for presentation to leadership was also undertaken.

S.4 RESULTS

S.4.1 Status of the Health Systems In 2002

a) Governance and leadership

Though all the fourteen facilities reported having the statutory administrative structures, the survey was unable to ascertain their functional status. This pivotal Building Block is also responsible for policing the other five BB. In particular, it is vital for ensuring delivery of quality care by enforcing consistent use of evidence proven clinical care guidelines. That such guidelines were seldom available in the hospitals indicated a fundamental weakness in governance and leadership.

b) Service Delivery

The facilities were together admitting about 36,000 children and home to just over 34,000 deliveries per year. They had 733 beds/cots for admitted children with a median (range) per hospital of 46 (33-94) respectively. Due to paucity of data, it was not possible to compute bed occupancy, a statistic helpful in determining adequacy of and preparedness to effectively deliver appropriately scaled health services for admitted patients.

c) Service delivery quality

This sub-component of delivery aims to ensure appropriate quality of clinical care. Its indicator was evidence of utilization of recommended guidelines and protocols for management of conditions associated with serious morbidity and mortality. Guideline adherence rates in most of the clinical care categories were less than 50% with some at 0%. The service delivery BB as measured by quality of care provided to admitted children was, therefore, grossly suboptimal in the DHs.

d) Human resources (HRH)

The hospitals had inadequate compliments of health workers for the given workload with only 3 and 6 of the fourteen having a paediatrician and at least one in-patient assigned medical officer (MO) respectively. The WHO recommended and internationally approved nurse patient ratios were not met in any of the fourteen facilities. The fourteen hospitals had nineteen clinical officers (diploma holding practitioners) between them. The number of beds per member of clinical staff was 36 (range 20–73) indicating a considerable coverage disparity. The status of HSR was, therefore, inconsistent and most likely suboptimal in all the hospitals.

e) Essential products and technologies

Availability of essential medical products and technologies was analyzed revealing considerable supply chain deficiencies across the hospitals. Pooled data from the fourteen hospitals reported many essential items as rarely or never available with some variability of individual products across the facilities. This BB was also not performing at the required level.

f) Health information systems (HIS)

Critically important health information for admitted individuals include accurate and sufficiently detailed entry of clinical notes in the designated files or other appropriate documents. The survey found little of this making historical assessment of clinical care processes extremely difficult. The only data consistently available were mortality statistics showing an overall median in-patient and still-birth rates of 7% (range 2.8-15) and 4.4 (2.6-6.6) % respectively.

Also available were case fatality proportions for; malaria 5% (2-10), Anaemia 17% (3-46), Pneumonia 6.5% (2-20), Diarrhoea/ dehydration, 6% (3-21) and new-born 26% (15-55). The wide inter-hospital ranges were difficult to interpret given the close comparability of resources across the facilities. Paucity of clinical notes make disease specific data unreliable.

g) Health Financing (HF):

Specific analysis of the financial profiles of the hospitals was not purposefully included. It was, nevertheless, confirmed that despite official policy advising free care for all children less than 5 years in the public sector eleven of the 14 hospitals were levying such fees. The survey also found evidence of frequent issuance of external prescription for essential medicines and other products for out-of-pocket purchase. These findings showed that HF as a BB was performing below expectations.

These survey findings advised the need for designing and undertaking studies aimed at bringing about change, hence, the HSR summarized in the next section.

S.4.2 Intervention Studies

These were undertaken in line with the Health Systems Research Sub-thematic tracks, of management, implementation, delivery and improvement sciences. The publications reporting these findings are presented in sub-thematic order below.

a) Management science

The first paper in this section was an extensive literature review of challenges of HSR in L and LMIC¹¹. These were found to include cost of well-designed studies, difficulties in generalizing results from small numbers of facilities and absence of sufficiently skilled researchers.

The review proposed a pathway for affordable HSR in LMICs based on the local experience. The second paper described the structure of the Clinical Information Network (CIN)¹² established and inaugurated in 2013.

The CIN was noted to have demonstrated capacity to become the source of robust clinical data taken in real time and capable of providing substrate for supporting clinical trials and evidence for policy mainstreaming. This paper also reports suggestions of how this invention could become a vehicle for revolutionizing HSR in LMICs.

Another paper, in the sub-theme, based on extensive literature review analysed the functioning clinical research networks which use routinely collected data as a substrate for policy and clinical guideline development¹³. Detailing the local CIN experience the paper provided suggestions for other LMICs to emulate. The possibility of such networks being embedded into official policy in Low and LMIC health systems was proposed by the paper. The third paper was a retrospective deconstruction of the processes deployed in the guideline development and dissemination as a rationalization of the methodologies used¹⁴. The paper described approaches employed to enhance wider by-in and acceptance of clinical practice inventions and strategies. The section includes a paper on the processes and strategies employed in developing and introducing evidence based clinical practice guidelines (CPG)¹⁵ for managing serious illnesses responsible for the bulk of admissions and deaths in primary referral hospitals.

This is followed by a fifth publication describing the prototype of guideline development for LMICs as successfully deployed in Kenya with recommendations of how such countries could replicate the approaches¹⁶.

A comprehensive review paper in this sub-theme analysed local efforts in Health Policy Research for improved care of newborns¹⁷.

The paper detailed the stepwise processes involving elaborate literature reviews to help establish evidence advised policy guidelines for enhancing new-born care in Nairobi City, engagement of a wide spectrum of key stakeholders for fine-tuning and by-in and finally establishing dissemination and up-scaling strategies for reaching high end decision makers. Upon request by the Ministry of Health a policy brief advising pilot introduction of a new vaccine into the country's routine immunization program was developed using desk review research, stakeholder engagement and elaborate deliberations by the relevant statutory advisory committee¹⁸. This, too, is an example of health policy research.

b) Implementation Science

The focus in this sub-thematic area was to bring about change in service delivery quality through research. The CPGs developed as described in the management sub-theme were subjected to scientific inquiry seeking to confirm their effectiveness for improving the poor clinical care performance revealed by the 2002 survey^{7,8}. The first paper in the sub-theme reported successful development and field testing of a Paediatric Admission Record (PAR) chart¹⁹. This was in response to the poor state of clinical notes revealed by the inaugural survey. It was expected that a good system of documentation would be useful in supporting implementation of the CPGs.

After introduction, the PAR improved capture of individual clinical records more than 4fold. The next three papers²⁰⁻²² report successful introduction and enhanced uptake of new CPG using the multifaceted intervention approach.

The section closes with a paper reviewing the use of digital versatile disc (DVD) as a training tool for enhancing new vaccine introduction²³.

c) The Delivery Science

The sub-theme interrogated the science of bringing best practices of care to patients. The publications in this sub-theme included three evaluating build-up in utilization of CPGs in managing high morbidity and mortality impact conditions²⁴⁻²⁶, three reporting enhancement of structural and process capacities in providing services within the health facilities ²⁷⁻²⁹ and one addressing coverage of these services in terms of ability to satisfy population needs³⁰. The papers were part of the evidence demonstrating the impact of HSR in enhancing service preparedness and quality.

d) Improvement science research

This discipline focuses on regular and timely upgrade of strategies and tools used in delivery of services for enhanced performance. Four papers conforming to this sub-theme are discussed in this section. These papers addressed; 1) adoption and scale up of recommended practices in low-income countries demonstrating improvement though at slower than expected rates³¹, 2) improvement in neonatal resuscitation in a large hospital following an abbreviated training³² and 3) testing appropriateness of a simplified clinical severity classification for improvement of care³³. The latter paper analyzed the pros and cons of outsourced protocol modification with emphasis on ensuring appropriate interrogation of such improvements before local deployment.

The fourth and final paper in this section established potential improvement in national acceptance of public health interventions through multi-country program engagements with rigorous idea sharing³⁴.

S.4.3 State of Health Systems Supporting In-Patient Care in 2015

This survey aimed to estimate the impact of HSR interventions advised by the 2002 survey. The new survey revealed considerable improvement in data quality compared to the 2002 status^{7,8}. Data on case fatality, multi-syndrome contributions and specific mortality risk factors was now available. The thesis includes a publication on new-born data which provided additional evidence of improved clinical data quality compared to the first survey of 2002. Additional data analysis demonstrated definite improvement in other HS performance indicators when compared to the same measures in 2002. Human Resources for Health also showed some improvement especially in the distribution of paediatricians.

S.5 CONCLUSIONS AND RECOMMENDATIONS

S.5.1 Conclusions

- The state of health systems supporting in-patient care of children was poor at the turn of the century coinciding with a period of steady deterioration in child health indices during the last decade of the 20th century.
- Concerted interventional HSR demonstrated significant value in improving policies, structures and process for in-patient care children of admitted in Kenya's primary referral hospitals.
- 3) In creating the CIN and commencing its transition to a Learning Health Systems platform, Kenya joins an elite group of countries with such innovation. The CIN is potentially part of a health information infra-structure, hence, its development also supports the governance BB.

- 4) The road to policy research is tortuous and often long. The thesis demonstrated some of the ways of overcoming such challenges. The stepwise multi-stakeholder approach with emphasis on building coalitions for enhanced by-in helped start the process of changing paediatric care policies in Kenya. Concerted and sustainable effort will be required to drive this important agenda further.
- 5) The post-intervention evaluation demonstrated improvements in three health systems building blocks; Governance and Leadership (improved availability of CPGs, Service Delivery (improved utilization of CPGs) and Health Information Systems (availability of robust data). These were direct consequences of the research

RECOMMENDATIONS

- 1. The clinical information network which covers in-patient care in Kenya's primary referral hospitals should be expanded to include all public hospitals providing related and other high impact care.
- 2. The HSR model elucidated in this thesis is recommended for other disciplines and in other countries for effective response to major health problems.
- Given the vastly important application(s) of Health Systems Research exemplified by this thesis, it is recommended that medical training institutions include the discipline within their curricula.
- 4. The three stage Health policy research (HPR) model elucidated by this thesis is recommended as a tool for similar deployment by others.

1.0 CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

1.1.1 Health Systems

Although concerns around organization of health care have been around since the 19th century elaborate attempts to define health in programmatic terms dates back only as recently as the 1960s³⁵. In the earlier years health care constituted accepted interventions without a uniting programmatic infrastructure. Health care was, therefore, being delivered longitudinally as independent interventions. The first major milestone in the genesis of HS as an integrated program begins with the global movement leading to the Alma Ata Declaration of 1978 whose ambitious target was to unify health issues into a broad based integrated platform³⁶. The overarching theme embodied in the Alma Ata Declaration was "Health for All by the year 2000", a milestone the world never got anywhere near achieving. A decade after launching Alma Ata a prolonged period of economic downturn ravaged much of the donor dependent developing countries resulting in re-direction of energy to cost rationalization at the expense of system enhancement. Developing countries, like Kenya, were enslaved by what was called the Health Sector Reform program³⁷ whose impacts were more negative than useful to hospital-based care services and population health in general. The 21st century was ushered in with the realization that the Alma Ata dreams had failed to deliver health for all. The world's health platform needed re-direction with the knowledge that major changes would be required if efficient and equitable programs for health were to be realized.

This realization contributed to the global push towards establishing integrated processes recognizing the diversity and range of factors directly or indirectly impacting on individual and population health. The transition from the *Health Items* approach of the past to *Health Systems* was upon the global community and the World Health Organization (WHO) was charged with the task of providing the necessary platform for guiding and overseeing its progression. The WHO then defined HS as *"that which consists of all organizations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities. A health system is therefore more than the pyramid of publicly owned facilities that deliver personal health services^{38."}*

The organization further granulated HS into six components called Building Blocks (described in figure 2A). The six building blocks; service delivery, health workforce, health information systems, medical products and technologies, health financing and governance and leadership collectively address pivotal components within the overall health care agenda. The building blocks are inter-dependent making dysfunction of any one capable of interrupting efficiency of all of them. Governance and leadership is, however, traditionally regarded as the fulcrum around which the others coalesce (see figure 2B). The building blocks need to be in optimal deployment to ensure realization of national and global goals of improving the health status of all while providing necessary protection against other societal threats to global wellness.


Figure 2: Health Systems Building Blocks

Deployed optimally, they should ensure health needs and costs do not collapse family and national economies. Like all programmatic processes there was need to set clear and robust Monitoring and Evaluation (M&E) processes with measurable indicators to track performances³⁹.

1.1.2 Health Systems Performance Indicators

Interventional systems of this nature require robust evaluation and monitoring mechanisms with reliable tools sensitive to set indicators³⁹. Such monitoring is expected to ensure uninterrupted, predictable and beneficial link between inputs (provision of health care through the deployment of organized HS) and outcomes (improvement and maintenance of individual and population health). Health funders and administrators also need this information which helps them in relevant planning. The HS performance indicators are primarily designed to provide standards for countries with overarching goals of helping them strike the balance between population requirements and service availability, quality and delivery. They advise political and administrative leadership on the resources needed to provide optimal health care for their populations while being able to measure the performance of the services so provided and compute the cost benefit of interventions. Global health advocacy movements often use such data in positioning health care as an investment.



Figure 3 shows the recommended WHO performance indicators for each Building Block.

The indicators include quantitative (number of hospitals or beds per population or inventory of health products, qualitative (development and utilization of policies and guidelines) and some multi-dimensional parameters (ratios and indices, budgets). Though the list in figure 3 refers to National and Regional units, extracts from these can be used for hospital or specific program evaluation. Expected norms of these indicators are periodically published by the World Health Organization

*The specific items included in the governance and leadership performance indicators are:

- i. Up to date published national medicines policy.
- ii. Policies on medicines procurement that specify the most cost-effective medicines in the right quantities, competitive bidding of suppliers of quality products
- iii. National strategic plan for prevention and management of tuberculosis
- iv. National malaria treatment and prevention strategy policy.
- v. National Composite Policy on prevention control and management of HIV/AIDS.
- vi. Comprehensive maternal reproductive health policy policy consistent with the International Conference on Population and Development (ICPD) action plan
- vii. Comprehensive and updated multi-year plan for childhood immunization
- viii. Health sector documents that are disseminated regularly (such as budget documents, annual performance reviews and health indicators)
- ix. Mechanisms, such as surveys, for obtaining opportune client input on appropriate,
 timely and effective access

These are each scored as 0 if absent or 1 if present to produce what is referred to as policy index.

1.1.3 Health Systems Research

In 2012 an expert opinion group defined HSR as "a multidisciplinary field of health research which studies governance, financial and delivery arrangements for health care and public health services, implementation considerations for reforming or strengthening these arrangements, and broader economic, legal, political and social contexts in which these arrangements are negotiated and operate. The purpose of health systems research is to improve the understanding and performance of health systems. Health systems research includes all of health services research, most health policy research, and some clinical and population health research, but does not include any biomedical research" ⁶. Programmatic health care research goes under many names. Steven J. Hoffman⁶ identified four terminologies namely Health Services, Health Systems, Health Policy, Population Health as well as Clinical-Behavioral Research as terms commonly used in contemporary literature. These and their interrelationships are outlined in figure 4.

The distinction between systems and services (the two most frequently used theme terms) research attracts the most controversy among experts with many using them interchangeably. There are those, however, who consider services research as that confined to individual interventions (treatment of diseases, deployment of care processes etc.) while systems research encompassing broader approaches often traversing the length and breadth of HS building blocks. Figure 4 (1) shows the four traditional Health Systems Research themes described above intersecting with each other implying that delineation in terms of themes is not always clear-cut and many study questions traverse two or even all four.



Figure 4: Inter-Relationships Between HSR Themes (1) and Subthemes (2)

The diagram indicates that policy research requires some or all the other three themes for effective implementation. This is not surprising given that policies require wide ranging stakeholder involvement if buy-in and acceptance is to be assured. In figure 4 (2) the main HSR themes are further granulated into 5 subthemes: Management Science (development and implementation of health policy and practice), Implementation Science (study of methods for converting evidence to practice), Delivery Science (bringing best practices of care to every patient every time), Improvement Science (determination of effective improvement strategies) and Operational Research (developing solutions to operational problems in health care delivery). There is considerable overlap among the sub-themes as well.

1.2 LITERATURE REVIEW

The thesis is premissed on two research themes, HS perfomance indicator surveys and intervention studies aimed at providing solutions thereon. The latter was triangulated alongside four of the established sub-themes of HSR, management, implementation, delivery and improvement sciences⁶.

1.2.1 Health Systems Performance

There are few publications in the public domain reporting comprehensive hospital based HS-BB performance scores and from LMICs. The first two such publication from kenya came after the first survey discussed in this thesis. These were the: Kenya Health System Assessment (KHSA) 2010⁴⁰ and Health Sector Monitoring and Evaluation Framework (HSM&EF) 2018⁴¹ included several hospital care based indicators. The KHSA was not a routine government activity having been made possible by a cross-section of donors leveraging on funds availed by the HIV/AIDS and Tuberculosis programs. It, nevertheless, provided the first published evaluation of Kenya's HS using a variaty of qualitative and quantitative methodologies. The KHSA processes consisted of consensus-building meetings with the ministries of health, large stakeholder meeting donors, implementing partners, bilateral organizations and government involving representatives. In addition, national-level key informant interviews and field visits to facilities and health management offices were undertaken. Several of these methodologies were used in the intervention studies discussed in this thesis. The report attempted to traverse all the 6 HS building blocks.

The survey reported presence of statutory governance structures in most facilities though their functional efficiency was hindered by difficulties related to the health portfolio being manged in two separate ministries at that time. Many strengths as well as inadequacies were identified amongst the HS-BB indicators and appropriate recommendations made available to the two Ministries of Health.

The Health Servises Monitoring and Evaluation Framework report published in 2018 was more granuler in the area of measurable indicators of HS performace. This survey focussed in 4 areas described as:

- 1. Impact which measured improvement of health outcomes particularly mortality among different categories of people
- 2. Pre-set health and related service outcome targets including disease prevention and elimination. These included uptake of measures necessary for achieving the targets.
- Health investment output. The indicators here included measures of access to and quality of health services
- Health input and process investment. The indicators here included those relevant to Service delivery systems, Health workforce, Health products, Health financing, Health leadership and Health Information.

This survey covered the HS-BB indicators with more granularity than the first one. These two reports constitute the most comprehensive assessment of Kenya's HS performance in the first two decades of the 21st century. The indicators used in the surveys supporting this thesis were extracted from these pioneer surveys.

1.2.2 Health Systems Research

By the time the research activities leading to this thesis were conceived (at the turn of the 20th century) the Global Health community and WHO had already proposed that HS and HSR be given utmost attention. This commitment was exemplified by former Director General, *Dr.* Margaret Chan's remark in 2007; "Something is wrong. For the first time, public health has commitment, resources, and powerful interventions. What is missing is this: the power of these interventions is not matched by the power of health systems to deliver them to those in greatest need, on an adequate scale, in time. In part, this lack of capacity arises from the failure of governments all around the world to invest in basic health systems. It also arises, in part, from the fact that research on health systems has been so badly neglected and underfunded. The two go together. So long as investments in health systems are given low priority, research in this area will also be neglected. In the absence of sound evidence, we will have no good way to compel efficient investments in health systems^{6°}. Such research, however, needed to be made relevant in-country for optimal impact.

Reducing child mortality in developing countries had again become the focus of some attention⁴² and increasingly, the critical role of functional health systems in delivering effective interventions was acknowledged^{43,44}. The delivery of several interventions, especially case management, needed to assume a pyramidal structure of primary health care, with the district hospital and associated district health administration at the system's apex^{45,46}. Such centers were expected to provide appropriate local expertise in-house while supervising peripheral units. The facilities were expected to contribute vital morbidity and mortality data to national health information systems.

This would, in theory, allow distribution of resources according to need. Care in district hospitals was therefore expected to have a large effect on the overall performance of health systems. However, little was known about the effectiveness of such facilities in sub-Saharan Africa, although broad based assessments for international benchmarking⁴⁷ had been optimistically proposed.

Reduction of child mortality by two-thirds in developing countries by the year 2015 was one of the Millennium Development Goals adopted by the major global economies⁴⁸. Large gains were considered possible with wide utilization of available, simple interventions⁴⁹. As many researchers acknowledged, health systems in poor countries were often incapable of delivering even currently recommended interventions⁵⁰. Understanding how care is provided and appreciation of attending barriers to effectiveness of the processes involved were important steps in tackling existing constraints. The first-referral level hospital (the district hospital) was an integral part of primary health-care systems, providing leadership, supervision, and care for the severely ill in support of a network of peripheral primary-care providers⁵¹. In view of these hospitals' potentially critical role in the delivery of health services and improvement of child survival it was deemed important to explore the role of HSR in enhancement of quality of services in these important facilities. This was also in the background of knowledge that perceived quality of care could be a major determinant of hospital use, and therefore efficiency and effectiveness⁵². The HSR undertaken following was aligned to the sub-themes of management, implementation, delivery and improvement sciences.

Health management comprises activity around the development and implementation of policy and the organization of services aimed at improving health. The focus is on delivery and effecting change in organizations concerned with improving population health⁵³. This sub-theme of HSR speaks to the pivotal HS-BB of leadership and governance. In the background of poor HS performance revealed by the 2002 survey the need for finding solutions through management research was paramount. There was need to set up the organizational infrastructure to support establishment of relevant innovations for better care, most important of these being clinical practice guidelines. Equally important was the need to set up reliable routine data collection systems.

Implementation research is the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice leading to improvement of the quality and effectiveness of health care. It includes the study of influences on healthcare professional and organizational behaviour⁵⁴. Implementation research constitutes the next step (after developing effective tools through management science) in the strive to improve services by ensuring effective deployment of interventions. This has been done previously using comparative studies including the multifaceted cluster randomised controlled method with multiple interventions⁵⁵.

Health care delivery science⁵⁶ focuses on how patients receive care. From using engineering principles to determine the most efficient way to schedule patient appointments to research focusing on the most successful, cost-effective means for delivering treatment, this discipline's aim is to enhance the patient's experience.

It does this by improving quality, outcomes and cost. The publications under review in the sub-theme have been granulated further into three categories, quality, capacity and coverage of health services. Quality of health service delivery referred to the uptake and appropriate use of clinical practice guidelines (CPG) for conditions contributing the highest burden of in-patient morbidity and mortality. The measured indicator was CPG utilization rates as recommended by The National Roundtable on Health Care Quality, Institute of Medicine⁵⁷. Capacity for service delivery is defined in this thesis as availability of system structures and processes supporting provision of in-patient care at levels commensurate with expected needs. For purposes of this thesis, coverage of services was regarded as a supply-demand balance of in-patient care services measured by geographic spread of facilities and fulfilment of the needs of the catchment population(s). The WHO has developed recommended norms for most of these parameters⁵⁸.

Improvement science⁵⁹ recently emerged to provide a framework for research focused on health-care delivery improvement. The primary goal of this scientific field is to determine which improvement strategies work as we strive to assure effective and safe patient care. Modern medicine enjoys rapid changes in both technology and practice. This invites the need for versatile ways of establishing if the new or improved inventions achieve the desired goals in real life. Three studies reported in this thesis involved designs related to this sub-theme.

1.3 AIMS, OBJECTIVES, HYPOTHESES AND CONCEPTUALIZATION

1.3.1 Aim, Objectives and Hypotheses

Aim

The overall aim of the thesis is to crystalize the role of Health Systems Research as a tool for enhancement of child health and survival.

Objectives

- To provide a thematic narrative of the author's 15 plus years of work leading to 30 high impact articles in health systems research supporting child health and survival with particular emphasis on in-patient care of children with serious and life-threatening illnesses in Kenya
- 2. To describe and analyze the impact of Health Systems Research based interventions in improving care of children admitted to primary referral hospitals in Kenya.
- To communicate the role of health systems research in supporting policy and practice for improved child health and survival outcomes as espoused by the author's literary outputs.
- 4. To present the author's health systems research experiences and outputs as tools usable by others in the child health and survival research community

Hypotheses

 Health Systems Research is growing at a much slower rate in LMICs compared to the HICs, therefore, concise communication of such development will help the LMIC researchers work towards bridging this gap. 2. Health system challenges are shared across geographies suggesting added value if corrective research were deployed through collaborative efforts. The communication coming out of this thesis may help initiate such collaborations in LMICs

1.3.2 Conceptual Framework

The conceptual flow of the thesis is illustrated in figure 5. The build-up starts with a survey in 2002 which evaluated performance indicators in line with the WHO HS-BB. The survey findings advised the need for research driven interventions aimed at improving are processes and quality. The thesis then describes the sub-thematic research around Management, Implementation, Delivery and Improvement sciences deployed in the postsurvey intervention period.



The second HS performance survey with its global findings constitutes the third part of the conceptual flow. The fourth and final component displays the collation of the scientific outputs to the thesis plus an indication of the overarching contributions of the thesis to science.

2.0 CHAPTER 2: MATERIALS AND METHODS

Executive summary of methodology papers

Health systems research in a low-income country: easier said than done¹¹. This paper described the evolution and final design of intervention studies attempting to improve hospital care for children in Kenyan district hospitals. It brought out many of the difficulties involved in reconciling epidemiological rigour and feasibility in studies at a health system rather than an individual level and the importance of comprehensive analysis when trying to provide a plausible answer to the question - does it work?

*Implementation of guidelines for improving in-patient Paediatric Care*²⁰. Given the poor quality of care found in the 2002 survey a cluster randomized controlled trial was used to support introduction of newly developed Clinical Practice Guidelines. This trial used four hospitals receiving a full package of interventions: evidence-based guidelines, training, job aides, local facilitation, supervision, and face-to-face feedback and four in the control group with only guidelines, didactic training, job aides, and written feedback. Prespecified structure, process, and outcome indicators were measured at baseline and during three and five 6-monthly surveys in control and intervention hospitals, respectively. The primary outcomes were processes of care measures, assessed at 18 months postbaseline.

How might a clinical information network be promoting implementation of recommended paediatric care practices in Kenyan hospitals?¹⁴. The creation of CIN was a means to promote implementation of recommended clinical practices targeting inpatient paediatric care.

This commentary described the network's activities conducted over its first 2.5 years by deconstructing the implementation process into specific components and providing an interpretation of the network function as an intervention. The paper reported with emphasis that these activities were achieved using published typology of implementation components to give greater granularity to this description from the perspective of those delivering the intervention.

Developing and Introducing evidence based clinical practice guidelines for Serious *Illness in Kenya*¹⁵. To help improve hospital management of the major causes of inpatient childhood mortality, simple clinical guidelines were developed to help improve quality and effectiveness of in-patient care in Kenya. The participatory process used to adapt existing WHO materials and further develop and build support for such guidelines is discussed in this paper. To facilitate use of the guidelines job-aides were also developed. Relevant training programs were used to support the implementation and dissemination of these guidelines. The training was based on modern theories around adult learning while deliberately attempting to reach a 'critical mass' of health workers within each institution at low cost. The process described here is among a handful of attempts globally to implement in-patient or referral care components of WHO / UNICEF's Integrated Management of Childhood Illness approach⁶⁰. Lessons from a Health Policy and Systems Research program exploring the quality and coverage of new-born care in Kenya¹⁷. In response to global calls for research to support health system strengthening in LMICs the nature and magnitude of gaps in access and quality of in-patient neonatal care provided to a poor urban population was examined using multiple epidemiological and health services methodologies for the larger Nairobi geography.

*Improving documentation of clinical care within a clinical information network: an essential initial step in efforts to understand and improve care in Kenyan hospitals*¹². In many low-income countries health information systems were poorly equipped for effective provision of detailed information on hospital care and outcomes. Information was rarely available or used to support practice or its improvement. This paper described efforts to tackle this challenge and further foster learning driven by collection and use of routine clinical information. It describes the process used in development of a Clinical Information Network involving primary referral hospitals, policy makers and researchers whose goal was for enhancement of HIS.

2.1 HEALTH SYSTEMS PERFORMANCE SURVEYS.

The two pioneer HS performance indicator survey reported from Kenya identified a number mesurable within available information^{40,41}. Figure 6 has the a selection of indicators extracted from these reports and those used in the surveys.



A selection of these were used in the 2002 and 2015 surveys to form gaps assessment and impact of interventions evaluation, respectively. These were both cross-sectional studies. The 2002 study used retrospective data in hospitals while the 2015 survey benefited from an already functional Clinical Information Network (CIN) which had preentered data easily available for analysis.

The 2002 team surveyed inpatient paediatric care in the designated district hospitals between July 8, and Oct 4, 2002. Data were obtained by three teams of three to four people working in parallel at separate hospitals. All survey staff were skilled Kenyan health workers trained for 3 weeks in survey procedures including pilot exercises in one district and one provincial hospital. The main source of this data was retrospective hospital records. General health worker and some key informant interviews were also done especially in search of inventory-based information. This survey attempted to describe indicators for all the 6 HSBB though in the end only the Delivery, Human Resources and the Medicines BBs had sufficient data for sizable reporting. The 2015 survey used data from thirteen hospitals engaged in the Kenyan CIN between April 2014 and March 2015. Data were captured from medical and laboratory records as well. The focus here was on delivery and health information systems with some contribution from some human resources from a sister research group.

2.2 THE INTERVENTION STUDIES

2.2.1 Designs

A review paper¹¹ analysed the challenges of, and potential solutions useful for, successful mounting of meaningful HSR under 4 sub-headings: 1) Assessment of structural competences of hospitals and quality of clinical practice as indicators of HS performance, 2) Selection of study designs appropriate for answering questions relevant for the selected interventions, 3) Identification of hospitals with sufficient workload, geo-epidemiological distribution representative of population of interest and 4) Selection of appropriate interventions with measurable process and if possible biological impact as well as appropriate tools.

Assessing hospitals and clinical performance. The most visible measure in line with common tradition for the intended studies was reduction of in-patient mortality as a primary outcome. This relatively easy to measure parameter comes with several challenges if it were to be used as the health service performance indicator in a hospital setting. If a randomized controlled trial design were preferred, each facility would represent only 1 observation. The sample size, feasibility and cost implications are obvious for coverage of a sufficient number of hospitals representative of Kenya. Even a census of all the 70 district hospitals available at that time may not have been adequate. The focus on mortality may also result in other valid outcomes like efficient resource use, prevention of errors or reducing hospital stay being ignored yet these are the ones more easily comparable across facilities. The quality of data for the determination would be questionable given the poor state of Kenya's health information systems at that time.

Then there would be the question of different disease patterns across the hospitals, for example prevalence of malaria which may bring about differences in mortality between hospitals depending on varied endemicity across the locations of the facilities. This could result in considerable residual confounding unless large, random samples of hospitals were studied.

While, in theory, it might have been possible to adjust for case-mix, this would have required very high-quality data which was not and is very rarely available in LIMC like Kenya. Variability of case severity at presentation posed another challenge, pneumonia mortality rates, for instance, will vary depending on the proportion of admitted cases with severe or very severe disease demanding high quality data with large number for reliability. In-patient mortality would, therefore, not be a reliable primary outcome for a policy informing HSR study notwithstanding the ease and cost benefits of using it as an outcome indicator. The use of simple process indicators^{61,62} reflecting the degree to which best practice was provided with appropriate endpoints was explored. This was found to have many desirable properties such as; allowing comparisons of individual health worker practice and hospital performance indicators as measures of differential quality of care, targeting of the most desired attributes of service delivery, cheap and easy to measure outcomes, ease of rapid incorporation of new or additional elements and capacity to provide results which are intrinsically meaningful to service providers. It was expected that process measures may be affected by the degree to which inputs (resources) are available. With these considerations selection of desired interventions to be applied and tools to be used in Kenya's first elaborate and focused HSR was undertaken.

Appropriate study designs. The ideal intervention study is a randomized placebocontrolled trial. This is seldom possible in HSR since research questions at this level will be about an intervention whose efficacy has already been proven by primary studies elsewhere. Randomised parallel group-controlled intervention designs whose end point was improved in-paediatric care for children was found most appropriate. In this design both groups receive interventions though the test arm has more.

Choice of hospitals to be included in the study. Kenya had eight provinces and 70 districts each with a primary referral hospital making selection a challenge if research costs were to be contained. There was a need to ensure representation of diversity while limiting selection bias with a relatively small sample size. The demands for research efficiency without compromising the value of the results had to be met as well. Another consideration was the need to insist on a minimum hospital workload to permit time limited performance assessment while restricting geographic sampling to limit the number of stakeholders who must be consulted and kept informed as important practical considerations. Steps to ameliorate these challenges were devised and deployed. The intervention hospitals were sort for selection in collaboration with the Kenyan Ministry of Health from four of Kenya's eight provinces avoiding areas with existing major hospital management intervention projects. Eight hospitals from these 4 provinces each having a minimum of 1,000 paediatric admissions and 1,200 deliveries per year were identified and selected for this phase of the work. Seven of the chosen hospitals had participated in the 2002 survey.

Table 1 shows the selected hospitals and their profiles. The actual names of these hospitals were not published as per agreement with the relevant authorities.

Hospital	Malaria transmission setting	Antenatal HIV prevalence	Infant Mortality per 1000	Catchment population poverty∞	Annual paediatric admissions
Intervention	Highland	High*	70	50 - 70	5,000
Control	Highland	High	>100	50 - 70	4,500
Intervention	Intense	High	>100	50 - 70	3,500
Control	Intense	High	>100	50 - 70	2,500
Intervention	Low	Mod**	40	35	3,300
Control	Low	Mod	40	35	1,800
Intervention	Arid	Mod	70	50 - 70	1,700
Control	Arid	Mod	70	50 - 70	1,100
>10%*, 5-10%**, Income <\$2/day %∞					

Table 1: Parameters of hospitals used in the randomized trials.

To ensure balance when the facilities were divided into two groups, one of the original eight hospitals was replaced with an alternative facility. The 8 hospitals were randomly assigned the 8 hospitals into intervention (n=4) and control (n=4) groups based on the parameters described in table 2.

Identifying intervention strategies. Suitable interventions using appropriate tools to bring about change of health worker practices were an essential requirement. Multifaceted interventions including training, job aides, feedback, quality improvement and supervision were employed for optimising uptake of practice guidelines.

These were incorporated in the response basket. There being no such tools or structures in Kenya at that time, they had to be developed de novo, in collaboration with the Ministry of Health and other stakeholders, keeping in mind what might be sustainable.

2.2.2 Processes

This section describes the processes employed in developing and introducing Clinical Practice Guidelines reported in a commentary paper from the network¹⁵.

2.2.2.1 Developing The Clinical Practice Guidelines

The preliminary stage involved definition of three important targets, diseases to be included, the most important users and a rationalised scope of the tools to be used.

The diseases: The illnesses responsible for more than 80% of paediatric hospital deaths locally^{19, 62} were identified as malaria, anaemia, pneumonia, asthma, severe diarrhoea, severe malnutrition, meningitis, neonatal sepsis, birth asphyxia and prematurity / low birth weight. In addition to these; basic life-support, convulsions, hypoglycaemia, and HIV were considered cross-cutting problems. This advised the decision to develop where absent, update if present and out of date and popularize those simply being underutilized (HIV testing and new-born / paediatric resuscitation) CPGs for all these conditions.

The potential users: In Kenya most initial clinical care for hospitalized children is provided by clinical officers (who undertake a 3-year diploma training) and nurses, the latter being the major providers of new-born life support and immediate care of the sick new-born in nurseries¹⁴.

Junior physicians provide some care but senior physicians or qualified paediatricians are rarely available early in an admission. In view of these observations, it was decided that nurses and clinical officers be the target trainees as this would lead to bigger impact and reach.

A rationalized scope of CPG: Most deaths of children in Kenya's hospitals occur within 24-48 hours of admission^{63,64}. The CPGs were therefore aimed at ensuring that appropriate initial care could be provided by health workers with limited paediatric training using highly directed guidance based on illness severity assessment. The guidance used the ten immediate and distinct therapeutic life-saving strategies (antibiotics, fluids, oxygen etc.) and some key laboratory tests. The stepwise process leading to production of the CPG is illustrated in figure 7.



<u>Training approach</u> to assist CPG implementation is summarized in table 2 which details the adult learning methodologies used.

Methodology	Description		
Behavioural	Didactic sessions in optimising achievable forms of care through		
change model ⁶⁵	repeated interactive learning sessions.		
Adult learning	Active participatory learning in small group interactive sessions		
theories ⁶⁶	with multi-method approaches.		
Social influence	Deliberate involvement of local experts in development of the		
theory ⁶⁷	CPGs, training facilitation by credible individuals thereby building		
	trainee trust.		
Diffusion of	Institutional dissemination of guidelines, extensive training' to		
innovation	create a critical mass of people supporting the new practices,		
theory ⁶⁸	simplified guidelines and introduction of time-saving job aides.		
Health education	Deployment three strategies; best practice lectures about the		
model ⁶⁹	CPGs based on available resources (predisposing), use of job		
	aides, practise of skills (enabling) and feedback on personal		
	performance (reinforcement).		
Reflection ⁷⁰	Using problem-based audit, hospital survey and feedback, small		
	group learning, role-play, case scenarios with team of hospital		
	colleagues emphasising successful performance and post course		
	evaluation.		

Table 2. Behaviour change teaching methodologies

This involved a rigorous course development process which created a modified WHO Emergency Triage Assessment and Treatment (ETAT)⁷¹. The modification being expansion of care from the first contact to the first 24-48 hours (period of most deaths^{63,64}) in the ward. This upgraded course and care principle was re-named **ETAT+.**

2.2.2.2 Promoting Local Ownership of the Clinical Practice Guidelines

Ensuring that evidence-based practice is adopted both as a policy and preferred practice is a well-known challenge. With this hindsight a 5-step process of building local ownership of the CPGs was embarked on.

a) Step 1

Initiating the process with a big stakeholder engagement in a national workshop hosted by the Division of Child Health (DCH) of the Ministry of Health. The meeting included representatives from other divisions of the ministry, senior paediatricians from national referral hospitals, the private sector, University Teaching Hospitals, the Kenya Paediatric Association and the Kenya Medical Research Institute (KEMRI). The purpose of this engagement was to initiate the process of adapting to the Kenyan context the WHO recommendations for in-patient care of children⁷². At this meeting, the algorithmic format of basic CPGs was presented and approved as a mechanism to assist in the implementation and eventual adoption of the guidelines for use throughout the country.

b) Step 2

Developing the CPGs using the highest level of evidence available. Thus, literature searches and evidence summaries were undertaken for all the identified conditions apart from infant and child resuscitation.

The latter were directly adopted from those suggested by the International Child Health Review Collaboration (<u>www.ichrc.org</u>) and complemented this initiative resulting in the development of a local database of evidence summaries and 434 key references.

c) Step 3

Holding a dissemination forum entitled 'Child Health Evidence Week' was hosted with 8 local and 2 international topic experts presenting and discussing the evidence alongside 36 participants of diverse backgrounds drawn from Kenya and Tanzania. This group was responsible for compilation of the first ever draft CPG.

d) Step 4

Draft copies of the CPGs were produced under the auspices of the MoH Division of Child Health. These were reviewed by senior paediatricians from the University of Nairobi and the Kenya Paediatric Association and discussed in the post-graduate teaching seminars at Kenya's largest university medical school.

e) Step 5

The final version of the CPGs was then reviewed within the Ministry of Health, endorsed and approved for publication as a 31-page booklet of "Basic Paediatric Protocols⁷³".

2.2.2.3 Training Innovations

The commentary articulates similarities between the methods used with the typology of behaviour change as had just been refined by the Expert Recommendations for Implementing Change (ERIC)⁷⁴. This was a retrospective deconstruction of the processes employed in guideline development and dissemination by the network.

The goal was to establish how the approaches used by the author's network could fit into the ERIC methodology. Table 3 makes a comparison of the author's network approach with the one refined by ERIC.

DOMAIN	ERIC STRATEGIES	NETWORK APPROACH	
Change infrastructure	Alter incentive structure	Recognition by the network team and peers	
Evaluative and iterative	Change of record system	Innovating medical records, introduction of PAR	
strategies	Change of mandate	Increased presence of seniors	
Provision of interactive Assistance	Audit and provision of feedback	Building a mechanism for capturing trustworthy data that enables measurement of practice against relevant and agreed indicators, CIN	
	Develop and implementation of monitoring tools Development and organization of quality monitoring system		
Stakeholder	Build a coalition	Deliberate effort to create a network ("a grouping that aims to improve clinical care	
interrelationship	Involve executive boards		
	Develop academic partnerships and service delivery usin		
	Conduct local consensus discussions	collegial approach to identify and implement a range of [improvement] strategies The network was initiated with a meeting of a paediatrician, a senior nurse and the health records information officer from each participating hospital and the	
	Capture and share local		
Training and	Create learning collaborative		
stakeholders	Recruit, designate, train leaders		
	Conduct educational meetings		
	Make training dynamic knowledge		
	Distribute educational materials	university partners.	
Support Clinicians	Revise professional roles	Fostering a shift of role norms for paediatricians allowing to provide ever more supervision of frontline workers through social influences	
	Facilitate relay of clinical data to providers		

Table 3: Com	ponents of the	ERIC behaviour	change methodology.

The association for qualitative research defines typology as "a way of describing groups of respondents displaying different clusters of behaviours, attitudes or views of the world" which generally consist of a set of descriptive names or "types", attached to thumbnail sketches of typical behaviour and/or attitudes for each group⁷⁵.

This was a powerful behaviour modifying set of tools with a good record in supporting implementation of intervention programs. The ERIC typology consists of 9 intervention domains which together have 73 strategies. The study employed 6 of these domains and 22 strategies in the cascade of processes which supported evidence-based guideline development (table 3). The three implementation domains from (Powell et al and Waltz et al) excluded from the retinue were 1) Adapt and Tailor to the Context', 2) 'Engage Consumers' and 3) Utilize Financial Strategies'. Adapt and Tailor domain was rejected because it would have required new. Direct financial incentives had not been budgeted for while direct engagement of consumers (the public) had not been among the objectives.

2.2.2.4 Policy development process

This was described by the Health Services that Deliver for New-borns (HSDNG) Program group¹⁷. The process followed three phases as illustrated in figure 8.

Phase 1, the preparatory activities involving establishing definitions of quality neonatal in-patient care, review of policy documents and stakeholder engagements. This required elaborate desk reviews spanning all current policies around the clinical care of admitted newborns.

Phase 2, engagement in comprehensive data collection to estimate burden, access and quality of care as well as attempting to develop care standards especially for nursing.

Phase 3, which involved the development, popularization and dissemination of in-patient new-born care policy alongside the existing Health Systems Capacity.



The broad areas covered were 1) Access, readiness and technical quality of neonatal hospital care whose findings have been extensively discussed in the delivery science research chapter with most results scoring sub-optimally and 2) Deeper exploration of the quality of care with a focus on nursing. The review analysed the impact of nurse short falls on overall quality of care on the sick new-born.

2.2.3 The Intervention Tool

The main implementation studies used a multifaceted intervention in cluster randomized controlled trials. In this method a total of nine interventions were identified for use in supporting introduction of CPGs. The nine are listed in table 4

Table 4. The intervention tools constituting the multifaceted cocktail.

Methodology and study flow					
Intervention processes		Intervention flow sequence			
1	6 monthly performance assessments	Timeline	Intervention	Control	
2	Feedback after each survey	Randomization			
а	Written feedback of survey findings	Baseline	1	1	
3	Training (based on WHO ETAT)	(time 0)	2 a	а	
b	Dissemination of CPGs		3, b, c, 4, 5	6, b, c	
С	Dissemination of job aids	6 months	1, 4, 5	1	
4	3 Monthly supervisory visits		2, a	а	
5	On-site problem solving capacity	12 months	1, 4, 5	1	
6	Introductory seminar on the CPGs		2, a	а	
		18 months	1, 4, 5	1	
			2, a	А	

The intervention group received all the nine interventions while the control group of hospitals had a smaller menu. Table 4 also shows the flow of interventions throughout the period of follow-up.

2.2.4 The Data Collection Tool

The clinical information network real time online data capture tool developed by the district hospital survey group is graphically described in figure 9.



The primary source of the data is paper records of routine clinical information written by frontline health care providers and contained in official hospitals documents. Access to this improved data was granted by formal agreement with hospital and county leadership. Extraction of this routine data constituted the first of the CIN processes step.

The second step involved activities described within the rectangle labelled Hospital Site Setup in figure 9. Here data of pre-determined variables is entered onto the Research Electronic Data Capture (REDcap)⁹ platform, a robust engine for web-based data transfer and sharing. The data is then quality validated by another software known as R: Language and Environment for Statistical computing¹⁰ and then transferred to the master store at KEMRI-Welcome Trust. The third step, at KEMRI-WT, involves storing the information into the master data base. Individual hospital reports are sent back to their origin for local consumption while pooled data is utilized for policy development and dissemination. After analysis, the data provides information for determining comparative /system performance, support pragmatic interventional trials and evidence assessment for development and updating of Clinical Practice Guidelines (CPGs).

This network was expected to support collaborative efforts towards improved care, provide better information for decision making and enable locally relevant research. It was a major milestone in enhancement of good governance and leadership by enabling availability of accurate data to advise policy and practice. This tool was pivotal in guideline development activities by the research group. The sequence of activities which supported the process of learning how to generate and effectively utilize this data tool for guideline development is presented as a flow chart in figure 10.


Trainings were provided for network and regular hospital clerks on the processes expected of them to ensure complete and accurate data capture in the Redcap platform alongside clinical teams being trained in guideline utilizations land further dissemination. These also included initial and regular reinforcements for key personnel including clinicians and administrators from the hospitals. Meetings with full hospital teams of paediatricians, nurse heads and records clerks as well as partial groupings were regularly conducted. The standard agenda was network reports, team leadership, cross hospital performance comparisons, priority setting for improvement, training on key issues and guideline development progress. In addition, feedback by either the network coordinator from Nairobi or the local paediatrician or sometimes both. The standard agenda of health care workers' meetings was review of performance records, development of solutions and support mentorship activities. There were also guideline development meetings which involved the network hospital paediatricians in panel discussions of the ongoing guideline development. Data Collection was continuously done beginning with 8 hospitals joined after 6 months by another 6 accompanied by additional training activities.

2.3 THESIS DEVELOPMENT METHODOLOGY

2.3.1 Theme and subtheme classification of the 30 papers.

Six papers were classified as Health Systems Performance indicator surveys. These were cross-sectional designs reporting indicators of HS supporting in-patient care. The commentaries and systematic reviews outlining processes used in developing the research and intervention methods were classified within the management science sub-theme. Implementation science research included papers using comparative experimental designs to test various locally developed clinical practice guidelines. On-going performances of both structural and process determinants of good practice were classified in the delivery science sub-theme. The improvement science section included papers reporting results of work done towards validating the impact of revised or modified delivery systems using experimental designs.

2.3.2 Design of the flow of the write-up

Description of the status of health systems supporting in-patient care was the first component followed by intervention studies beginning with management science systematically analysing the tools required and developed for intervention. This was followed by processes used in testing these tools using implementation science methodologies. The delivery science section was designed to analyse and report the progressive uptake of locally developed guidelines as well as other structural developments that may have been enhanced by the efforts. The thesis then evaluated recently altered delivery methods to establish value of such changes in conformity with improvement science research strategies. The thesis then draws conclusions on successes of the HSR based on improvements noted from the second evaluation.

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2.3.3 Articulation of thesis contribution to science

The final thesis methodological consideration was the articulation of the author's opinions on the contribution of this thesis to knowledge, practice, policy and perhaps childhood mortality in Kenya.

3.0 CHAPTER 3: OBSERVATIONS AND FINDINGS

3.1 THE STATE OF IN-PATIENT HEALTH SYSTEMS IN 2002

To set the stage for this HSR platform an evaluation of the status of HS performance indicators in these facilities was undertaken using retrospective data available in the respective facilities. The specific indicators for HS-BB included policy and guideline availability on-site (governance and leadership), infrastructure, workload, and service quality (service delivery), staff numbers by carder (human resources for health), stock-out rates (medical products and technologies), mortality statistics and clinical notes (health information systems) and adherence to existing policies and out-of-pocket contributions (health financing).

Executive Summary of Pre-Intervention Survey Methods

Assessment of in-patient paediatric care in first referral level hospitals Kenya⁷

Government hospitals providing first referral level care were prospectively sampled from 13 Kenyan districts using a cross-sectional survey`. Workload statistics and data documenting the management and care of admitted children were obtained by specially trained health workers. Additional information such as in-patient mortality, specific case fatality and resource constrains was also collected.

Delivery of paediatric care at the first-referral level in Kenya⁸. This publication resulted from an investigation aimed to investigate provision of paediatric care in government district hospitals in Kenya. Fourteen first referral level hospitals from seven of Kenya's eight provinces were surveyed for information on workload, outcome of admission, infrastructure, resources and the views of hospital staff and caretakers of admitted children

Service Delivery

3.1.1.1 Preparedness

Workload

Workload data is considered essential in determining the preparedness of hospitals for effective provision of in-patient care. The total annual admission was 35,794 with a range of 668 - 6275 across the hospitals. There were 34,219 deliveries per year with a range of 948-6000 across the hospitals. The breakdown is summarized in figure 11.



Figure 11 Annual Admissions and Deliveries Across the Hospitals

Based on expected population dynamics it would be expected that hospitals with large birth cohorts also have commensurately higher admission rates. This synchrony was not consistently observed across the hospitals, for instance hospital H with only 948 deliveries recorded 3,388 admissions while hospital I with 2,055 deliveries registering an almost identical number of admissions (n = 3,348). Across the hospitals, some had more admissions (e.g., B, G, L) than deliveries while others had it the other way round (e.g., A, C, D).

Infrastructure

These included numbers of bed/cots per hospital, status of hygiene infrastructure and availability of essential utilities (electricity and water). A separate survey of health workers and caregivers was performed to assess their views on infrastructure needs and adequacy. A summary of these findings is presented in figure 12.



Figure 12: Available infrastructure and interviewee perspectives on its appropriateness

The bed capacity did not always mirror admission numbers provided in figures seven, for instance, hospital L with 73 paediatric beds divided into 2 wards had only 668 admissions in a year while hospital A with only 35 beds had more than 2400 implying diverse bed occupancy statistics across the facilities. Ambulance services are essential for any health facility and primary referral hospitals were expected to even support these services in lower-level facilities within their catchment population(s). This service was available in only nine of the 14 hospitals and absent or inconsistent in 5 (36%) of the facilities. Hygiene infrastructure (hand washing for staff and caregivers) were not consistently available further degrading efficiency and safety of services provided.

3.1.1.2 Service Quality

This key component of the Service Delivery BB is deliberately discussed in a separate section. It was measured by the rates of guideline advised case management. It is an important indicator of quality and effectiveness of care and accurate gauge for appropriateness of care provided by clinicians in health facilities. The focus diseases were malaria, pneumonia, meningitis, diarrhea and malnutrition. This selection of disease specific and some cross-cutting indicators of diagnostic and therapeutic interventions were reported as median utilization rates from pooled data for all the survey hospitals. The information in the first segment of figure 13 reported adherence $\leq 51\%$ for 5 of them including danger sings and the most basic of all, weight taken at admission. The middle segment histogram has the frequency of uptake and appropriate utilization of laboratory tests for supporting care in these facilities.



Figure 13: Guideline Utilization Measuring Quality of Care

Malaria microscopy and hemoglobin levels were the only tests routinely used for diagnosis in available records with uptake of 88% and 85% respectively.

Interpretation of results was not always appropriate in advising care, for instance, haemoglobin accurately advised transfusion in only 27% of the cases. The final segment shows guideline utilization in treatment decisions. These included drug choices and doses as well as use of therapeutic supplements and support medications. In five of the 7 guidelines evaluated appropriate utilization rates for various items were less than 50%. Guideline utilization, a key hospital-based indicator for the service delivery performed poorly in all the three categories.

3.1.2 Human Resources for Health

Human Resources for Health (HRH) is the term used to describe all individuals providing health services in any geography or system. Their importance has been amplified by having a HS building block dedicated to them. The 2002 status of key HRH in the fourteen hospitals is summarized in Table 5.

Only four of the 14 hospitals had a paediatrician within the clinical workforce. The category specific numbers of frontline clinicians responsible for in-patient care in all the fourteen hospitals included 6 medical officers, 18 clinical officers and 90 nurses. This computed to an in-patient bed clinician ratio of 36:1. Assuming a worst-case scenario of full bed occupancy, available clinicians would have been grossly inadequate for providing required services in any of the hospitals. The nurse shifts were covered by an average of 4 and 2 during the day and night, respectively. None of these hospitals were, therefore, able to provide effective in-patient care in the event of 50% or more bed occupancy.

Numbers of Observations							
Hospital	Admissions	Deliveries	Paediatricians	Ward Medical officers	Ward Clinical officers	Nurses Day	Night
А	2,316	1,800	1	0	1	2	2
В	3,188	5,842	0	1	1	4	2
С	6,275	6,000	1	1	2	6-8	2-4
D	2,910	1,427	0	0	1	4	2
E	4,512	2,500	1	1	2	5	2
F	1,216	1,048	0	0	1	2	2
G	2,236	3,702	0	0	0	4	2
Н	3,388	948	1	1	4	2	2
1	3,348	2,055	0	0	1	4	2
J	1,371	1,305	0	1	1	4	2
К	1,110	1,200	0	0	1	3	2
L	668	1,317	0	0	1	3	2
М	1,710	2,549	0	0	2	8	2
Ν	1,546	2,526	0	1	0	4	2
Totals	35,794	34,219	4	6	18	59-61	28-30

Table 5: Distribution of clinical human resources against workload

It was further noted that in four of the fourteen hospitals only clinical officers were responsible for in-patient care despite presence of doctors. The health worker interview revealed that in-service training and mentorship expectations were not met in any of the fourteen hospitals and presumably all others in Kenya.

3.1.3 Medical Products and Technologies

Essential medical products and their stock-out rates grouped as, laboratory services, antiinfective agents and replacement fluids, supportive medications and equipment are presented in figure 14



Figures 14: Availability scores for essential medical products and technologies

The list includes medicinal products (dugs and biologicals for primary and supportive care) laboratory services and medical equipment (care delivery machines).

The specific requirements for these products and technologies are dependent on the level of service in question. The list of items in each group selected for evaluation is presented in the top segment. The indicator of deficient performance was set as the number of hospitals reporting availability as rare or never for any item. Basic laboratory services were available in most hospitals, the exception being measurement of total bilirubin. Supportive medication and equipment were the worst performing in that order with more hospitals reporting constrints. Overall, 26 (54%), 12 (25%) and 10 (21%) shotfals of items were reported in 1-2, 3-6 and 7-14 hospitals respectively. This important building block was therefore, found to be grossly underperforming.

3.1.4 Health Financing

The core WHO indicators for health financing as of 2010⁴³ were.

- a) General government expenditure on health as a percentage of the total government expenditure
- b) Total health expenditure as a percentage of Gross Domestic Product (GDP)
- c) Off-budget resources for health as percentage of total public sector resources
- d) Percentage of health expenditure reaching the end users.
- e) Percentage of total health expenditure from out of pocket

None of these were determinable with the data available to the survey teams except some indication of out-of-pocket expenditure which was going on in 11 of the hospitals despite prevailing government policy of free care for all children less than 5 years of age.

3.1.5 Health Information Systems

The 2002 survey sort to obtain morbidity and mortality through sampling physical evaluation of data from clinical notes. Figure 15 summarizes the findings from this process.



Figure 15: In-Patient Mortality, Sill Birth Rates and Case Fatality Rates.

The survey found between scanty and no records within the patient files regarding most of the in-patient care processes undertaken in the target hospitals. Available data could only allow estimation of in-patient paediatric and neonatal mortality, crude case fatality ratios for common conditions and stillbirth rates. Some notable characteristics were apparent from these findings. There was a wide range of overall in-patient mortality (4-15%) which may have been related, in part, to differences in data quality. It is unlikely for hospitals J and L with over 2600 annual deliveries between them to have had 0% newborn deaths even if extrapolated data from a three-month period may have been in their low delivery season. Poor reporting of deaths in this age group is a more plausible reason. The wide range of case fatality rates; 2-10%, 2-20% and 16-55% for malaria, pneumonia and neonatal sepsis respectively was difficult to explain. Stillbirth rates ranging between 2.8 and 6.6% across the hospitals while equaling or outnumbering overall in-patient deaths in two facilities may also have had more to do with data quality than any plausible biological mechanisms.

3.1.6 Governance and Leadership

Conversations with hospital administration revealed presence of some of the key organs governing the services including:

- Hospital management committee. This was responsible for day-to-day administration of all activities within the hospital. It was typically led by a senior clinician or younger person usually a medical officer and was responsible for running the hospital. The membership included unit/department heads of, medical specialties, nursing, pharmacy, laboratory, radiology and overall administration. Specific activities of these groups were not included in the detailed survey analysis.
- 2. District Health Management Committee. This included the hospital leadership and other external participation and was usually responsible for broader governance issues. It was led by an individual not working in the hospital. These activities were also not analyzed by the survey.
- The nine indicators for performance evaluation of this building were described in chapter two including availability of key policy documents relevant to the 6 HS-BB which included service delivery guiding tools.
- This BB is also responsible for ensuring service delivery yet there were very few of the existing clinical practice guidelines on site indicating gross failure of governance and leadership.

In conclusion, there were system gaps in all building blocks with particular concerns in the governance and leadership (unavailability of evidence-based guidelines), service delivery quality (low uptake of evidence-based care guidelines), health information systems (scantily captured clinical data) and human resources (inadequate ward coverages). These gaps advised the structuring of intervention studies that followed. Strengthening governance was addressed by development and effective dissemination of clinical practice guidelines (CPG) and some work in policy development. Delivery quality improvement was approached by use of implementation science strategies in driving acceptance and enhanced use while additional studies in line with delivery and improvement sciences further enhanced visibility of CPGs. The following HSR related chapters provide the main results of the implementation work following the survey.

3.2 INTERVENTIONAL STUDIES

3.2.1 Management Science Research

Executive Summary of Management Research Methods

Developing and Introducing evidence based clinical practice guidelines for Serious

Illness in Kenya¹⁵. Summarized in methodology section

Developing guidelines Low and Lower Middle-Income Countries: lessons from Kenya¹⁶. It was noted that few examples of sustained nationally organized, evidence-informed clinical guidelines development processes in Sub-Saharan Africa existed at that time. This paper described the evolution of efforts supporting evidence-informed decision making to guide admission hospital care practices in Kenya. The approach involving conducting reviews, presenting evidence and promoting transparency of consensusbased procedures for making recommendations improved over four distinct rounds of policy making.

Building Learning Health Systems (LHS) to Accelerate Research and Improve Outcomes of Clinical Care in Low and Middle-Income Countries¹³. An argument was tabled for a deliberate and strategic emphasis on building learning health systems (LHS) within LMIC capable of identifying those interventions and implementation strategies that work in routine contexts and improving quality consistently across the health care ecology. The focus here was on important patient outcomes, solving practical problems of service delivery and generating new evidence where required by research. **Developing a seasonal influenza vaccine recommendation in Kenya**¹⁸. The Kenya National Immunization Technical Advisory Group was asked by the Ministry of Health to provide an evidence-based recommendation on whether seasonal influenza vaccine should be introduced into the national immunization program. The approach used involved deployment of a consultant who undertook a committee guided extensive desk review of existing technical manuals from the MOH and WHO, other published reports, meeting minutes and published literature on the subject. This was followed by several synthesis and decision-making committee meetings leading to the final policy advisory.

3.2.1.1 Findings from Management Research

There were three major deliverables from this sub-theme.

- The first ever guideline booklet for care of children with life threatening illnesses and conditions in Kenya. The contents of this booklet are summarized in table 6. This booklet has since been disseminated throughout the country and adopted in neighbouring countries with minor modification.
- A guiding summary process for deployment by any other group seeking to undertake similar activities in other LMICs. A sketch of the pathway used in Kenya is presented in figure 16.
- Using an example of policy changes to improve care of sick new-borns a suggestion of task shifting for nurses in the wards. Figure 17 simulates the thinking behind the proposed policy change.

Primary conditions	Supportive care			
1. Malaria Quinine [2005], Artesunate [2010]	1. Feeding the malnourished [2005] and [2010]			
2. Pneumonia (1st line therapy [2005],	2. Feeding the preterm			
Amoxycillin [2010, 2015])	Initiation timing [2005 & 2015]			
3. Meningitis (1st line [2005], steroids	Breastmilk fortification [2005 & 2010]			
[2010])	feed increments [2010 & 2015]			
4. Diarrhoea therapy (Zinc [2010])	3. Respiratory care for pre-terms			
5. Neonatal Sepsis (Gentamycin [2005])	Caffein [2010]			
6. Sickle Cell Disease (Hydroxyurea	Continuous Positive Airway Distention			
[2013])	CPAP [2015]			
Treatment of emergencies	Disease Prevention			
1. Anticonvulsants for children [2005]	1. Alcohol hand rubs for infection control [2010]			
2. Anticonvulsants for New-borns [2010]	2. Chlorhexidine cleaning for the umbilical			
3. Glucose for hypoglycaemia [2005]	cord [2013]			
4. Fluid bolus for the severely ill [2013]	3. Antibiotic prophylaxis to prevent			
5. Neonatal resuscitation [2005] revised [2010]	infection in high-risk new-borns [2015]			

Table 6. Composition of the guidelines developed

The CPGs were developed in the thematic areas of therapeutics for primary conditions, treatment of common emergencies, disease prevention and essential supportive care. These guidelines have since been converted to the 31-page basic paediatric protocol booklet universally used in Kenya and now available in free literature online⁷³.

A prototype of process and pathway for moving guidelines into policy

The processes of moving from evidence to policy demonstrated in Kenya and published

as an example for other LMICs is illustrated in figure 16.



A steady growth of capacity and reach is seen across the fifteen years with increasing acceptance by other stakeholders and countries in the region.

Proposed newborn care policy change

The health policy research undertaken in Nairobi scoped for several aspects of newborn care in nearly all facilities with in-patient services¹⁷. The scoping was established that the care of these babies is largely upon nursing staff though this was not in written policy. It was also observed that available nurse patient ratios would not support quality care of these newborns.

Figure 17 is a computation based on available data and some modeling hypothesizes on the relation between coverage and quality of services using Nairobi County data and some assumptions.



With a target population of sick new-borns likely to need in-patient care of 21,966 in the year 2018, multiple data sources were used to estimate proportions (x-axis) of sick new-borns accessing care represented as an ordered cascade of progressively more stringent quality criteria. In this approach, probability estimates from different studies were multiplied as additional quality criteria were introduced to provide an indication of the points, or steps, in the cascade where coverage and quality gaps have most impact on the reference population (the initial bar).

The parameters were defined as follows:

(1) Service contact: the proportion reaching a facility potentially capable of offering such care based on the survey of all neonatal unit admissions in a year.

(2) Service readiness: the proportion of those accessing care that reach a facility that has a minimum set of resources to support essential care.

(3) Basic quality-adjusted coverage: the proportion reaching a facility with needed resources who are then likely to receive technically competent medical care.

(4) Public sector nursing care adjusted coverage, which further adjusts for the likelihood that nurses in public sector hospitals that provide >70% of in-patient new-born care will be able to complete 80% or more of tasks comprising a minimum standard of nursing care. The percentages provided in figure17 refer to the proportions of new-borns who are estimated to have accessed the given level of care. No new-born received the highest quality clinical care described in number (4) above. These findings advised the proposed policy changes regarding the role of nurses in provision of in-patient new-born care.

The Ministry of Health requested Kenya National Immunization Technical Advisory Group (KENITAG) for a policy brief for seasonal influenza vaccine introduction

The policy brief advised regional introduction of the vaccine to establish program feasibility, efficacy and cost-benefit. The recommendation was contingent on implementation of a pilot study to address gaps in local data on the socio-economic impact of influenza vaccination programs, strategies for vaccine delivery, and the impact of the vaccination program on the healthcare workforce and existing immunization program.

3.2.2 Implementation Science Research

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The main purpose of management science and relevant research supporting clinical care is to provide the necessary tools and organizational infrastructure for supporting such care. In case of in-patient care, this would be manifested in ensuring availability of tools needed for providing such care, CPG. Having developed the same, the next step was to ascertain not only potential impact but also ensure reliable ways of effective and sustainable uptake. The first step was, therefore, ascertainment of suitability of the tool through implementation science.

Executive Summary of Implementation Science Methods

Implementation of a structured paediatric admission record (PAR)¹⁹.

The PAR form is a simple measure for improving data quality which would strongly better the status found in the 2002 survey^{7,8}. It was speculated then that motivation, supervision, resources and other factors were barriers to their successful use in a Kenyan public hospital setting. The feasibility and acceptability of such a tool for district hospitals as a means of improving documentation of illness was explored.

Implementation of guidelines for improving in-patient Paediatric Care²⁰.

Already summarized in the methodology section. This section reports the findings of the research.

*Effect of enhancing audit and feedback on uptake of childhood pneumonia treatment policy in hospitals*²¹. The WHO revised the clinical guidelines for management of childhood pneumonia in 2013. It was known that significant delays were experienced during previous introductions of new guidelines into routine clinical practice in LMICs. This advised the decision to evaluate the impact of enhanced as opposed to routine standard audit and feedback in accelerating adoption of these guidelines by clinical teams within the network hospitals as an example for possible escalation country-wide and to other low-income setting. A parallel group cluster randomized controlled trial using two groups of hospitals assigned to either enhanced feedback (n = 6 hospitals) or standard feedback (n = 6 hospitals) using restricted randomization was preferred.

*Quality of hospital care for sick new-borns and severely malnourished children*²². The 2002 survey reported particularly high mortality associated with neonatal illnesses and severe malnutrition despite availability of intervention packages in their service delivery mechanisms. It was hypothesized that multifaceted interventions could improve delivery of these services in Kenya's primary referral hospitals. This sub-component of the larger study²⁰ evaluated care within surveys conducted in the same 8 rural district hospitals (described in b) using samples of case records. After baseline data compilation, hospitals received either a full multifaceted intervention (intervention hospitals) or a partial

intervention (control hospitals) aimed at comparing the care received against national guidelines disseminated to all hospitals.

Evaluation of a Training DVD on Pneumococcal Conjugate Vaccine for Kenyan EPI Healthcare Workers²³. Kenya's Ministry of Public Health and Sanitation was the first in Africa to introduce the new ten-valent Pneumococcal Conjugate Vaccine (PCV-10) in 2011. For successful implementation specific training on handling and storage of the PCV-ten vaccine was considered necessary since some of its logistics were fundamentally different from those of existing products.

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Findings From Implementation Research

This started with the development and testing of a new Paediatric Admission Record (PAR) whose initial implementation data is summarised in figure 18.



Figure 18: Impact of implementing the Paediatric Admission Record

The locally developed paediatric admission record chart was subjected to proof-ofconcept test. The design of the PAR reflected both key IMCI symptoms and signs and approaches to severity classification. It was also advised by local information needs identified after meetings with hospital staff. The PAR was therefore administratively accepted as the first stage in the official hospital record and was not a study form. The form was formally introduced using a before and after intervention design.

The first segment reveals progressive uptake of the tool by all practitioners which grew steadily from pre-intervention level of 0% through the first post-intervention assessment level of 50% finally reaching 84% by the time of the 4th and final evaluations 8 months after commencement.

The second segment repots the impact of PAR introduction on recognition and recording of danger signs. Introduction of the PAR saw an increase in recording of cyanosis, respiratory distress and consciousness from less than 45% for each parameter to between 67 and 80%.

Data on individual practitioners revealed PAR utilization rates ranging from 50-100% for different categories of frontline health workers.

To assess the impact of newly developed or domiciled CPGs a cluster randomized controlled trial using a multifaceted intervention cocktail was employed as the main implementation study, figure 19.



Figure 19: Results of the multifaceted intervention for implementation of clinical practice

guidelines

Figure 19 summarizes the findings for both structural and process indicators. Compared to baseline, all measured parameters improved for both groups though the intervention hospitals registered significantly higher benefits.

The first segment of figure 19 reports the changes in structural domain parameters after intervention with all the six showing higher change magnitudes for the intervention compared to the standard care group. Indicators such as availabilities of consumables, essential drugs and impact on staff (perception of readiness to prefer using CPGs consistently) were higher in the implementation hospitals for instance. The contribution of the PAR was also appreciated.

The second segment shows results of comparison of completeness of clinical notes using the PAR (developed by the same research group) before and after intervention. Record keeping was enhanced by this multifaceted intervention driven introduction of CPGs.

The third segment also compared achievements in process domains using accuracy of drug dosing as examples. The results suggested improvement, more among the intervention group.

Another implementation study tested the use of a narrower range of interventions on improvement of pneumonia care in these hospitals. This enhanced audit feedback model was used to build uptake of revised pneumonia treatment guidelines. The aim of this intervention was to rationalize adoption of simplified childhood pneumonia care guidelines which were in the process of introduction in Kenya. The findings are summarized in figure 20.



The findings are summarized in figure 20 showing no overall improvement in both primary (pneumonia classification accuracy, 38.4 versus 38.2%), and secondary (prevalence of treatment change from oral to injectable antibiotics, 12.8 versus 12.6%) outcomes for standard and enhanced feedback. In the second segment some interaction between type of feedback and duration from commencement of intervention was seen (OR=1.25, 95% CI 1.14 to 1.36, P<0.001), demonstrating some favourable impact if enhanced feedback was sustained for a longer period.

Quality of care for new-borns and malnourished children had been worse than the other aspects of service delivery in the 2002 survey. A sub-component of the larger multifaceted intervention study focused exclusively on these two categories of sick children aiming to ascertain if they had benefited from the regime. The findings are summarized in figure 21.



Figure 21. Quality of care for sick new-borns and severely malnourished children

The 8 (4 intervention and 4 controls) hospitals were similar at baseline in the measured parameters of clinical documentation and guideline utilization in the care of new-borns and children with severe acute malnutrition. In the case of new-borns both clinical documentation and several treatment guideline utilizations improved significantly after intervention. Adherence to feed prescription guidelines on the other hand did not benefit from the intervention. Drug dosing had unexpected results with more cases of gentamycin overdose occurring in the intervention arm for new-borns.

A small interventional study used Digital Versatile Disc as a tool for vaccine introduction. This effort from the Network for Education Supporting Immunization (NESI), an international organization based in the University of Antwerp, Belgium whose mission was to strengthen immunization policy and service delivery capacity in developing countries. Kenya was selected to assess health worker acceptance of this new interventional method for supporting introduction of a new vaccine with unique demands. The results confirmed acceptability of the content and format as well as feasibility of using the DVD in combination with face-to-face teaching. To improve the quality and adoption of the DVD, key suggestions made by the trainees included inclusion of all EPI vaccines and other important health issues in this training format, encouragement of broad geographic distribution of the DVD for others to benefit and expanding the utilization by using subtitles in other languages across Africa. The DVD spread across Africa gaining appreciation by a heterogeneous and international audience and rendering it suitable for translation. There were some differences between feedback from nurses (most appreciative) and other vaccinology course participants (less satisfied with value of the process).

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3.2.3 Delivery Science Research

This HSR sub-theme draws heavily from both management and implementation. It represents the real-life testing of interventions developed and proven effective through management and implementation science research respectively. This is when impact at population level is measured. Several studies in this thesis were aligned to this sub-theme.

Executive Summary of The Delivery Science Methods.

Assessment of neonatal care in clinical training facilities in Kenya²⁴. The study reported an audit of neonatal care services provided by clinical training centres and identified areas requiring attention as part of wider efforts to improve new-born survival in Kenya. The cross-sectional study set in neonatal units of 22 public hospitals reported on both structures and processes related to service delivery quality.

Evaluating the level of adherence to Ministry of Health guidelines in the management of Severe Acute Malnutrition at Garissa Provincial General hospital, Garissa, Kenya²⁵. Malnutrition is in the background of 2 out of every 5 of Kenya's high under five mortality and Severe Acute Malnutrition (SAM) is a direct contributor. Proper implementation of WHO Evidence Based Guidelines for management of SAM can reduce some of these deaths. The retrospective cross-sectional study described the level of adherence to WHO guidelines for management of SAM in a Provincial General Hospital (PGH), one classification level above primary referral facilities.

Adherence to pneumonia guidelines for children 2 – 59 months at Garissa provincial general hospital²⁶. The article reported an evaluation of adherence to pneumonia CPGs contained in the Ministry of Health Basic Paediatric Protocols⁷³. This retrospective hospital based cross sectional study was also undertaken in a PGH using clinical data abstracted from hospital records

Moving towards Routine Evaluation of Quality of In-patient Pediatric Care in Kenya^{27.} Regular assessment of quality of care allows monitoring of progress towards system goals and identifies gaps that need to be addressed to promote better services and outcomes. This paper focused on efforts to initiate routine assessments in a lowincome country in partnership with government. This cross-sectional survey of twenty-two internship training hospitals across Kenya examined availability of essential resources and processes of care based on review of 60 case-records per site focusing on the common childhood illnesses (pneumonia, malaria, diarrhea/dehydration, malnutrition and meningitis).

Are hospitals prepared to support new-born survival? -an evaluation of eight firstreferral level hospitals in Kenya²⁸. The findings reported by this publication emanated from a cross-sectional study which assessed availability of resources for supporting basic neonatal care in eight first-referral level hospitals. Two hospitals were selected from each of four of Kenya's eight provinces to represent some diversity of disease epidemiology and health system infrastructure. The methodology involved assessing availability of fiftythree structural and 10 process indicator items at each of the eight hospitals by direct observation (structural) and interview (process). What capacity exists to provide essential in-patient care to small and sick newborns in a high mortality urban setting^{29.} Demand for, and supply of, high quality essential neonatal care is key to improving new-born survival but evaluating such provision has received limited attention in low- and middle-income countries. Such local data were deemed needed to support healthcare planning for this vulnerable population. This process involved health facility assessments through retrospective review of 2014-2015 admission events together with estimates of population-based incidence of neonatal conditions in Nairobi to explore access and evaluate readiness of public, mission and private sector facilities providing 24/7 in-patient neonatal care in the County.

*Effective coverage of essential in-patient care for small and sick new-borns in Nairobi, Kenya, a high mortality urban setting*³⁰. This was a detailed retrospective review of medical records of neonatal admissions to public, mission and private sector facilities providing 24-hour in-patient neonatal care in Nairobi City County. The goal was to estimate the proportion of small and sick new-borns receiving such care as per recommended guidelines across six process domains as the basis for quality of care. The relationship between facility measures of structure and process as estimates of effective coverage was also explored.
Findings From Delivery Science Research

Quality of care delivery

Three studies reported quality of service delivery measured as uptake or adherence to established care guidelines. Figure 22 contains the main results.



Figure 22: Quality of care score in provincial and internship training institutions.

The first paper evaluated 22 of 40 hospitals which in 2013 were recognized as internship training centres to determine their readiness for provision of evidence driven neonatal services measured as utilization of relevant CPGs. The results in the first segment show appropriate utilization of CPGs rates in internship training centres scoring between 35 and 97%. The indicators covered were in documentation, identification of clinical signs, clinical care and monitoring and therapeutic interventions.

The second segment has results from an evaluation of adherence to guidelines for the management of Severe Acute Malnutrition (SAM) in a PGH, a higher level of health facility hierarchy than the primary referral). The SAM study interrogated adherence to the first eight of the 10 steps in management of SAM: 1) Hypoglysaemia, 2) Hypothermia, 3) Dehydration, 4) Electrolyte imbalances, 5) Infections, 6) Micronutrient deficiencies, 7) Initial stabilization and 8) Catch up growth. Numbers 1-3 representing the admission emergencies (when mortality risks are highest) were poorly performed with adherence scores <30% in all. The 4th to 8th steps performed much better though not to highest level possible.

The pneumonia care CPGs study at the same PGH focused on appropriate classification and treatment as presented in the third segment. Though the rates of appropriate classification were low those describing more severe disease enjoyed much better coverage. In the very severe disease category both parameters attained 80% score.

Capacity to deliver effective care

The capacity to deliver services was defined as evidence of structural and process-based preparedness by facilities to provide care to admitted newborns and children. Figure 23 has the key findings from assigned studies.



Figure 23: Capacity preparedness of rural and Nairobi hospitals for care of new-borns.

The structural capacity domains used consisted of physical infrastructure, laboratory preparedness, availability of medicines and technologies as well as other consumables. Processes were derived from data on clinical coverage by nurses and availability of job aids and CPGs in the hospitals.

Structural capacity to deliver effective care.

This is exemplified by the findings from twenty-two internship training facilities as summarized in segment 1. The study identified twenty-one items within 6 structural domains and recorded availability in each hospital. The domains (number of items) were, ward organization (n=2), hand hygiene equipment (n=2), emergency care (n=5), routine care (n=2), special care (n=6) and laboratory services (n=6). No hospital had the complete menu of items. The capacity was, nevertheless, better than that revealed by the 2002 survey. The hospitals were improving their infrastructure though not as fast as would have been preferred. The data in the second segment comes from an evaluation of neonatal in-patient care preparedness in 8 CIN network hospitals. This study also evaluated a retinue of structural domains similar to those used in the 22-hospital survey above but with 53 items within the same domains. The eight hospitals collectively had poor scores in 3 key structural domains: organization of staff and systems (median 3 of 11), equipment availability (4.5 of 8) and hygiene and safety infrastructure (5 of 10). Only laboratory services were present at levels commensurate with good capacity preparedness.

The cumulative availability scores out of fifty-three specific items in each of the 8 hospitals showed a wide range from 17 to 96% across the facilities with 3 hospitals scoring less than 50%. Structural capacities were, therefore, poor across the primary referral hospitals. Notwithstanding these challenges it appears that items within domains

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measured in 2002 like laboratory and other clinical care equipment were beginning to build up even in these non-CIN facilities.

The third segment comes from a cross-sectional study estimating the capacity of health facilities in Nairobi City County to provide essential in-patient care for small and sick newborns. Structural capacity data from four public, 6 mission and 21 private health facilities for the year 2015-2016 was obtained by direct observation and document review. A total of 126 items distributed among six domains were used to determine percent availability of these items.

Availability of essential items as a measure of capacity to deliver care for children under 5 years was also reported for the 22 internship training centres as seen in figure 24.



The evaluation included six domains of structural indicators consisting of: Equipment, Guideline documents and wall charts (for process capacity), Resources for supportive care, Vitamins, minerals and feeds, Intravenous fluids and Availability of antibiotics were also evaluated. Percentage availability in this analysis was determined as the proportion of twenty-two hospitals in which the specific item is present. Three items found available in less than 20% (4/ 22) of the hospitals were omitted from the final analysis. These were otoscopes, torches and ampicillin omitted from essential equipment and antibiotics, respectively. Overall, good performances were observed in availability of drugs, intravenous fluids, antibiotics and essential equipment with the most items in these three domains scoring around 80%. Intermediate performance was observed in two domains (resources for supportive care and minerals vitamins and feeds) while the worst performing domain was guidelines' and wall charts' availability.

The estimates also provided data on cumulative availability of the six resource domains for each of the 22 hospitals. Figure 25 presents the findings computed as the proportion of items available per domain in each of the six domains across the hospitals.



If all items were available a hospital would score 100%. None of the twenty-two hospitals attained 60% with a low of about 30% and a high of just under 60%.

Process capacity to deliver effective services

Adequacy of neonatal care in Nairobi County was assessed as cot/incubator capacity and availability of nurses in these facilities as illustrated in figure 26. Four large facilities (2 public and 2 low-cost mission) had > 100% (117% and 149%) occupancy. Overall, occupancy varied between and within sectors. Medical staff data were available from twenty-nine facilities (26B). All facilities reported having at least one paediatrician (range 1–23) to consult.

In 7/29 facilities (all private) the consultant managed the neonatal unit supported only by nurses with no medical or clinical officers assigned duties covering neonatal care. Three other facilities (all private) had clinical officers but no medical officers covering the new-born unit.



There was a log-linear relationship between the total number of in-patient days for a facility and the number of cots and incubators available for new-born in-patients (Fig 26A). Of the 29 facilities with relevant data half (mostly private) had occupancy of $\leq 10\%$ while another 9 attained only 10–50%.

Only twelve facilities had dedicated nursing staff for neonatal patients. In nineteen facilities nurses shared their time between sick new-borns and patients on the maternity or other wards during each shift. The number of nurses were fewer in many facilities during the night shifts. There was no commensurate increase in the number of nurses on duty during a typical shift as the number of patient days increased (26B). Among the four public facilities the ratio ranged from 4–15 patients per nurse. The ratio in other largest facilities ranged from 3–15 patients per nurse. There was, therefore, facility type related disparity in bed occupancy and nurse coverage.

Data obtained from eight rural hospitals were also used to describe their new-born care process capacities as a measure of preparedness to support new-born survival in Kenya. Figure 27 shows availability of the essential items as indicated.



Figure 27: Preparedness of first referral level hospitals to support new-born survival.

Two important items, new-born care guidelines and dose charts were not available in any of the eight hospitals while only 1 facility was consistently providing vitamin K. Thermotherapy was the only item available in all the hospitals. Preparedness in terms of process was behind that of the structural domains. These Hospitals appeared not adequately prepared to fill their proposed role in ensuring new-born survival.

Processes supporting in-patient new-born care were also assessed in thirty-one facilities within Nairobi County representing the urban group. The domains and their scores are presented in figure 28.



Figure 28: Performance scores of processes supporting in-patient new-born care.

When stratifying by sector and size, different patterns emerge, with generally lower domain scores for the process of care in the private (summary process score= 0.49 [95% CI: 0.44–0.54]) and mission sectors (0.48 [95% CI: 0.43–0.53]) compared with public-sector facilities (0.61 [95% CI: 0.56–0.67]), which account for 71% of admissions. Large facilities tended to have higher domain scores (summary process score=0.59 [95% CI: 0.52–0.66]), while medium and small facilities scored less well (0.54 [95% CI: 0.48–0.60] and 0.45 [95% CI: 0.42–0.48], respectively).

Coverage of effective services

This was defined as accessibility of in-patient services within a catchment area (geographic, figure 29) with sufficient capacity to satisfy specified catchment population (demographic, figure 30) needs.



Geographic Coverage. Optimal coverage of clinical services is only guaranteed if the population can reach the facilities with ease. When this is not the case, care is either not sort or obtained from less reliable or even harmful sources. Figure 29 shows the situation in Nairobi. The results demonstrate gross inequity in geographic distribution of In-patient Neonatal Care facilities in Nairobi demonstrating existence of access challenges. It can be seen, from the map, that some areas with potentially large numbers of new borns were not necessarily in proximity with the facilities. The city county needed to rationalize of In-patient Newborn Care facility distribution while also enhancing the emergency transport system in the city. Demographic Coverage. Figure 30 reports findings of a retrospective review of medical records for neonatal admissions to public, mission and private sector facilities providing 24-hour in-patient neonatal care in Nairobi City County to estimate the proportion of small and sick new-borns accessing such care.



From modelled data it was estimated that 21,966 babies required in-patient care in health facilities within Nairobi County during the 2015-16 year though 44.5% of them were unable to access any level of care. The other 55.5% were estimated to have received quality care in the following proportions: 24.9%, 19.5, and 10.9 for high, medium and low, respectively. Less than half of the new-borns who access in-patient care in Nairobi receive what can be categorized as good quality care (high and moderate) leaving the majority with poor quality or no care at all. Assessment was done regarding the quality of neonatal care for an entire population capturing information across sectors and working towards defining effective coverage.

The results provided insight into key actionable quality gaps and unearthed large heterogeneity in care contexts and quality for neonatal patients in this high mortality setting. Deficits were most identified in small, often private facilities, although severe workforce deficits and overcrowding undermine the quality of care in the public sector. Taken together with results of linked studies, it was estimated that effective service provision was unavailable for 75% of sick new-borns in Nairobi City County, this gap being made up of failures in access (44.5%) and receipt of lower quality services (30.4%).

Relationship between process and structural capacity.

Using data available computation of the relationship between process of care (quality of service measured as guideline adherence) and structural capacity (physical and organizational resources) was done producing the results presented in figure 31.



The relationship between summary process of care score and structural capacity score for each facility, by patient volume and sector was determined and is presented in figure 31. Each bubble represents a facility. Bubble sizes are proportional to the number of admissions received by the facility between during the 2014-2015 year. Sectors are represented by bubble colours: blue=public, mission=orange and private=yellow. Process of care was computed as summary scores for patient records within each facility. The results in figure 31 also suggest a possible relationship between facility size and summary process and structural capacity scores, with larger facilities tending towards higher scores and smaller facilities tending towards lower scores for both process and structure.

3.2.4 Improvement Science Research

Improvement science intersects with both delivery and implementation sciences as the pie chart in figure 4 shows. This is not surprising given the dynamic nature of modern health care. Delivery tools often require improvement science strategies to maintain desired care to the satisfaction of consumers. Delivery science, therefore, needs the improvement discipline for timely upgrades. Improvement itself employs implementation science methods to achieve its goals. The overall message here is that these three HSR sub-themes are tightly interrelated.

Executive Summary of Improvement Research Methods

Adoption of recommended practices and basic technologies in a low-income setting (CIN)³¹. With the advent of HS as a globally recognized program, there was increasing focus on improving quality of health care supported by evidence and innovation. Tracking adoption of such innovations in routine hospital settings from low-income countries were rare or absent in published literature. As a contribution to this pool of information data was collected on a consistent panel of indicators during four separate cross-sectional hospital surveys in Kenya to track changes over a period of 11 years (2002–2012). The desired outcome measures were improvements in basic resource availability, use of diagnostics and uptake of recommended practices.

Appropriateness of clinical severity classification of new WHO childhood pneumonia guidance^{33.} The WHO revised the classification (from 3 to 2 severity levels) and treatment (altering admission criteria) choices of childhood pneumonia. To establish the appropriateness of this improvement in Kenya a study was undertaken aiming to determine whether some children categorized as eligible for outpatient treatment might have a risk of death warranting their treatment in hospital instead. This was a retrospective cohort study of children aged 2–59 months admitted to a Kenyan hospital with pneumonia in a 24-month period between 2014 and 2016, before revised WHO pneumonia guidelines had been adopted in the country.

*Effect of new-born resuscitation training on health worker practices in Pumwani Hospital, Kenya*³². This was a randomized controlled trial with health workers receiving early (intervention) or late (controls) new-born resuscitation training. The trial training was adapted locally from the approach of the UK Resuscitation Council. The primary outcome was appropriate initial resuscitation steps with the frequency of inappropriate practices as a secondary outcome. The study was a collaboration between Welcome Trust group of scientists, the department of Paediatrics, University of Nairobi and Pumwani Maternity Hospital, the largest such facility in Kenya with an annual birth cohort of more than 20,000 and frequent negative press on new-born outcomes.

Improving skills and institutional capacity to strengthen adolescent immunization programs and health systems in African countries through Human Papilloma Virus (HPV) vaccine introduction³⁴. By the year 2014, several African countries had introduced or were in the process of introducing the HPV vaccine.

Because this vaccine was being introduced in a non-traditional population (adolescents), a collaborative project was developed to strengthen country immunization programs in relation to this population which potentially posed unique public health considerations. The findings of this project are reported here.

Findings From Improvement Science Research

Adoption of recommended practices and basic technologies was evaluated by four separate cross-sectional hospital surveys tracking changes in adoption of CPGs over a period of 11 years between 2002 and 2012. This exercise aimed to demonstrate improvement in uptake over time. Figure 32 has the key findings.



Figure 32: Progressive improvement in adoption of CPGs across twenty-two hospitals.

Seven process items including some which had performed dismally in uptake in the 2002 survey were tracked through 2006, 2009 and 2012. The results showed steady improvement in rates of appropriate prescription of medicines. This improvement was, however, not accompanied by commensurate changes in utilization of laboratory services whose uptake rose at a slower rate. The changes were more appreciable in therapeutic interventions with laboratory testing demonstrating much slower change.

Another study testing the impact of using an abbreviated new-born resuscitation protocol demonstrated significant value. The results of this case-controlled trial undertaken in a large urban maternity hospital are presented in table 7.

Group Comparison for appropriate initial steps											
Resuscitation			Mean %		Risk	Risk Ratio (95%			p-value		
	Quality		Intervention (Early)	Controls (Late)							
	Perfect		28	10.8	2.6 (1.53-4.43))				<0.001		
	Adequate		68.1	30.8	2.22 (1.64-2.99)				<0.001		
	Resuscitation scores (scale 1 (poor) – 5 (perfect)										
	Staff category	ry Resuscitation episodes 129		Mean Scores	res (95% CI) Scores			p-value			
	Intervention (early)			2.4 0(2.18-2.61)							
	Controls (late)	127		1.83 (1.61-2.0	04)	4)		0.0003			
Group Comparison for unsafe/dangerous practices											
	Staff category	Re	suscitation	Mean (9	5%	CI)	per	p-v	alue		
		episodes 132 130		resuscitation episode							
	Trained			0.45 (0.2-0.61) 0.87 (0.72-1.02)							
	Not Trained						0.0002				

Table 7: Short- term impact of 1-day New-born Resuscitation training on practices

This hospital-based human resource capacity improvement research was undertaken in a large urban maternity hospital using new-born resuscitation training as an intervention whose uptake could be enhanced by shortening the process. The study created and used three categories of resuscitation processes as outcomes; 1) perfect when performed with minimal and insignificant or no fault, 2) adequate with notable errors deemed to be of minimal effect to the overall outcome and 3) unsafe or dangerous. A quantitative score scaled from 1 (poor) to 5 (perfect) based on a list of good practices was developed and applied. The results in table 4 show that the proportions of individuals whose performances were judged as adequate or perfect were 68 and 38% for intervention and controls, respectively. The trained staff also did much better in the resuscitation scores. Resuscitation episodes reported as having dangerous or unsafe mistakes were almost twice as common among the untrained compared to trained cohorts.

A new World Health Organization clinical pneumonia severity classification and treatment guidance was launched in 2013. The essence of this new or updated guidance was reduction of the categories of pneumonia classification to only two; pneumonia (with fast breathing and/or chest indrawing) and severe pneumonia (with any general danger sign). The previous one had three levels; pneumonia, severe pneumonia and very severe pneumonia. The treatment regime also changed allowing those with the first category to be allowed home therapy with oral amoxicillin with only the second group (severe pneumonia) needing hospital care involving injectable antibiotic treatment. Chest indrawing without danger signs was downgraded to home treatment with oral antibiotics. Figure 33 presents the findings.

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The change of classification was considered an improvement since it would be simpler to apply enhancing uptake. The key question was whether the new guidelines were safe for Kenya. Figure 31 presents risk factor analysis for causes of mortality among children with pneumonia in the study hospitals. A total of twenty-five factors were tested for association with increased in-patient mortality. The confirmed risk factors included those defining pneumonia severity, general constitutional illness severity, child demographics, nutritional status and other routine interventions. Three characteristics were strongly associated with death of children retrospectively classified as having non-severe pneumonia. These were moderate or severe pallor and weight-for-age Z score (WAZ) less than –3 SD. Based on these finding it was concluded that unmodified implementation of the new WHO guidelines would be dangerous in Kenya.

Finally, a study was put together by the NESI group aimed at using an improved intervention to strengthen adolescent health programmes across Africa using the papilloma virus vaccine introduction platform. The improvement strategy was an attempt to get national programs to work together in creating common approaches to improve uptake of this vaccine in a non-traditional primary immunization age group. The group involved countries from Eastern and Southern African Regions. Twenty countries at various stages of introduction were involved in the project.

The engagement achieved four important deliverables: 1)Establishment of an Africanbased network that will advocate for incorporating the HPV vaccine into national immunization programs, 2) Creation of a possible platform for experience exchange and thereby contributed to novel ideas of revitalizing and strengthening school-based health programs as delivery platform of adolescent immunization services and other relevant health interventions, 3) Identification of ways for reaching out-of-school girls through facility and community-based programs and 4) Laying the foundation for incorporating future adolescent vaccination programs into regular exchange activities.

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3.3 STATE OF HEALTH SYSTEMS SUPPORTING IN-PATIENT CARE IN 2015.

All these interventions were intentioned to make a difference in health systems supporting in-patient care of children in primary care hospitals. A few of them were focused on disease prevention though still relevant to child survival as a broad theme. The 2015 survey was designed to identify changes in health systems performance that could be attributed to the interventions. The HS-BB whose performance indicators are reported here are governance and leadership, delivery and health information systems from the primary network (DHSG-CIN) with human resources for health and delivery of newborn care from another network.

Executive Abstracts Of Post-Intervention Survey Methods

*Characteristics of admissions and variations in the use of basic investigations, treatments and outcomes in Kenyan hospitals within a new Clinical Information Network*⁷⁶. Clinical networks offer one means to advance methods for data collection and use, informing wider health system development. Such are, however, rare in LMICs. The paper reported data from CIN demonstrating improvement in HIS from the 13 CIN hospitals which had been part of the DHS survey of 2002 and continued participating in the intervention activities.

Delivery outcomes and patterns of morbidity and mortality for neonatal admissions *in five Kenyan hospitals*⁷⁷. This cross-sectional survey was conducted in neonatal and maternity units of five public hospitals. Data for 1 year were obtained for purposes of determinig maternal and neonatal workload data and mortality rates. This paper reported the first multi-hospital information on the status of in-patient new-born care profiles in Kenya. The paediatrician workforce and its role in addressing neonatal, child and adolescent healthcare in Kenya⁷⁸. To examine the availability and distribution of paediatricians in Kenya data was gathered from multiple sources combined with local expert insight in Kenya with a focus on the public, non-tertiary care sector as a measure of growth in HRH potfolio in a typical LMIC. This was based on the hyposthsis that, if HRH were appropriately addressed, the capacity to improve the survival and longterm health of new-borns, children and adolescents would be enhanced.

Variation in and risk factors for paediatric in-patient all-cause mortality in a low income setting: data from an emerging clinical information network⁷⁹. Hospital mortality data can inform planning for health interventions and may help optimize resource allocation if they are reliable and appropriately interpreted. However such data are often not available in low income countries. The CIN data from 12 county (former disrict) hospitals' paediatric admissions aged 2–59 months for the periods September 2013 to March 2015 were used to describe mortality across differing contexts and explore whether simple clinical characteristics used to classify severity of illness in common treatment guidelines are consistently associated with in-patient mortality.

3.3.1 Service Delivery

Preparedness

The findings on in-patient paediatric workload are summarized in figure 34.



Figure 34: Admissions, Bed Capacity and Disease Profiles for the children in 2014-15

The parameters evaluated included; workload (segment 1, annual admission and causative disease profiles) and infrastrucure (segment 2, bed space and inicators of service delivery. Annual Admissions showed considerable diversity of workload between the 13 participating hospitals though with smaller ranges 1,279-4,110 compared to 668-6.275 in 2002. The hospitals continued to have satisfactory infrastructural preparedness to provide the services in terms of bed space. Lack of synchrony between bed capacity and workload was still present across the hospitals. Disease specific admissions (third segment); with vastly improved records in the CIN database reliable disease specific workload was available this time round. Some patterns emerged; malaria, as expected, led in the facilities within the high-risk while pneumonia toped in the low-risk regions. Meningitis and severe acute malnutrition were among the top five in both groups. Sickle cell disease admissions were only reported in the high malaria risk areas. This was not surprising given the traditional link between these two diseases. This may also be explained by differences in frequency of clinical or laboratory diagnosis of Sickle Cell Disease in the two geographic areas.

Improved data quality allowed compilation of new-born workload statistics across several hospitals within the primary referral status, the first such report from Kenya, figure 35. The overall, syndrome and birth weight specific workload data for the five survey hospitals. The annual admissions per hospital ranged between 211 and 693.



Figure 35: In-patient new-born workload statistics across five hospitals

The top three indications for admission were birth asphyxia (34%) prematurity and LBW (32%) and neonatal sepsis (15%). Jaundice was responsible for 8% of all the admissions. Additional data not included in figure 35 reported maternal mortality ratio of 276 per 100,000 live births and fresh stillbirth rates of 11- 43 per 1000 births across the hospitals. The survey reported a disproportionately large representation of term babies probably related to the magnitude of asphyxia which is more frequently diagnosed in term babies.

Service Quality

Utilization rates of nineteen (each) diagnostic and treatment guidelines were used as measures of quality of care provided to admitted children. Figure 36 presents a selection of indicators from each group used as examples in this thesis.



Figure 36: Frequency of guideline driven care decisions in 2014-15

From pooled data recognition of clinical danger signs, occurred in median percentage of 67 (first segment) suggesting an improvement compared to the 2002 survey. The median proportions of appropriate deployment of laboratory investigations were between 9% and 80%. As expected, malaria microscopy was performed more frequently in the high-risk areas. There was notable improvement in performance of lumber punctures reporting a change from close to zero in 2002 to 66%. Blood sugar in the presence of danger signs and Chest X-rays remained grossly under-utilized. Uptake of the 6 CPGs presented in third segment showed marked improvement compared to levels reported in the 2002 survey. Zinc supplementation in management of diarrhoea and appropriate use of therapeutic feeds for severe acute malnutrition may still need further enhancement but were relatively better accomplished. There was continuing concern around rates of guideline use in treatment of severe malaria where despite a national policy change of preferred drug from quinine to artesunate less than half of cases showed compliance. Antibiotic prescription errors occurred in 4% (down from 10% in 2002) of children receiving gentamicin.

3.3.2 Human Resources for Health

Data from multiple sources and local expert insights were reviewed to determine the output of doctors from local universities and availability of paediatricians in the geopolitical units which host the primary referral hospitals of Kenya (Figure 37).



The output of doctors from local universities was tracked through the 1972 – 2018 period. An estimate of paediatrician distribution is compared for the years 2002 and 2020. This output was expected to add some insight into the adequacy of clinicians (especially paediatricians) providing care to in-patient children in these important facilities.

There was a slow build-up of graduate outputs between 1972 and 1988 when the country had only one school of medicine followed by a nearly six-fold increase between the 1984-88 and 2013-18 periods when the schools increased to 8 in the country. There is a sizable number of citizens of Kenya who graduate out of country and return to join the workforce. The number of primary referral hospitals with at least one paediatrician seems to have improved from 35 to about 55% between 2002 and 2020.

3.3.3 Health Information Systems

Mortality statistics for children aged 2 months-15 years

Quality of and retrievability of mortality data was used as a surrogate indicator for improved health information systems. Figure 38 summarizes this data with children aged 2 months- 15 years as the denominator.



Figure 38: Mortality and care fatality rates from 2014-2015 data

Higher quality data allowed computation of multiple disease contribution to many of the deaths. The case fatality rates are presented separately for the two malaria prevalence categories. As single entities, malaria (13.6%) followed by pneumonia (8.6) had the highest case fatalities in high malaria endemic areas while pneumonia (28%) and dehydration (18.6) led in the low prevalence zones.

Neonatal mortality

Five (5) urban facilities provided the neonatal mortality data presented in figure 39. The data comes from a combined cohort of more than 1,800 new-borns.



All-cause neonatal mortality varied between the hospitals while birth weight specific

deaths were as expected inversely related to birth weight (and presumably gestation).

Risks factors for all-cause mortality

Data from admissions of children aged 2–59 months for the periods September 2013 to March 2015 were used to describe mortality across different contexts and explore whether simple clinical characteristics used to classify severity of illness in common treatment guidelines were consistently associated with in-patient mortality (figure 40).



Clinical Danger Signs Predictive of High Mortality



HM=High Malaria Risk Areas LM=Low Malaria Risk Areas

Figure 40: Risk Factors for In-Patient All Course Mortality in 12 CIN Hospitals

Regression models accounting for hospital identity and malaria prevalence were used. Figure 40 presents a summary of the findings of this analysis. Twenty-two predictor variables spread across the traditional clinical systems (general state, respiratory, cardiovascular, neurological and abdominal) were assessed. The most predictive parameters were identified in four domains: neurological, cardiorespiratory, malnutrition and comorbidities. The symptoms and signs associated with increase of all course mortality cut across the systems with the most prominent predictors being reduced circulation, abnormal neurological signs and symptoms, respiratory failure and syndromic SAM (Kwashiorkor and Marasmus).

4.0 CHAPTER 4: DISCUSSION AND INTERPRETATION.

This section is divided into three sub-chapters analysing the findings of; the status of health systems supporting in-patient care in 2002, the sub-thematic intervention studies that followed and the second evaluation of the in-patient care in 2015.

4.1 STATUS OF HEALTH SYSTEMS IN 2002

It has been stated in this thesis that the HS building blocks must be simultaneously addressed if the health care agenda is to be met at all levels given their cyclic interactions. An attempt was made towards obtaining data on as many indicators as possible for all the six of HS-BB.

Governance and leadership

Though governance and leadership are considered central to the labyrinth the survey was unable to comprehensively evaluate key indicators like the detailed administrative structures in the hospitals and their functionalities. The survey focused more on clinical governance indicators like presence of statutory policies, practice guidelines and technical leadership by specialists. The consistent absence of policy guidelines in many of the relevant work areas was noted as a failure of governance and leadership. The survey reached the conclusion that the governance and leadership BB was underperforming and effort would be required to support the functions of this BB whose mandate includes overseeing the effective deployment of the whole HS program.

Service Delivery

Referral hospitals are expected to be fully prepared for delivery of in-patient care. This is evidenced by availability and appropriate utilization of all essential infrastructure as well as tools for enhancing delivery of the highest levels of quality care possible. The hospitals were deemed in satisfactory preparedness measured by bed space, notwithstanding, inconsistencies between available facilities and annual workload indicating obvious inequity across the facilities. Service quality is a component of the health delivery BB. Its most measurable indicator is the extent to which evidence based clinical care guidelines are deployed on day-to-day case management. Information extracted from patient records showed very low rates of clinical care decisions made according to established protocols. These findings implied that improving the technical component of care by targeting frontline workers through; pre-service and in-service training, development and implementation of appropriate guidelines, ongoing supervision, and focus on guality improvement might help. Understanding the factors affecting hospital performance and developing simple performance monitoring tools that allow the most effective use of interventions were also needed. Until these processes exist, the data constituting this thesis indicated that simple instruments used by non-specialist staff might be valuable as advocacy tools, focusing attention on key illnesses and basic services. Because the geographic spread of the fourteen hospitals approximated a national outlook, the findings could be considered sufficiently representative of the country to advice national and subnational levels of governments of the universal need to address the gaps in infrastructure supporting in-patient paediatric care.
Given the paucity of actual guideline documents in these hospitals it was hard to fault the clinicians alone for failure to follow the said protocols, the predominant factor was likely to have been leadership/supervision laxity. Reliable, consistent and sustained functions of the governance and leadership BB was, therefore, lacking in all the fourteen hospitals and by extension the whole country. The goals of reducing in-patient deaths of children in these hospitals which are at the apex^{46,47} of primary care could not be met without strengthening this BB. Full success towards the MDG 4 mortality reduction targets may depend on this.

The components of health care delivery also included in the survey revealed potential infrastructural imbalances such as inadequate beds and cots against projected needs in some hospitals while others had what seemed like more beds available for relatively small annual patient loads. The difficulty of knowing actual catchment population for any one hospital made it impossible to ascertain if these were true imbalances. The service quality component performed very poorly probably because the guidelines were not available in the hospitals to begin with. This is a fundamental failure of governance and leadership probably more than the human errors and other aspects of sub-optimal delivery infrastructure.

Human resources for health

A skilled health workforce commensurate with specific service needs is essential for effective provision of in-patient care and where children are the focus such services should be provided and/or led by a qualified paediatrician. In this survey, only four of the 14 hospitals had a paediatrician whose involvement in in-patient care seemed minimal. Most the care of admitted children was left to nurses, clinical officers and junior doctors.

The bulk of these clinicians were properly qualified in terms of basic training though deficient in skills renewal. Despite less-than-optimal clinical staff ratios commendable outputs were visible. It was and always is paramount for the health leadership to ensures adequate HRH in primary referral hospitals which are the pillars of in-patient care in any of the LMICs. On a positive note, it was apparent that despite prevailing difficulties occasioned by the gaps described above health workers remained positive even though they often worked in difficult circumstances. Their desire for further training and better information suggested that there was considerable capacity for improving performance through interventions directed at both personnel and systems. This in turn would increase the benefit that hospitals impart upon the catchment population(s). Targeted improvements in primary referral hospitals might then benefit the entire pyramid of primary health care, provide accurate data to monitor health outcomes, and address issues of equity.

The HRH groups include the direct (doctors, nurses, clinical officers, laboratory, pharmacy) and indirect (administrators and other support staff). Low and LMICs tend to have adequate or even excess numbers of support staff at the expense of direct service providers. The shortfall in HRH is almost always among the clinician categories. This was the case from the survey findings making it a major concern in all the health facilities. Adequate staffing in hospitals is important since effective health care delivery depends on it. In addition, appropriate pre-service, in-service and continuing medical education programs are essential. Professional support (supervision and mentorship) and staff welfare (including but not limited to salaries) are also pertinent.

Medical products and technologies

Availability of medicines and technologies would score the highest among the BB in these hospitals though this may also be due to ease of data availability for the indicators used. Nevertheless, there were some gaps in the supply chain management of these items probably caused by deficiencies at local and national levels. Out of pocket purchase of drugs and related supplies were common indicating sub-optimal support of this BB from the health financing side. Supply chain management for medical products and technologies needed to be enhanced if the goal of improving child survival was to be in tandem with the national MDGs expectations.

Health Information Systems

Regarding HIS, the results of the survey prompt a reflection that frontline health care providers failed the system due to their overly substandard capture of clinical notes. The need for improvement in this regard could not be overemphasized. Better supervision (the role of governance and leadership) may have alleviated the situation to some degree. The importance of accurate information on structures, processes and outcomes cannot be over-stated since it is the most essential tool for monitoring performance which by extension provides impetus for ensuring better outcomes. Quality of care assessment enshrines the famous phrase "if it is not recorded it was not done." These gaps in information advised the commencement work towards creation of a system to support continuous generation of clinical data for easy clinical audit.

Health Financing

The Health Financing model deployed in most of the hospitals was against the norm of the period and most likely to have been related to inadequacies in supplies needed for effective delivery of services. The Ministry of Health's position in 2002 regarding services for children under 5 years proscribed any charges yet ten of the 14 hospitals admitted levying fees for this population⁸. Outsourcing of drugs prescribed in the hospitals due to unavailability was also a common occurrence. These two findings constituted failure of adherence to item e) of Kenya's HF performance indicator at hospital level. Kenya had already established health financing guides which were not followed by most of the survey hospitals. This was, therefore, an area seeking political intervention for sustainable solutions.

In response to all these HS gaps, studies focusing on four HSR subthemes; management, implementation, delivery and improvement sciences were undertaken aiming to identify strategies for positively changing this state. The next section is dedicated to the interventions which responded to the said gaps granulated into the four sub-thematic areas of HSR included in the work constituting this thesis. Some of the contributing research work and publications were not dated is the same sequence as the flow of the chapter sub-units, particularly those from subsidiary networks. They, nevertheless, conformed the HSR categorization used in this thesis and had the same goal improving child survival towards attainment of MDG 4. The discussion is framed within the four HSR sub-themes of management, implementation, delivery and improvement.

4.2 INTERVENTIONAL STUDIES

4.2.1 Management Science Research

There were three aspects of the research supporting this thesis driven by the management science agenda; establishment of a reliable source of clinical data to support research (CIN), initiation and implementation of clinical practice guideline (CPG) development processes and creation of a framework for health policy generation. These were deemed essential for supporting primary referral hospitals expected to be apex of the pyramid of primary health care for the majority rural communities^{46,47}. Such hospitals were expected to have relevant capacity and readiness for consistent and sustainable provision of in-patient care commensurate with the needs of their catchment populations. There was, however, little published information on the performance of these facilities from LMICs including Kenya.

The Clinical Information Network

Development of the CIN was one of the key sustainable outcomes of the management research agenda. It followed the approach of other clinical networks which have been a feature of efforts to improve care in high-income countries such as the Northern Neonatal Network which coalesces data from 10 units in England allowing annual reports on workload, disease profiles, mortalities and facility utilization rates, among others. This information has been instrumental in building a larger policy advising data base than any one of the facilities could have individually provided while enhancing shared values that come with such unity of opinion and practice⁸⁰. The Vermont Oxford Network⁸¹ is another example of high-income countries-based research group.

As of 2015, it had over 1300 hospitals and many individual collaborators contributing towards improved neonatal care around the world with data-driven quality improvement and research. The group's data has been used globally as a resource for improving newborn care. The Child Healthcare Problem Identification Programme⁸² is one of the few examples of networks outside HICs. This South African program assembled findings from in-country hospitals used for paediatric mortality auditing over the three-year period, 2005 to 2007, to assess the quality of child healthcare measured by a locally developed audit tool.

Over time, clinical information networks have helped improve outcomes of care^{83,} and accelerated knowledge discovery⁸⁴. Central to such networks is the collection of standardised data across sites that can be used for tracking or benchmarking performance while promoting the sharing experiences and innovations to improve care. Most of these are in HICs. This thesis describes a unique achievement by the Kenyan group in this respect and demonstrated that clinical information or research network can be realized in LMIC or even LIC within manageable budgetary limits.

As CIN grew the functions were moving towards a Learning Health Systems (LHS) concept as known and practiced in high income countries while suggesting uptake of the same in LMICs. The details of this potential transformation were analysed in a commentary from the research group which is featured in this thesis¹³.

The Institute of Medicine defines a learning health care system as one "that is designed to generate and apply the best evidence for the collaborative health care choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in health care. The LHS (https://en.wikipedia.org/wiki/Learning_health_systems) platform has also been simply defined as "a health care organization that is purposefully designed to produce research in routine care settings and implement evidence at the point of care . The model's focus is on important patient outcomes, solving practical problems of service delivery, generating new evidence where required by research including the full range of patients encountered in routine practice, and rigorous evaluation of intervention effectiveness. The LHS approach thus deliberately combines concerns for improving quality through focus on appropriate infrastructure, resources, and understanding the process and outcomes of health care. The platform would support service delivery and implementation research needed to extend effective coverage in varying contexts within LMIC health systems.

There are five points (potential beneficiaries of LHS) considered pivotal in the 21st century as the world strives to realize the fruits of SDG, UHC, PHC strategies and targets for improved health:

 The global community seeks to achieve universal coverage of all humanity with requisite health services. This goal has been fully integrated in Kenya's health agenda with implementation being piloted in four counties as of December 2019. It is expected that national escalation will follow shortly after. Ensuring that UHC employs high-quality care will require that health systems be designed to integrate the delivery of health services with the generation of new knowledge about the effectiveness of these interventions.

- System strengthening and research will need to be better integrated to achieve this in LMIC so that changes in coverage, quality, and impact are measured, costs are contained, and health systems are responsive to users' needs and concerns.
- 3. High-income countries (HIC) responded to the challenges in 1 and 2 by initiating the evolution of LHS, a shift in strategy from traditional health care systems to one whose vision aspires to engage policymakers, researchers, service providers, and patients in learning that uses and strengthens routinely collected data to conduct pragmatic, contextually appropriate research, promote rapid adoption of findings to improve quality and outcomes, and promote continuous learning.
- 4. Notwithstanding expected challenges, development of LHS in LMIC should commence for their immediate and longer-term benefits and to avoid having to retrofit health systems with the capability to promote learning later and even greater cost.
- 5. A global coalition on how to build LHS that effectively share accumulating learning could enable LMICs to realize such a strategy which will enhance quality health services delivered at scale and within affordable budgets. The CIN work could be the launchpad for Kenya's entry into the larger family of health data giants of the world. It may be among the pioneers for Sub-Saharan Africa.

There are several successful examples networks in HICs which evolved into the LHS platforms. The United States Children's Oncology Group⁸⁵ relies to a substantial extent on the willingness of practicing health workers for establishing the large routinely collected clinical data base from which an increasing number of large comparative effectiveness evaluations are made possible. These groups have also been able to embed randomized trials at markedly reduced cost⁸⁶ and increase the speed of research requiring high levels of internal validity⁸⁷using the LHS platform. It is noted that LHSs that emerged in some HIC had their origins in smaller⁸⁸⁻⁹¹, often geographically or thematically linked networks. The CIN together with a few others in the Eastern or even Sub-Saharan Africa could be the origins of a more global organization with proper support and integration.

Challenges and Opportunities are envisaged in Low-Income Settings wishing to take this path. Research partnerships and capacity is one major challenge as these require steady funding to sustain and LMIC provide little such support. Even in HIC, the most available funds are usually donated vertically to support illness specific, explanatory, short term, or small-scale research work. The few substantially funded health programs are often poorly integrated into the wider health system research agenda. A migration towards low-cost research approaches is therefore essential as LMICs move towards embarrassing HSR as a component health budgets. The CIN and similar groups in LMICs provide such opportunities but astute local leadership is required to expand research capacity. This will additionally need globally recognized research capacity which actively engages the medical education community to produce health workers familiar with the principles of research and evidence-based medicine.

The fact that in LMIC most of the care is provided by practitioners with limited training and experience often operating in relative isolation does not help yet the simplicity of LHS may be what helps the situation. Kenya's rapidly growing CIN is one step in the right direction.

Clinical Practice Guidelines

Among the most important drivers of effective clinical care is the use of evidence-based guidelines. Developing such guidelines requires evidence from well-designed studies preferably systematic reviews and/or randomized controlled trials. Traditionally, guidelines used in LMICs are developed by WHO and devolved to countries for domiciling, a process which should incorporate local dynamics. Guideline domiciling should bring about realignment to local situations advised by disease epidemiology and prevailing health system conditions. Health systems research driven by reliable locally collected data is an essential approach for the processes of re-calibration of externally sourced guidelines for local use.

The methodologies and processes detailed in the thesis should benefit other countries within the same health sector developmental level as Kenya. It is envisaged that this impetus will lead to development of similar networks in the region with eventual broadening of international linkages for supporting uniformity of clinical practice guidelines. Guideline development and dissemination^{15,16} was considered a key deliverable of the HSR work constituting this thesis. The processes and activities used in provision of introductory training of users and promotion of enhanced uptake of CPGs were developed or modified locally.

This was considered essential given the findings from the 2002 survey which revealed un-availability of these important tools. Capacity to develop CPGs was considered a major challenge whose solution was paramount for improvement of in-patient care in these hospitals. This challenge was overcome and appropriate CPGs developed and tested in district hospitals in Kenya.

District hospitals in 2002 seldom had highly skilled clinicians at their disposal making them the primary targets for the CPGs. This would in turn benefit the clinical service area with the greatest potential for reducing mortality. Interestingly although aimed at the district hospital the CPG booklets were also introduced by the MoH and WHO-Kenya to major provincial, national hospital settings as well as training facilities at a cost of \$0.85 per copy. This reflected the fact that the development of the CPG booklet was a long term, careful process including the government, academics, clinical teachers, paediatricians and others from the stage of priority setting through drafting guidelines, evidence review, development of job aides, peer review of draft guidelines and dissemination, hence, enhancing local ownership. The CPGs produced consisted of clear and direct recommendations for 'best practice' in delivering emergency and early inpatient care for common problems and reflect international recommendations in line with those in the WHO Pocket Book of Hospital Care for Children⁷². As such the CPGs developed for Kenya reflect an attempt to implement referral level or in-patient IMCI. It is noted that CPGs are useless if they are not understood and if recommended practices are not delivered appropriately.

To ensure this, the deployment included a locally designed training approach around the CPGs adapting and extending the scope of an existing WHO course (ETAT) to produce ETAT+. This course linked the local CPG booklet and training to standardized admission forms. It was hypothesised that the approach of 'institutional learning' would promote change in the short term and minimize negative social influences as had been reported elsewhere⁹². Such an approach could go some way to mitigate the effect of the rapid staff turnover that was and still is a feature in many Kenyan hospitals. Training health providers of different clinical backgrounds together was also thought to empower cadres with less perceived authority while prompting and promoting change.

Although there were challenges to delivering training at an institutional level it was discovered that district hospitals in Kenya were willing to work towards making the approach possible if given adequate time to prepare. Despite absence of the then popular allowances for attendance up-to 99% of the participants completed the courses. Because decay of knowledge and loss of skills pose a real threat to the ongoing success of best practice care interventions⁹³ frequent evaluation of the real-life effectiveness of CPGs allied to support supervision in selected district hospitals was recommended. Further challenges for implementing and maintaining best practice care at a national scale include the capacity to update CPGs and sustain provision of job aides, to provide peer leadership and expert instructors, and, ideally, to integrate best practice into training institutions. Following presumed success in Kenya a comprehensive commentary was published to show-case the successes with suggestions on how other LMICs could replicate the example.

While global guidance provides a useful benchmark, this should inform but not replace such processes. The Kenya experience suggests that long-term partnership may enable successful, timely and credible national guideline development. Sustaining such approaches and embedding them within local institutions should be considered a part of the health system strengthening agenda.

The possible lessons for other LIC embarking on this journey are.

- 1. A credible guideline process will probably require at least two or three individuals who are familiar with the technical process of systematic review and use of the GRADE approach⁹⁴. This small team can help present and explain the evidence to a guideline panel, so it is formally and critically discussed (a process that builds ownership). Ideally one person should have more specific training in clinical epidemiology. Joining a team undertaking a formal Cochrane review, taking short courses in review methodology, and building links with the growing international community involved in evidence synthesis and evidence-informed decision making can provide a useful training for this small team while helping link them to a wider community of practice.
- 2. The next step is identification of specific target conditions and the intended users of the intended guidelines. The focus here was on the care for common, acute conditions aiming to define first-line treatment strategies. Targeting junior providers was not meant as an attempt to replace expert opinion which may have resulted in resistance to guidance, but to standardise practice in those with little training. An initial country effort might only tackle one or two pressing guideline questions as a demonstration of the process and its value.

- Identifying topics for guideline development where concerns exist in routine practice and outcomes, establishing value of new technology or treatment or where new research findings raise questions about existing practice.
- 4. Engaging appropriate stakeholders is clearly important from the start. Those involved in the decision making should have the authority and credibility to support any guideline's claims to be a national (or regional) recommendation. Government, professional associations, academic institutions and potentially regulatory bodies may thus need to be involved. At the same time, it is important to engage those involved in frontline practice. A guideline panel of 16–20 seems adequate to span all these groups. They must be given a real opportunity to discuss the evidence and reach consensus. By providing well-written reading materials and with skilled facilitation, 1 day seems sufficient to discuss a single topic in detail even when panellists themselves have little experience in evidence appraisal and use.

This report contributed to a relatively small body of existing literature exploring the process of national guideline development in Low Income Countries⁹⁵⁻⁹⁸. Clearly, rigour and transparency are important going forward in this platform. The report emphasized that efficiencies in provision of care can be gained by countries sharing their systematic reviews, so they do not need to be repeated, a clear aim of organisations such as the Cochrane Collaboration and WHO. This does not obviate the clear requirement for making country-relevant decisions locally to consider context and national values and preferences and promote ownership.

Health Policy Development

An example of policy research (a component of management science) is the work undertaken towards modifying in-patient care policies for human resources with a focus on Nairobi City County which has a large sick new-born population and persistently scores worse in new-born survival than even some rural less well served geographies⁹⁹. The impetus of this policy change drive was the identification of major gaps in access to guality care and sub-optimal coverage of nursing staff in the background of consistent absence of doctors in these units. Preliminary work suggested that major policy change in nursing duties was essential since they are the primary providers in these facilities. It was considered that allowing task shifting of some nurse duties to lower carder workers freeing the former to concentrate on skilled clinical work would be desirable. This needed a major policy shift as existing rules did not permit persons without nursing certification to undertake such duties. Such a policy would help in this country where most new-born care in public and to some extent private facilities is primarily or even fully upon the nursing staff. The processes described in this thesis and results thereon outline the considerable intensity of work needed to bring about change in policies, especially those around HRH. The multi-sector landscape evaluation of almost all facilities providing inpatient services to small and sick new-borns in Nairobi City County demonstrated the value of estimating effective coverage and identifying gaps in access and quality. There still seemed to be a pervasive notion, reinforced by some global health funding calls, that if the right intervention, innovation or technology were found, it would be possible to dramatically reduce neonatal mortality. The findings of this thesis indicate this notion is most likely misguided.

They suggest, instead, that the intervention most likely to improve neonatal hospital outcomes in the short term was a substantial increase in the number of health workers, especially nurses, in facilities that provide free or very low-cost care. This must be combined with longer term investment to redesign services around functional tiers and referral systems to improve coverage and quality together with improved information systems that support effective governance across all sectors. The proposed recommendations are still being reviewed by key decision makers.

Before the widespread dissemination of the CPGs described in this section it was necessary to establish their suitability, acceptability and impact on changing practice in the real world. This was undertaken using the implementation science research platform as described in the next section.

4.2.2 Implementation Science Research

Major gaps in availability and use (of the few available) CPGs were identified in the 2002 survey^{7,8}. In response, a concerted effort was made towards development or streamlining of the guidelines for use in Kenya's hospitals^{15,16}. This chapter describes the processes employed towards ensuring appropriateness of locally developed or adapted guidelines for routine care.

The Paediatric Admission Record

Aware of the major gaps in clinical records from the original survey and convinced that simplifying clinical data tools would be effective a standardized paediatric admission record chart was developed and field-tested yielding good results. The tool was well accepted by clinicians improving documentation of illness for admitted children and is presently in use countrywide. It was satisfying to note the success achieved for specific disease related signs such as conscious level, chest indrawing and skin turgor. Introduction of the PAR with focused interventions was the first step in the move towards improving service quality in response to the gaps identified in 2002. The instant acceptance and rapid uptake of this tool by most health workers was very encouraging. Since the good documentation was not sustained in cases admitted in the postintervention period when a PAR was not in use the tool was further confirmed having been responsible for the reported improvements. Comparable findings had been reported previously in similar environments¹⁰⁰⁻¹⁰². The fact that clinicians accepted the new tool introduced by an external group with no specific incentives and without close supervision was another plus point.

The locally developed PAR had received good acceptance and has since been adopted as a standard tool for routine use throughout the country.

Introduction of Clinical Practice Guidelines

The implementation research sub-theme also evaluated the locally developed CPGs using a multifaceted cluster randomized controlled trial confirming effectiveness. The multifaceted approach may, however, be intervention and/or recipient sensitive since a sub-study found less impact when deployed for enhancing utilization of guidelines for management of sick new-borns and the severely malnourished children. The conclusion from these findings was that a multifaceted intervention can improve use of guidelines and by extension the quality of in-patient paediatric care. This model warrants wider consideration as one approach to strengthening health systems in low-income settings. The challenges of standardizing such complex interventions remain but can be overcome by frequent practice and collaboration with more mature users. Some systematic reviews had previously indicated uncertainty in the value of multicomponent interventions justifying the need for local hypothesis testing¹⁰³. This evaluation, based on the classical Donabedian approach to assessing structure, process, and valued health system outcome measures¹⁰⁴ agrees with what others from some middle and even high-income countries^{105,106} have reported.

The data from this study had several important implications:

 Within Kenya it would obviously be a mistake to consider that the intervention package assessed can be scaled up simply by aiming for much broader coverage with the training course designed.

Effectiveness has been demonstrated only for the multifaceted intervention. Thus, scaling up should aim to further refine the intervention inputs.

- 2. Current efforts to implement and scale up improved care in low-income settings need to go beyond the existing tradition of producing and disseminating printed materials even when linked to training¹⁰⁷. Broader health system strengthening efforts, guided by current understanding of local contexts and capabilities and theories of change, are required.
- Routine information systems should be enhanced to generate the data required for evaluating care and capacity for conducting and disseminating analyses as part of routine feedback.
- 4. Countries other than Kenya considering adopting the approach need to tailor some intervention components to their setting. For example, the detail of a clinical guideline or job aide or approach to training may need to reflect available resources or local evidence.

In any case, such adaptation would need to be complemented by careful consideration of how systems can be made ready to support implementation of new practices and improved quality of care. The present findings support the need for due attention to influencing the institutional culture and context of rural hospitals although willingness to invest in more integrated approaches often seems lacking.

Audit and feedback

In one of the sub-studies enhanced audit feedback methodology as the implementing tool for guideline uptake was used.

The method was un-rewarding in the short term (less than 1 year) suggesting that there was need for defining the optimal durations for this implementation. This time-definition would be useful given that it is much simpler and less costly than the more elaborate multifaceted design. These results and others¹⁰⁸ suggest that some interventions may take longer to bring about guideline uptake than expected though the optimal duration is itself unclear. In the case of enhanced audit feedback, interventions lasting more than 1 year may produce better results. Future feedback intervention designs could also target individual clinicians as an additional approach to promote policy uptake. This would control for health provider rotations which reduced individual intervention intensity in this trial. Innovative methods like phone text messaging which had been implemented successfully in previous randomized trials¹⁰⁹ could also be used. It was noted that, logistically, such interventions would be much harder to sustain at scale.

This work demonstrates that modest investments in information systems may support improvements^{110,111}, and could support audit and feedback interventions¹¹². Investments in information systems within the field of adult and pediatric HIV care demonstrated feasibility of using such systems to improve guideline adherence at scale under routine care conditions in LMICs ^{113,114}. The 2002 survey revealed high mortality from neonatal illnesses, 26% (16-55)⁸ compared to all the other common conditions and little to no clinical data sufficient for estimation of case fatality for severe acute malnutrition.

The apparent lag of new-born care in Kenya's hospitals had been reported by another paper also included in the thesis²⁸. Focus on this vulnerable appears less intense than that of older children.

Regarding management of malnutrition, there were improvements in documentation of clinical syndromes and supportive care in both groups compared to baseline though the intervention group did marginally better. The intervention did not, however, bring about meaningful improvement in adherences to treatment protocols for severe acute malnutrition. This was surprising given the parent study demonstrated marked improvements in the use of other paediatric care guidelines²⁰. These findings may suggest that lower emphasis on supervision and feedback in these clinical areas were contributing towards disproportionately worse performance after intervention. It was speculated that health workers, who often received as little as 2 weeks pre-service training in neonatal care had limited knowledge and skills on the use of essential drugs or appropriate supportive care including feeding in vulnerable, often preterm, babies and children with severe malnutrition. Such shortcomings emanate from limitations in basic training for many health workers. These observations advised an opinion that many health workers at hospital level were unable to provide appropriately planned care for sick new-borns or children with severe acute malnutrition. Inadequacies were seen in key tasks such as prescription of antibiotics and feeds even when resources were available. These findings suggested that without improvements in hospital-based information systems it will be impossible to know whether the frequent calls for deployment of and investment in interventions to improve care are being heeded. Problems exist despite a long history of development and formulation of international guidelines even when adapted nationally. Future research should examine how best to implement better care in rural hospitals, enabling them to serve their expected role in global efforts to reduce neonatal and child mortality in LMIC settings such as Kenya.

A previous report suggested that focusing greater attention to improving information systems while enabling monitoring and feedback interventions can promote adoption of effective interventions as part of wider efforts to reduce new-born and child mortality¹¹⁵.

DVD as an implementation tool

A none-traditional implementation approach employing the use of use of Digital Versatile Disk (DVD) to supplement classroom learning in supporting introduction of new vaccines into a national program was undertaken. This approach whose impact was evaluated primarily by a behavioral science study demonstrated feasibility of the tool for preintroduction preparation. At present there is still limited work on how to implement new national policies at scale in LMIC. The failure to monitor implementation means a lot of research evidence is not effectively translating to health benefits.

Management science and research around it aims to develop, sustain and govern appropriate application of health services, in essence, speaking to the pivotal HS-BB, governance and leadership. Upon production of tools and strategies, implementation science research establishes fitness for purpose. The real-life experiences of application of any of these is supported by the principles of delivery science and research. The next section discusses the dynamics of delivery of the locally developed CPGs together with additional reports within the sub-theme from other contributing networks.

4.2.3 Delivery Science Research

In this thesis the sub-theme delivery science research has been granulated further into three categories:

- Quality health service delivery, referring to the uptake and appropriate use of CPGs for the conditions responsible for highest impact on in-patient morbidity and mortality. Findings from work done in a Provincial General Hospital (PGH) provide some data for this.
- Capacity for service delivery is defined in this thesis as availability of system structures and processes supporting provision of in-patient care at levels commensurate with expected needs. Studies from rural general and urban new-born units were used to support this discussion.
- Coverage of services is a supply-demand balance of in-patient care services measured by geographic spread of facilities and fulfilment of the needs of the catchment population(s). The thesis reports this issue using data for newborns in Nairobi facilities.

Evidence based clinical practice guidelines are fundamental in provision of quality services, however, their availability does not necessarily translate into effective deployment by frontline health workers responsible for day-to-day care of new-borns and children in hospitals. The governance and leadership structures are often oblivious of these situation(s). Having helped develop and successfully introduced a comprehensive retinue of CPGs between 2005 and 2015 there remained some concern about appropriate utilization of these tools in the years following introduction.

Though subsequent reports and observations have confirmed the pivotal value of CPGs challenges remain in the drive toward universal use. Maximal benefit from these tools can only be realized if they are made available and routinely used in the day-to-day care of patients with relevant conditions.

Quality of service delivery

In this chapter quality of care with these tools has been used as a measure of appropriate delivery of health interventions this time in a higher-level facility, Provincial General Hospital and 22 internship training facilities from which optimal services are expected. The studies interrogating quality of care were measured by retrospective recreation of steps taken by providers in the treatment of Pneumonia and Severe Acute Malnutrition in a larger hospital than the primary referral group. The results compared closely with the average primary referral facilities included in the CIN group suggesting that HS problems in Kenya manifested across all levels of public health service infrastructure. By the time these two studies were undertaken, the CPGs⁷³ had been disseminated to all public sector and some small private facilities providing in-patient care to children and newborns. It was, therefore, not reassuring to find a regional hospital performing that at such levels in key aspects of management of SAM and Pneumonia, two of the high morbidity and mortality diseases whose management was included in the original CPG booklet. The internship training centres performed much better than the 2002 reports and, in some instances, even the PGH. Nevertheless, more is still expected of them. Though the newborn admission record (NAR) chart had already been introduced to improve clinical information capture, only had 57% of the sampled case notes had evidence of use of this tool.

The utilization of the other process parameters ranged from 35 to 95% with only 3 scoring more than 70%. It was observed that though this level of adherence to CPG use in newborn care was suboptimal it was still considerably higher than was found in the 2002 survey^{7,8}. From these results, it was concluded that some improvement was beginning to appear beyond the facilities affiliated with DHSG/CIN. It is noted that the evaluations were undertaken at a time when the Kenya Medical Practitioners and Dentists Board had a strict regime of regular inspection of these hospitals for fitness to continue enjoying the status. Regulatory bodies can also help in health systems strengthening.

Capacity to deliver care

Structural capacity was evaluated by three studies formatted as structural and process preparedness. The studies evaluated preparedness for care of newborns and older children separately. The assessment of capacity to deliver services conducted in twenty-two training hospitals was perhaps the first attempt to institute quality monitoring in partnership with government at reasonable scale and using well defined methods. While earlier work was less comprehensive there are indications that overall, the quality of pediatric care has improved compared to previous reports^{27,116}. Because the core of this assessment was in establishing defined structures and processes, an elaborate capacity description for these hospitals was realized. The findings across these studies visible improvements in capacity to deliver services to children and newborns across the country. Processes and strategies used to deliver health care often need re-evaluation to establish sustainability of both efficacy, user acceptability, cost or changing health worker dynamics among other issues. The structural capacity for care of newborns in Nairobi was graded between 50 and 100% depending on availability of 126 items in 6 domains. The research

team had estimated that structural capacity score of ≥50% would be able to provide satisfactory services if well utilized. The four public hospitals with the largest patient numbers scored between 81 and 90% while the mission and private facilities had capacities distributed across the range. It was also noted higher structural scores do not always translate into quality of care delivered to the patient, they only indicate available strengths which if well used could result the desired care goals being attained. Capacity to deliver new-born care in Nairobi is challenged by sub-optimal availability and utilization of structural implements and strategies in both private and public health facilities as well as mission hospitals.

Coverage of service delivery

The best examples of service delivery coverage was availed by the Health Services that Deliver for New-borns Expert Group. While gathering data to help in development of human resource policy for care of sick new-borns needing admission in Nairobi data was available to determine geographic distribution of and population access to facilities providing such care, a first such estimate. It was found that Nairobi scores poorly in both parameters. Such information is useful for both infrastructure optimization and service expansion.

Improvement science and research are responsible for dealing with modifications of delivery processes required to responds to these needs. The next section discusses how delivery science was deployed in the research work supporting this thesis.

4.2.4 Improvement Science Research

Improvement science is a fundamental component of health care advancement. It complements the other sub-thematic systems research because there is always need to ensure that interventions remain fit for purpose. The science also allows systems researchers to adjust existing tools and strategies in tandem with new knowledge and experiences. Health care intervention improvement come in various forms: 1) Re-inventing processes through use of innovative approaches to better deliver and existing intervention, 2) Revising application as in changing deployment of an existing strategy or equipment and 3) Alteration of the primary structure such as upgrading equipment or restructuring a CPG in line with new knowledge.

Adoption of locally developed guidelines

Progressive increment in utilization of the locally developed CPGs as a measure of temporal improvement in uptake was described for a period of 11 from 2002 t0 2012. This was brought about by enhanced dissemination of process guidelines to scale. The enhancement was in form of sustained advocacy and stakeholder expansion in building acceptance of the locally developed of CPGs. Nevertheless, full availability of basic resources was not attained and major gaps still existed in building demand for these important clinical tools. Optimal utilization of simple diagnostics and technologies was noted to have been heading in the right direction. From these findings it was confirmed that CPG utilization scale up was possible in low-income settings using introduction process re-invention. More sustained efforts to maintain or enhance uptake momentum for guideline clusters according to respective needs were recommended.

Having not found any comparable studies in published literature, it was concluded that routine monitoring of hospital care outcomes and uptake of innovations are absent or inadequate. This information when available should be shared to help others seeking to benchmark especially in L and LMICs. The twenty-two facilities involved in the study offered both pre-service and immediate post qualification training for doctors, nurses and clinical officers hence better performance had been expected from them.

Appropriateness of new WHO pneumonia guidelines

An example of delivery simplification was articulated by the interrogation the WHO change of pneumonia classification to two-level (from three) as a possible vehicle to increased clinical diagnostic accuracy and management of Pneumonia. This had been advised by new evidence indicating that the three-tier classification did not effectively distinguish treatment options. The new recommendation was designed to simplify training of health workers at the primary care and community level by reducing decision making as to whether a child requires in-patient or outpatient care. On further analysis, it was observed that the recommendations did not consider very low WAZ or mild to moderate pallor as important risk factors justifying admission. In that case, 1272 (11%) of 12 025 children defined as having non-severe pneumonia with these two risk categories in the 2014-2015 cohort would have been managed at home putting at high risk of death. The downgrading of lower chest wall indrawing, previously a sign defining the need for admission had also been challenged by others in settings of high mortality¹¹⁷, where it is associated with fatal pneumonia¹¹⁸. The findings established that in Kenya and elsewhere in L and LMICs this advisory needed additional calibration.

These findings provide evidence that improvement strategies may be population specific, hence, requiring more rigorous inquiry before adaptation in different environments. Notwithstanding the negative findings, the process exemplified a case of strategy revision for enhanced efficiency.

Abridged new-born resuscitation

Another example of simplification was the controlled trial on newborn resuscitation which compressed the traditional three-day training into one day at a large urban maternity hospital. It was believed that if found effective program costs would be saved since the full training took three days at that time. Reducing raining duration was also considered advantageous for time constrained health workers. The abbreviated training performed very well in terms of appropriateness and safety of procedure. The findings add to a body of knowledge suggesting improvement in clinical outcomes^{119,120} or in acquisition of knowledge and skills of providers following resuscitation training¹²¹. Other studies have demonstrated rapid decline of knowledge and skills after training¹²². This would mean that training needs to be repeated at regular intervals to reduce knowledge and skills erosion.

The findings confirmed that a simple one-day new-born resuscitation training can be followed by significant, short-term improvement in health worker practices. Evidence on effects on long term performance or clinical outcomes, however, remain inconclusive and can only be established by larger trials. Nevertheless, the findings of this study advised the inclusion of newborn resuscitation in the ETAT⁺ platform as a one-day component significantly up-scaling its reach.

Introduction of HPV Vaccine

The thesis also reports a study which attempted to bring about improvement of services scaled regionally through engagement of stakeholders from twenty countries at different stages of implementing a new intervention. This peer- to-peer engagement hoped to have earlier implementers driving improved approaches among those at later stages of implementation. This was an example of change of strategy for better outcomes.

After completing the interventions responding to the gaps identified in 2002, a second evaluation was undertaken to measure change. The HS-BB included in the 2014-15 survey were, governance and leadership (availability of CPGs), delivery (workload and utilization of working groups), health information (availability and quality of data) and from a different research network, human resources (distribution of paediatricians). The next section discusses the findings.

4.3 STATUS OF HEALTH SYSTEMS SUPPORTING IN-PATIENT CARE IN 2015

The DHS data and its deficits pioneered thoughts of injecting quality clinical care data in the routine record system. The activities following this inaugural survey provided the impetus advising creation of the Clinical Information Network which in 2014-15 undertook a second survey focusing on governance and leadership, service delivery and health information systems BB indicators. A side study provided some human resources data. This chapter discusses the findings of the survey as evidence of potential impact(s) of the HSR interventions undertaken between the two surveys.

Overall, the second survey revealed several achievements and lessons learned in exploring the place of HSR for enhancing child survival in Kenya and by extension other countries in LMICs.

Health Information Systems

The value of establishing the Clinical Information Network, a robust system of routine data collection independent of the one by the Ministry of Health was one of the most important outputs of this process. The weaknesses in data availability and quality identified in the first survey were almost erased.

The county coverage of this network grew from thirteen to eighteen between 2013 and December 2020 uniquely positioning the country as one having the largest and most nationally representative data base of its kind in typical LMICs. Using this data, it is now possible to report accurate morbidity and mortality statistics as well as computation of multi-risk factors for all-cause mortality. The work has significantly built the capacity of HIS for supporting in-patient care. Mortality is the most frequently reported outcome in audit-based health research. The statistic is easy to explain to health workers, administrators, politicians, donors and governments. It is the most socially visible measure at population level. Unfortunately, it is also the most unreliable indicator for assessing or comparing performances of health institutions. In the two surveys analyzed in this thesis, mortality was used more for assessing performance of the HIS than as indicator of the other BB performances. Like the 2002 survey most deaths were associated with the same retinue of common illnesses. The syndrome specific mortality was now more accurately obtained. It was also easy to determine that these deaths occurred most frequently within the first 48 hours of admission as had been reported by other workers^{63,64}. The latter is usually thought to be related to delays in presentation. The continued occurrence of many deaths within 48 hours of admission suggested sustained need for improved early referral from primary care settings. Almost two decades after the global launch of the Integrated Management of Childhood Illnesses strategy and more recently Integrated Community Case Management, referral systems remain weak.

The need for efforts to ensure that health workers can perform effective triage and emergency care followed by proper management of common causes of childhood admissions cannot be over-emphasized.

Although admissions of children aged over 5 years were less common, mortality in this group was high. More work to explain this finding through systematic audit of deaths will be necessary and can now be tackled within the CIN.

All-course in-patient mortality is frequently used as an indicator of performance of health institutions. Properly audited deaths often identify gaps in key aspects of care capable of potentiating death in children with otherwise recoverable conditions.

In addition to simply determining this useful statistic good quality data allowed computation of clinical parameters associated with increased chances of death. Using the wealth of data from CIN a comprehensive analysis was undertaken to estimate parameters deemed predictive of all-cause mortality regardless of the primary diagnosis. The findings were comparable with those reported by one large study involving four public hospitals in Uganda with more than 50,000 admissions annually¹²³. This comparator study also reported increased risk of in-patient paediatric mortality in the presence of neurological, circulatory and respiratory parameters.

The other important observation from this analysis was that it was possible to use readily available routine data to advance knowledge and advice policy prioritization of care through improved triage parameters. In general, all-cause crude and cluster adjusted mortality rate was highly variable across hospitals. Such variation was explained by variation in severity of illness at the time of clinical presentation.

The data supports the use of clinical risk factors drawn from guidelines in day-to-day use for prioritizing care and identifying children at the highest risk of death. The data can also help in developing risk adjusted mortality estimates for pooled and hospital specific. It was further, demonstrated that having a large patient dataset from multiple geographically diverse sites may improve understanding of health system challenges and performance.

Such work provides a learning platform for the design of common data frameworks that are relevant to clinical practice and might be incorporated into future electronic medical records (EMRs) that go beyond a focus on cost accounting needs¹²⁴.

Another measure of great strides in improved HIS was availability of more reliable neonatal data. The overall neonatal mortality from the pooled data was 19% (range 13.4-31.6). Birth weight specific rates were inversely related to the respective sizes with up to 80% of those weighing below 1000 grams at birth succumbing. Additional data in the publication (not included in figure 39) reported maternal mortality ratio of 276 per 100,000 live births and fresh stillbirths ranging from 11 to 43 per 1000 births. There was a large representation of term babies probably related to the magnitude of asphyxia (more frequently diagnosed in term babies) reported. The burden of maternal mortality, fresh stillbirths and birth asphyxia was high in these facilities suggesting that opportunities to earn the triple return on investment offered by improving referral and the quality of perinatal care¹²⁵ existed and needed to be explored. In addition, given the disproportionately poor outcomes among LBW babies, enhancement of capacity to offer care for this vulnerable group was deemed paramount.

Both overall and birth-weight specific in-patient mortality remains high in Kenyan hospitals demanding major structural and process adjustments to improve new-born survival which is behind overall child survival. Such adjustments have been suggested by the sub-thematic HSR findings reported in this thesis.

Service delivery

Improvements were found in service quality through, enhanced use of CPG, even though this was unequal for different conditions and diseases despite all being in one booklet implying that more efforts will be needed to optimize the use of this important booklet.

Clinicians may have been apportioning different importance to sections of the CPGs. The service quality improvements were also asymmetrical across hospitals suggesting the need to focus on individual clinicians separate from the institutions they serve.

Governance and leadership

The improvements in service delivery were partly owed to enhanced and more consistent presence CPGs in all facilities. These had been developed within the management science research platform which could not succeed without strong involvement of leadership from the system. The much enhanced HIS infrastructure available in 2015 is another structural evidence of improved governance and leadership. Notwithstanding these improvements, there remains room for further work as the country enters the Sustainable Development Goals (SDG) era.

Human Resources for Health

The HRH paper demonstrated a steady growth in local production of young doctors over the previous 40 years. Regrettably, there is low up-take and retention of these essential workers in the public service. The paper reports 55% of the county hospitals as having two or more paediatricians, a noticeable improvement from 2002 when only 28% of the surveyed hospitals had a paediatrician. It was also established (from Kenya Medical Practitioners and Dentists Council) that in 2019, there were 305 paediatricians in clinical practice, 1.33 per 100 000 population of individuals aged <19 years. Most of these paediatricians were in the tertiary facilities with only ninety-four in the 47 rural primary referral hospitals in Kenya. Twenty-one (45%) of the forty-seven counties had between 0 and 1 paediatrician. Government policy aims to have 1416 paediatricians in the public sector by 2030 though this remains aspirational as there is no comprehensive training or financing plan to reach this target. In any case, health workforce recruitment, financing and management is now devolved to forty-seven counties with little to no central government control. Most of the paediatric care is, therefore, provided by non-specialist clinical workers. On the positive side 55% of the counties (the current primary referral facilities) had at least one paediatrician compared to only 4 (<30%) of the 14 similar facilities surveyed in 2002⁸.
5.0 CHAPTER 5: CONCLUSSIONS AND RECOMMENDATION

5.1 CONCLUSIONS

- i. The state of health systems supporting in-patient care of children was poor at the turn of the century coinciding with a period of steady deterioration in child health indices during the last decade of the 20th century. This was particularly pronounced in the important pillars (building Blocks) of governance and leadership, health delivery quality, health information systems and human resources for health.
- ii. To support the governance and leadership structures there needs to be a functioning management science research platform supporting policy articulation and practice guideline development ensuring effective leadership and availability of critical tools for the clinical workspace. The need for equitable dissemination of policies and evidencebased guidelines is also demonstrated in the thesis.
- iii. In creating the CIN and commencing its transition to a Learning Health Systems platform, Kenya joins an elite group of countries with such innovation. It is envisaged that expansion of this system to capture a wider spectrum of data for all patients at any age is possible with great advantage. The fact that the MOH is now preparing to take over the support of CIN and scale it further is a commendable outcome of great national value. The CIN is part of a health information infra-structure, hence, its development also supports the governance BB.

- iv. Low and Low Middle Income countries like Kenya traditionally rely on clinical care guidelines and protocols developed by the international health agencies such as WHO and UNICEF. These are not always fully accepted by Health Care Workers or even easily adaptable for local use. The thesis provides evidence that locally developed or domiciled and appropriately introduced guidelines can enjoy high uptake by clinicians potentially enhancing quality of care. To support this, though, strong and robust implementation-based intervention studies are pivotal. This should whenever possible be undertaken using the multifaceted intervention model.
- v. Health care evolves rapidly these days inviting many innovations and changes in delivery systems. Innovations, however, do not always apply uniformly across different populations. Part of a robust HSR culture or platform should aim to evaluate all such innovations or improvements before deployment as was done here. This should preferably be accomplished before launch. To accomplish this the improvement science component of HSR needs to be developed and natured by user countries.
- vi. The road to policy research is tortuous and often long. The thesis demonstrated some of the ways of overcoming such challenges. The stepwise multi-stakeholder approach with emphasis on building coalitions for enhanced by-in helped start the process of changing paediatric care policies in Kenya. Concerted and sustainable effort will be required to drive this important agenda further.

- vii. The post-intervention evaluation demonstrated improvements in three health systems building blocks:
 - a) Governance and leadership; near universal availability of CPGs in primary referral hospitals. The uptake eventually reached faith, private and even higher-level facilities.
 - b) Service delivery; improved utilization of clinical practice guidelines implying better status of evidence driven care. Workload data is now available for newborns as well. Most hospitals are growing their structural and process delivery capacity portfolio.
 - c) Health information systems; following the operationalization of the clinical information network, clinical data can now be obtained in real time. This will support research for policy formulation and science in general.
 - d) Human resources for health; from a study outside of the main 2014-2015 survey the number of paediatricians in primary referral hospitals compared with 2002.
 Availability of at least one paediatrician was reported at 55.3% in 2020 compared to about 28.6% in 2002.

5.2 RECOMMENDATIONS

5. There is need to establish regular clinical audits using nationally representative samples of hospitals with goals of identifying practice or other gaps potentially impeding service delivery. Such audits will advise periodic interventions as deemed useful.

- 6. Given the success of the clinical information network which covers in-patient care in Kenya's primary referral hospitals this program should be expanded to include all public hospitals providing such care. The coverage spectrum should eventually grow to include all conditions in all primary referral hospitals while serving all clinical disciplines within these facilities. Such a multidisciplinary approach would include maternal heath, adult medicine, general surgery and many others. The evolution of this network into a Learning Health Systems (LHS) platform should be supported through public funding.
- 7. Given the vastly important application(s) of Health Systems Research exemplified by this thesis, it is recommended that medical training institutions include the discipline within their curricula. Tertiary training and primary health research institutions should establish, develop or expand their HSR portfolio to participate more effectively in supporting health care in Kenya.
- 8. The three stage Health policy research (HPR) model adopted by the work leading to this thesis is also recommended as a tool for similar inquiry.

6.0 CHAPTER 6: CONTRIBUTIONS TO SCIENCE AND SOCIETY

This chapter provides the author's views on the scientific contribution of this thesis segmented into; the value of synchronized Health Systems Research in promoting and improving care of sick children, building and disseminating knowledge behind the lens of LMIC community and contributing to policy development.

6.1 ELUCIDATING THE VALUE OF SYNCHRONIZED HS-RESEARCH

The research activities leading this thesis were undertaken and published between the years 2004 and 2020. Most of them covered in-patient care of new-bons and children with a small number (N=3) focusing on the preventive platform. The ethos of the research was in response to the high child deaths which in 2000 had been on the rise from 1990 giving Kenya an additional urgency in answering the call of the MDG 4. Such response would have to include improvement of in-patient care in the health facilities home to most of severely ill children and in-hospital deliveries. In 2000 little if anything was known about the functional capacities of these hospitals in Kenya. This thesis proposes an effective sequence of research driven necessary for mounting adequate responses to situations such as was Kenya's 2000 dilemma (figure 41).

This sequence was largely followed by the main research group, DHSG in the work originating with a situation analysis (2002 survey) through reactive responses (sub-thematic HSR) culminating in a second situation analysis (2014-15 survey).



The author opines that this process demonstrated significant value in advising policy and practice confirming its usefulness. The author further contends that this pathway should be used by others in similar situations with additional refinements to meet local needs as necessary. The model is presented as a prototype invention.

6.2 IMPROVING CARE OF CHILDREN WITH SERIOUS ILLNESSES

The thesis articulates four aspects demonstrating improvement in clinical practice for sick children admitted in Kenya's hospitals brought about by the innovative Health Systems Research approaches described in 6.1 above.

- Successful development of the first locally generated Clinical Practice Guidelines encompassing recognition, laboratory evaluation and care of the illnesses responsible for over 80% of admissions and deaths of children. Because of innovative introduction and dissemination methods these guidelines were integrated into the country's health systems almost seamlessly.
- 2) By establishing and enhancing regular and facility managed Continuous Education (CME) Activities, service delivery quality is further supported with sustainable cost implications. This CME program is expected to help in maintaining clinicians' practice standards in keeping with new evidence. The program also supports clinicians towards fulfilment of health regulatory bodies' stipulations for annual licensure.
- 3) The evolution of the Clinical Information Network towards a Learning Health Systems platform which will revolutionize clinical data capture and utilization in support of improved care and clinical research in Kenya. It is speculated that adoption of this tool by others in the LMIC will be of tremendous benefit.
- 4) Creation of easy-to-use behavior change training model for promoting adoption and uptake of care guidelines at all levels. This is based on the intervention components drawing on the Expert Recommendations for Implementing Change (ERIC) typology.

6.3 ENHANCING POLICIES SUPPORTING CHILD HEALTH

The thesis also communicates adaptable processes and methods for undertaking effective health policy research. Three such examples are:

- a) Proposing a nursing task shifting regime aimed at freeing them from more menial duties so they can concentrate on clinical care commensurate with their skill levels. Those duties which, include simple clinical observations and recording, would then be performed by less skilled workers. This was proposed as a solution to nursing staff deficiencies identified. Kenya's Ministry of Health is presently evaluating the findings for purposes of formulation of relevant HRH policy.
- b) Development of a well-researched recommendation for introduction of a new vaccine in the public sector program. The policy brief was adopted by the Ministry of Health and is now at pilot introduction.
- c) Providing compelling evidence indicating that a Ministry of Health owned data infrastructure such as the Clinical Information Network qualifies to be embedded into the Country's Health Information Systems Policies.

These simple and relatively low-cost approaches in important aspects of health care research are summarized in this thesis for others to domicile and deploy.

6.4 BUILDING AND DISSEMINATING KNOWLEDGE

The thesis summarizes and unites into a monogram 30 publications in high impact journals. The performance of these papers is summarized in figure 41.



The Google and PubMed visibility confirm the growth of HSR in Kenya and contribution of the author thereon. On their own, each of these papers give isolated results but in integrating and communicating their findings in one monolithic document their contribution to HSR in Kenya and its impact in the global arena is emphasized.

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