

Safety of essential surgery performed by non-physicians in low and middle income
countries

by

EMILY SLIZ

DISSERTATION

Presented to the Faculty of the Medical School
The University of Texas Southwestern Medical Center
In Partial Fulfillment of the Requirements
For the Degree of

DOCTOR OF MEDICINE WITH DISTINCTION IN GLOBAL HEALTH

The University of Texas Southwestern Medical Center
Dallas, TX

Copyright

by

Emily Sliz

ACKNOWLEDGMENTS

First, a special thank you to Dr. Mihalic for advocating for me to be in the IMEP program.

Thank you to the countless doctors, medical students, nurses, and surgical technicians who welcomed me and taught me at Necker Hospital and Cochin Hospital in Paris, France, in the orthopedic surgery department at Calmette Hospital in Phnom Penh, Cambodia, and in the surgery department at Padar Hospital in Padar, India.

Thank you to Erica, Julia, and Trevor for their friendship and support.

And last but not least, so many thanks to my wonderful family for bring love and happiness into my life.

ABSTRACT

Safety of essential surgery performed by non-physicians in low and middle income countries

Emily Sliz

The University of Texas Southwestern Medical Center, 2016

Supervising Professor: Angela Mihalic, M.D.

Background: A lack of surgically trained providers in low and middle income countries (LMICs) is a major contributor to high morbidity and mortality from surgical conditions in these settings. Some countries train non-physician clinicians (NPCs) in surgery to help solve this problem. The World Health Organization recommends this practice in some cases, although data on its safety is limited.

Hypothesis: Complication rates of NPCs and physicians practicing essential surgery in LMICs are similar.

Methods: A literature search using PubMed and OvidMEDLINE identified studies reporting complication rates of NPCs when performing essential surgery in LMICs.

Results: I identified 28 articles and 2 abstracts reporting the complication rates of 57,578 procedures performed by NPC and MD surgeons in LMICs, as well as 4 systematic reviews and/or meta-analyses on the safety of NPC surgery. Studies came from 4 world regions and the majority were from sub-Saharan Africa. Studies addressed 5 areas: major general surgery (13,253 procedures), medical male circumcision (14,248 procedures, 70% in adults), emergency obstetric surgery (18,853 procedures), tubal ligation (7,179 procedures) and first-trimester abortion (4,045 procedures). Complication and mortality rates for NPC and MD surgeons were similar when performing a variety of general surgery procedures, tubal ligation, and abortion. One out of 7 studies on circumcision found increased complications when NPC performed the procedure. One out of seven studies found increased maternal and perinatal mortality when NPCs performed emergency obstetric surgery, although these differences were not found in meta-analysis. Meta-analysis did find increased rates of wound healing problems and wound infection in patients of NPCs after obstetric surgery. The majority of studies in this review are limited by factors related to study design.

Conclusion: NPC surgeons contribute significantly to surgical practice in at least 7 LMICs, all in sub-Saharan Africa. In the majority of cases, NPC and MD surgeons had similar complication rates when performing essential surgery. In areas with large unmet need for surgical care, NPC providers offer a significant mortality and morbidity benefit by increasing access. More research is needed to define the scope of NPC surgical practice that will maximize this benefit and to develop the proper supervision and support mechanisms that MDs must provide to these clinicians.

TABLE OF CONTENTS

LIST OF TABLES.....	VI
INTRODUCTION.....	1
METHODS.....	7
RESULTS.....	11
DISCUSSION.....	37
CONCLUSION.....	45
REFERENCES.....	46

LIST OF TABLES

Table 1: Estimated need for surgical procedures in selected world regions.....	2
Table 2: Surgical providers in selected countries.....	4
Table 3: Recommendations for an essential surgery package.....	8
Table 4: Literature review results.....	12
Table 5: General surgery study design details.....	14
Table 6: General surgery NPC provider details.....	15
Table 7: General surgery procedure-specific results.....	16
Table 8: General surgery aggregated results.....	17
Table 9: Circumcision study design details.....	20
Table 10: Circumcision NPC provider details.....	21
Table 11: Circumcision results.....	22
Table 12: Emergency obstetric surgery study design details.....	26
Table 13: Emergency obstetric surgery NPC provider details.....	27
Table 14: Emergency obstetric surgery results.....	27
Table 15: Tubal ligation study design details.....	30
Table 16: Tubal ligation NPC provider details.....	31
Table 17: Tubal ligation results.....	32
Table 18: Abortion study design details.....	34
Table 19: Abortion NPC provider details.....	35
Table 20: Abortion results.....	36

INTRODUCTION

A growing body of evidence demonstrates a large unmet need for surgical care in many low and middle-income countries. The emergence of this data, along with a shift in global health policy from disease-specific interventions to a strengthening of health systems approach and increasing awareness of an impending “epidemiologic transition” in the developing world have all supported the emergence of a new interest in surgery as a global health priority (1, 2). The World Health Organization (WHO), the World Bank’s Disease Control Priorities, 3rd edition (DCP3), the *Lancet*, and various advocacy groups (The International Collaboration for Emergency Surgery (ICES), and the Bellagio Essential Surgery Group, for example) have all contributed to this movement by supporting research and major projects to advance knowledge and action on surgical care in low-resource environments (2-6).

Understanding the need for surgical services in LMICs

Until recently, a quantitative understanding of the need for surgical services at the country and regional level has been lacking, especially in the developing world where records of surgical output and cause of death are scarce. Consequently, a number of studies based on expert opinion and extrapolation of data have been undertaken to fill this gap in knowledge and guide policy. In 2006, a model to estimate the global burden of surgical disease was created by asking surgeons from around the world to estimate what percentage of patients with given conditions would need a surgical intervention. This model concluded that 11% of morbidity and mortality worldwide is due to surgical conditions (7). In 2015 a more inclusive model was created, asking experts what percentage of patients with given conditions would benefit from having a surgeon involved in their management. This model estimated that 28% of deaths and 32% of disability-adjusted life years (DALYs) lost globally are due to surgical disease. Good inter-rater reliability and agreement with real-life estimates suggest that this model provides a more realistic estimation of the substantial role of surgery in modern medicine (8). Another study estimated the unmet need for surgical services by using a well-performing country

(New Zealand) to create benchmarks for number of surgical procedures needed in one year to “optimally” care for patients with a given condition. Disease prevalence data was then used to estimate the number of procedures ideally needed on a global and regional level. This data becomes useful when coupled with data on actual surgical output by world region met (9), allowing a calculation of unmet surgical need in terms of procedure numbers. In this analysis, four regions were meeting substantially lower than 50% of their surgical need: Western, Eastern, and Central sub-Saharan Africa and Southern Asia. Data for selected regions is show in Table 1 (10).

Table 1: Estimated need for surgical procedures in selected world regions (10)

Region	Ratio of met need: unmet need
Western sub-Saharan Africa	0.13
Eastern sub-Saharan Africa	0.20
Southern Asia	0.21
Central sub-Saharan Africa	0.31
Southeast Asia	0.52
Southern sub-Saharan Africa	0.92
Eastern Europe	1.17
Southern Latin America	1.18
Western Europe	2.52
High Income North America	4.01

To put this data into economic terms, Alkire et al. used the WHO’s Projecting the Economic Cost of Ill-health (EPIC) model and found that surgical conditions at currently levels of mortality would result in loss of 1.25% of potential gross domestic product (GDP) globally during the next 15 years. In addition, losses in this study were inequitably distributed, with Western Europe losing 1% of GDP and Central sub-Saharan Africa losing over 2.5% of GDP, for example (11).

A series of three papers published in 2014 undertook a disease specific analysis of the unmet need for surgical care, estimating the burden of obstetric complications, digestive diseases, and injuries that could have been averted during one year by universal access to basic surgical interventions in LMICs. Findings indicated that in 2010, 37% (21.1 million) of the DALYs lost to maternal hemorrhage, obstructed labor, obstetric fistula, abortion, and neonatal encephalopathy in LMICs could have been prevented by access to a package of emergency obstetric interventions¹. In terms of mortality, 67,859 maternal deaths and 165,800 neonatal deaths could have been prevented (12). The study of digestive disorders included appendicitis, intestinal obstruction without hernia, inguinal and femoral hernia, and gallbladder and bile duct disease. Analysis estimated that 65% (or 4.8 million DALYs) and 145,000 deaths due to these conditions could have been prevented by universal access to surgical treatment (13). The study of injuries included ten categories of injuries² and estimated that 21% of the burden from these conditions (or 52.3 million DALYs) and 1 million deaths could have been prevented by universal access to a set of basic surgical interventions³ (14).

Availability of surgical providers

This large unmet need for surgical care results from a variety of factors on both the supply and demand side, ranging from lack of functioning operating room equipment to inability of patients to afford surgery. One significant barrier in many areas is lack of surgically trained health care providers (15-18). Holmer, et al. reported on the numbers of surgical specialists, obstetricians, and anesthesiologists per country for 167 countries in their April 2015 article in *Lancet Global Health*.

¹ Cesarean, instrumental delivery, dilatation and curettage/evacuation, manual vacuum aspiration, salpingectomy, manual removal of placenta, repair of vaginal/perineal/cervical tears, and hysterectomy

² Road injury, other transport injury, falls, fire, heat and hot substances, unintentional injury others, interpersonal violence, self-harm, poisoning, drowning, intentional injury others

³ Basic resuscitation, surgical airway, peripheral venous access, suturing, laceration and wound management, chest tube/needle decompression, fracture reduction, escharotomy, fasciotomy, skin grafting, trauma-related amputation, trauma-related laparotomy

Results for selected countries discussed in this literature review are shown in Table 2. This data showed that surgical providers are inequitably distributed throughout the world, with critical shortages in low and lower-middle income countries. Specifically, the low income countries surveyed contained 12% of the world's population and had 2% and 3% of the world's surgeons and obstetricians, respectively. This should be compared to high income countries, where 35% of the world's surgical specialists and 40% of the world's obstetricians care for 18% of the world's population. Africa and Southeast Asia are the two regions hardest hit by surgical workforce shortages, with 13% and 26% of the world's population and 3% and 9% of surgical specialists, respectively. Southeast Asia fares somewhat better in terms of obstetricians, with 13% of providers, while in Africa obstetrical providers are just as scarce as surgeons, representing 3% of the world supply (19).

Table 2: Surgical providers in selected countries (19)

Country	Population	Combined number of surgeons and OB/GYNS
Burkina Faso	16.5 million	46
Malawi	15.9 million	68
Mozambique	25.2 million	249
South Africa	52.4 million	5,084
Tanzania	47.8 million	150

These numbers certainly portray a maldistribution of surgeons, but one may ask if this is relevant to patient outcomes. In fact, combined density of surgeons, anesthesiologists, and obstetricians correlates with maternal mortality. Specifically, there are steep decreases in maternal mortality as specialist density increases from zero to 20 per 100,000 population. When specialist densities exceed 40/100,000, decreases in maternal mortality are much smaller (20). On average, low and lower middle income countries are well below the 20/100,000 mark at 0.7 and 5.5 specialists per 100,000 population, respectively, while upper-middle and upper

income countries meet or exceed it, at 22.6 and 56.9 specialists per 100,000 population, respectively. Again, the most underserved region is sub-Saharan Africa, with an average specialist density of 1/100,000, followed closely by Southeast Asia, with 3 specialists per 100,000 population on average (19). Certainly correlation does not imply causation; many confounding factors influence both maternal mortality and surgeon density.

Non-physician surgeons in LMICs

A variety of strategies have been developed to cope with these critically low surgeon densities. In many countries, surgical practice is concentrated in central hospitals where surgeons and OB/GYNs are more likely to practice. In some countries, efforts to expand access to surgery involve training general practitioners and entry-level physicians to perform common surgeries in peripheral hospitals (16, 18, 21-23). Other countries have opted to train non-physician clinicians (NPCs) to perform surgery. This training takes a variety of forms. It may be an informal, organic process similar to apprenticeship where-by experienced nurses take on additional responsibilities in the operating room until they are capable of performing a certain set of procedures independently, often in the setting of severe physician shortages (24, 25). In other places it may take the form of a government program designed specifically to improve access to surgical procedures by training mid-level providers to perform common operations. Non-profit organizations such as Doctors without Borders and the International Red Cross have also trained NPCs in surgery in areas of high need, particularly as a way to reach people living in conflict zones where violence is considered to be prohibitive to the deployment of aid workers (26, 27). Finally, as seen in the recent case of male circumcision, training has been provided in the context of research studies investigating methods to increase access to these procedures (28, 29).

With the surgical training of NPCs occurring in a variety of settings including informal settings unlikely to be documented in government or scientific literature, a determination of the true scale and scope of surgery performed by NPCs is difficult to arrive at, and any estimation will almost certainly be an underestimation. Efforts have been made, however, including a 2007 paper that investigated the use of NPCs

in 47 sub-Saharan African countries by contacting key informants. The results showed that NPCs are trained in 25 out of the 47 countries of sub-Saharan Africa, and their scope of practice includes major surgical operations in seven countries: Burkina Faso, Ethiopia, Ghana, Malawi, Mozambique, Tanzania, and Zambia. In Burkina Faso, Ethiopia, and Ghana the only major operation they are licensed to perform is caesarean section. In Malawi, Mozambique, and Tanzania a subset of NPCs are trained in major general surgery (30, 31). In Zambia NPCs may pursue advanced training in orthopedic surgery, and nurses may obtain training to perform manual vacuum aspiration (32). In Vietnam and South Africa trained NPCs may perform manual vacuum aspiration for first-trimester abortion (33). These nine countries were the only LMICs I could identify in the literature where NPC surgeons are trained in major surgery via a standardized curriculum on a large scale as part of their country's present day national health plan. Pertinent to my previous remark concerning the underestimation of non-physician surgery, it is interesting to note that according to official reports only caesarean sections are performed by non-physicians in Ghana, however, personal accounts describe these practitioners performing other major operations including hernia repair (34).

Interest in NPC surgery seems to be growing not only in the global health literature but also among national policy makers in sub-Saharan Africa. An example is Sierra Leone, where a pilot program for the training of NPCs in surgery is ongoing, run by the National Ministry of Health in collaboration with a non-profit organization from Norway (35-37). Similarly, an Italian non-profit has been training and implementing NPC surgery in what is now South Sudan since 1991, and the new government has recently announced plans to include this strategy in national health policy (38, 39).

Current recommendations for surgical task shifting

International health policy makers currently recommend task shifting for four surgical procedures: emergency caesarean section, tubal ligation, manual/electric vacuum aspiration in the first trimester for induced and incomplete abortion, and medical male circumcision in areas of high HIV prevalence (40-42).

Essential surgery

In order to assist policy makers in their efforts to improve surgical care in low resource environments, a number of groups have developed the concept of “essential surgery”. The WHO developed a Primary Surgical Package (PSP) of procedures which should be universally available, along with a number of procedures requiring advanced training that should be available according to local need (3). Inspired by the WHO’s concept of essential medications, the International Collaboration for Emergency Surgery (ICES) defined essential surgery as “...basic surgical procedures, which save lives and prevent permanent disability or life threatening complications. Such surgery should be of appropriate quality and safety, accessible at all times and affordable to the community.” ICES then goes on to name fifteen surgical conditions the care of which it considers to be essential surgery (5). In addition, the DCP3 has proposed a list of forty-four essential surgical procedures which should be available at different levels of the health care system (2).

METHODS

Hypothesis

Complication rates of NPCs and physicians practicing essential surgery in LMICs are similar.

Definitions

For the purpose of this study I will define NPCs as any practitioner who does not hold a degree equivalent to an MD (United States) or MBBS (British system), but who has received instruction (whether standardized and leading to a degree, or informal on-the-job training) in surgical practice. In the studies included in this review, many of the NPC surgeons are licensed as mid-level providers, but they also include nurses, midwives and paramedics. The physician operators who serve as

Table 3: Recommendations for an essential surgery package (1/2)

	DCP3	WHO PSP	ICES
Dental	*Dental extraction *Drainage of dental abscess *Treatment of dental caries		Dental extraction
OB/GYN/FP	*Normal delivery **Vacuum extraction or forceps delivery **Caesarean **Hysterectomy **MVA and D&C **Ectopic pregnancy ***Repair of obstetric fistula **Tubal ligation **Vasectomy **Visual inspection with AA and cryotherapy	^^Caesarean ^D&C ^^Uterine rupture/ectopic	Assisted or manipulative delivery Caesarean Symphysiotomy Repair uterine perforation ERCP
General Surgery	*Drainage of superficial abscess **Urinary catheterization, suprapubic cystostomy **Appendectomy **Emergency surgery for acute cholecystitis **Bowel obstruction **Repair of perforations **Colostomy **Hernia repair **Hydrocelectomy *Male circumcision	^Incision & drainage of abscesses ^Suprapubic puncture/cystostomy ^^Biopsies & needle aspiration ^^Hernia repair ^^Hydrocelectomy ^^Male circumcision	Incision & drainage of abscesses Suprapubic catheterization Appendectomy Hernia repair

*Primary health center, **First-level hospital, ***Referral hospitals, ^Primary Surgical Package, ^^Procedures requiring advanced training, MVA = manual vacuum aspiration, D&C = dilation & curettage, ERCP = evacuation of retained products of conception

Table 3: Recommendations for an essential surgery package (2/2)

	DCP3	WHO PSP	ICES
Trauma	*Resuscitation with basic life support measures **Surgical airway **Tube thoracostomy *Suturing laceration **Trauma laparotomy~ *Management of non-displaced fractures **Fracture reduction **I&D of open fractures **External fixation; use of traction **Trauma amputations **Escharotomy or fasciotomy **Skin grafting **Burr hole	^Resuscitation (airway, bleeding, CPR) ^Peripheral venous cut down ^Cricothyroidotomy/tracheostomy ^Chest tube & needle decompression ^Suturing & wound management ^Removal of foreign body ^^Laparotomy for acute abdomen ^Fracture immobilization ^^Fracture reduction ^^Amputation ^Burn management ^^Skin grafting/contracture release	Airway management Cricothyroidotomy/tracheostomy Intercostal drainage, thoracostomy Suturing, hemostasis Removal of foreign body (airway) Emergency laparotomy Casting & splinting Fracture & dislocation reduction External fixation Amputation Escharotomy, fasciotomy Skin grafting Wound/burn debridement Elevation of depressed skull fractures Burr hole Tympanotomy
Congenital	***Cleft lip and palate repair ***Club foot repair ***Shunt for hydrocephalus ***Repair of anorectal malformations, Hirschsprung's	^^Club foot repair	Simple cleft lip repair Casting & splinting for club foot Tenotomy
Vision	***Cataract extraction and IOL ***Eyelid surgery for trachoma		Cataract extraction and IOL
Orthopedic	**Drainage of septic arthritis **Debridement of osteomyelitis	^^Curettage for chronic osteomyelitis	Arthrotomy Bone drilling
Anesthesia		^Local, Ketamine, spinal & general anesthesia	

*Primary health center, **First-level hospital, ***Referral hospitals, ^Primary Surgical Package, ^^Procedures requiring advanced training, ~including splenectomy, splenic repair, packing of hepatic injury and repair of bowel perforation, IOL = intraocular lens, I&D = irrigation & debridement

controls in this review are also a heterogeneous group and include surgical specialists (SSs), obstetric and gynecology specialists (OB/GYNs), general practitioners (GPs) and medical doctors not otherwise specified (MDs). Medical doctors who have completed a residency training program in general surgery are considered SSs. GPs encompass all medical doctors who have not completed or are not in the process of completing a surgical or obstetric residency training program. The GPs in the included studies may or may not have received targeted surgical training for the procedures they practice. Most of the studies in this review did not include this level of information. I will use the term MD to refer to a physician when their advanced training has not been specified. For the purpose of this study I define essential surgery as any procedure included in the DCP3, WHO, or ICES definitions of essential surgery. However, some studies included in this review perform analysis on the aggregated outcomes of all the procedure in their data set, so exclusion of procedures not within the scope of essential surgery was not possible at times. The World Bank's 2016 classification of national economies by income is used to define low and middle income countries.

Search protocol

I searched Ovid MEDLINE using MESH terms including "Developing Countries", "Surgical Procedures, Operative", "General Surgery", "Allied Health Personnel", and "Physician Assistants", and "Outcome Assessment (Health Care)". I searched PubMed with these terms plus keywords including "essential surgery", "task shifting", "task sharing", "clinical officer", "assistant medical officer", "mid-level health provider", "tecnico de cirurgia" and "non-physician clinician". I did not place any language nor publication date restrictions on my searches. I then searched the references of all relevant studies.

RESULTS

Overview

I identified 28 studies (26 articles and 2 abstracts) presenting original outcomes data for surgical procedures performed by NPCs in LMICs. A total of 57,578 procedures were reported in these studies, with 44,103 performed by NPCs and 13,475 performed by MDs. I also located 4 meta-analyses and/or systematic reviews that addressed surgical task shifting. A summary of these results is shown in Table 4. The majority of these studies (51.7%) were conducted in low income countries; the remaining studies were divided equally between lower middle and upper middle income countries. The majority of studies were conducted in sub-Saharan Africa (72%), followed by East Asia (17%), South Asia (7%), and the Middle East (4%). Sixteen countries were represented; the most studies came from Malawi (4 studies) and Thailand (4 studies), followed by Kenya (3 studies) and Uganda (3 studies). Studies included in this review were published between 1975 and 2014. The majority of the literature (61% of studies) reported on obstetric and gynecologic surgery; these studies addressed 3 main topics: emergency obstetric procedures (7 studies), tubal ligation (7 studies), and abortion (4 studies). The remaining 12 studies reported outcomes for procedures falling within the domain of general surgery, with the majority of articles (7 studies) reporting on medical male circumcision. The 4 review articles I identified addressed outcomes for caesarean section, tubal ligation, surgical abortion, and medical male circumcision when performed by NPCs.

Table 4: Literature review results

Authors	Date	Country	World Bank region	World Bank income group	Subject
Ahmed et al. (28)	2007	Comoros	SSA	Low	Circ.
Beard et al. (43)	2014	Tanzania	SSA	Low	GS
Buwembo et al. (44)	2011	Uganda	SSA	Low	Circ.
Chilopora et al. (45)	2007	Malawi	SSA	Low	EmOB
Chowdhury & Chowdhury (25)	1975	Bangladesh	S Asia	Lower-middle	TL
Dickson-Tetteh & Billings (46)	2002	South Africa	SSA	Upper-middle	Abortion
Dusitsin et al. (47)	1980	Thailand	E Asia	Upper-middle	TL
Fenton et al. (48)	2003	Malawi	SSA	Low	EmOB
Ford et al. (49)	2011	SR & MA	-	-	Circ.
Frajzyngier et al. (50)	2014	Kenya	SSA	Lower-middle	Circ.
Gessesew et al. (51)	2011	Ethiopia	SSA	Low	EmOB
Ghorbani (52)	1979	Iran	Middle East	Upper-middle	TL & Abortion
Gordon-Maclean et al. (53)	2014	Uganda	SSA	Low	TL
Hounton et al. (54)	2009	Burkina Faso	SSA	Low	EmOB
Jejeebhoy et al. (55)	2011	India	S Asia	Lower-middle	Abortion
Kanchanasinith et al. (56)	1990	Thailand	E Asia	Upper-middle	TL
Koetsawang et al. (57)	1981	Thailand	E Asia	Upper-middle	TL
Krieger et al. (58)	2007	Kenya	SSA	Lower-middle	Circ.
McCord et al. (59)	2009	Tanzania	SSA	Low	EmOB
Ocero et al. (abstract) (29)	2011	Uganda	SSA	Low	Circ.
Odingo et al. (abstract) (60)	2010	Kenya	SSA	Lower-middle	Circ.
Osuigwe et al. (61)	2004	Nigeria	SSA	Lower-middle	Circ.
Pereira et al. (62)	1996	Mozambique	SSA	Low	EmOB
Renner et al. (63)	2012	SR	-	-	Abortion
Rodriguez et al. (64)	2014	SR	-	-	TL
Satyapan et al. (65)	1983	Thailand	E Asia	Upper-middle	TL
Tyson et al. (66)	2014	Malawi	SSA	Low	GS
Vaz et al. (67)	1999	Mozambique	SSA	Low	GS
Warriner et al. (33)	2006	South Africa, Vietnam	SSA, E Asia	Lower-middle, Upper-middle	Abortion
White et al. (24)	1987	Former Zaire	SSA	Low	GS & EmOB
Wilhelm et al. (68)	2011	Malawi	SSA	Low	GS
Wilson et al. (69)	2011	SR & MA	-	-	EmOB
Abortion = 1st trimester surgical abortion, Circ. = medical male circumcision, EmOB = emergency obstetric surgery, GS = general surgery, TL = tubal ligation, SR = systematic review, MA = meta-analysis					

General surgery results

Five studies from Mozambique, Malawi (2), Tanzania, and former Zaire reported data on a total of 13,253 general surgery procedures, with 11,791 procedures performed by NPCs and 1,462 performed by MDs. The majority of these procedures were performed on adults; only one study (Tyson et al.) reported on pediatric surgery (883 operations). Studies were published in 1987, 1999, 2011 and 2014 (2 studies). All studies were retrospective cohort studies; one study was non-controlled. Three studies provided a statistical comparison of outcomes, and one study controlled for confounding factors. See Table 5 for more information on study designs. The majority of studies reported on mid-level providers trained in nationally approved programs. The one exception, White et al., reported on laparotomies performed by 5 RNs trained by a group of missionary surgeons in 1987. See Table 6 for more information on the NPC providers in each study.

Three studies reported procedure-specific complication and mortality rates for 6 procedures: elective hernia repair, emergency hernia repair, hydrocelectomy, laparotomy, VP shunt and prostatectomy. No significant difference in complication or mortality rates was found for any of these procedures when comparing non-physician and physician operators. See Table 7 for procedure specific results. Three studies reported aggregated complication rates for all procedures included in the study. Two of these studies were controlled; after accounting for confounding factors, neither study found a difference in complications or mortality rates between NPC and MD operator groups. Vaz et al.'s single arm retrospective cohort study reported a complication rate of 3.7% and a mortality rate of 0.5% for 10,258 procedures performed by NPC surgeons. See Table 8 for aggregated results.

Table 5: General surgery study design details

Study	Study type	Study group	Control group	Population	Outcomes	Method of sorting patients	Follow-up period	Lost to follow up (%)	Statistical comparisons	Adjustment for confounding variables
Beard et al.	Retrospective cohort	MLP	SS, GP	All patients undergoing MSP at any hospital in Pwani Region (1 regional, 5 district, 1 missionary hospital)	Reoperation, readmission, blood transfusion, wound infection, urinary retention, in-hospital mortality, other (not specified)	PRCP	30 days	16.4	Yes	Yes
Tyson et al.	Retrospective cohort	MLP	SS	All pediatric patients undergoing operative procedure (excluding orthopedics) at tertiary hospital in the capital city	Complications requiring reoperation, length of stay, in-hospital mortality	PRCP	To hospital discharge	50	Yes	No
Vaz et al.	Single arm retrospective cohort	MLP	n/a	Any patient undergoing operative procedure performed by 14 MLPs working in rural hospitals	In-hospital mortality, complications not otherwise specified	n/a	NS	NS	n/a	n/a
White et al.	Retrospective cohort	RN	MD	Any patient undergoing laparotomy for ruptured uterus in 2 rural missionary hospitals	In-hospital mortality	PRCP	NS	NS	No	No
Wilhelm et al.	Retrospective cohort	MLP	SS	Any patient undergoing selected operations at a central hospital	Wound infection, reoperation, length of stay, in-hospital mortality, shunt explant (VP shunt only), bladder leak (prostatectomy only), conversion to laparotomy (hernia repair only)	PRCP	To hospital discharge	NS	Yes	No
MLP=mid-level provider, SS=surgical specialist, GP=general practitioner, PRCP=per routine clinical protocols, NS=not specified										

Table 6: General surgery NPC provider details

Study	Type of NPC	NPC basic clinical education	NPC practical surgical training
Beard et al.	CO	3 years	None
	AMO	3 years	2 years
Tyson et al.	CO	3 years	3 months GS, 3 months OB/GYN
Vaz et al.	TdC	NS	1 year
White et al.	RN	2 years	1-2 years
Wilhelm et al.	CO	3 years	3 months GS, 3 months OB/GYN
	AMO	3 years	2 years
NS = not specified, GS = general surgery, CO = Clinical Officer, AMO = Assistant Medical Officer, TdC = surgical technician			

Table 7: General surgery procedure-specific results

Procedure type	Study	Number of Procedures		Complication	Number of Complications (%)		P
		NPC	Control		NPC	Control	
Elective hernia repair	Beard et al.	225	50	All complications	23 (13.4)	5 (12.5)	0.883
				Mortality	2 (0.9)	1 (2.0)	0.454
Emergency hernia repair	Beard et al.	77	17	All complications	6 (9.5)	2 (13.3)	0.614
				Mortality	3 (3.9)	0 (0)	1
	Wilhelm et al.	21	32	Wound infection	5 (23.8)	5 (15.6)	0.36
				Anastomotic leak	1 (4.8)	0 (0)	0.15
				Re-operation	1 (4.8)	2 (6.3)	0.73
				Mortality	1 (4.8)	1 (3.1)	0.64
Hydrocelectomy	Beard et al.	105	31	All complications	17 (22.4)	5 (21.7)	0.949
				Mortality	0 (0)	0 (0)	None
Laparotomy	Beard et al.	106	93	All complications	28 (35.4)	26 (34.7)	0.92
				Mortality	7 (7.1)	6 (6.8)	0.931
	White et al.	16	21	Mortality	2 (13)	9 (43)	
VP Shunt	Wilhelm et al.	61	51	Wound infection	2 (3.3)	2 (3.9)	0.99
				Shunt revision	0 (0)	2 (3.9)	0.21
				Re-operation	2 (3.3)	1 (2.0)	0.99
				Mortality	4 (6.6)	3 (5.9)	0.99
Prostatectomy	Wilhelm et al.	113	101	Wound infection	34 (30.1)	27 (26.7)	0.65
				Bladder leakage	12 (10.6)	9 (8.9)	0.99
				Re-operation	9 (8.0)	3 (3.0)	0.14
				Mortality	5 (4.4)	4 (4.0)	0.99
	Beard et al.	157	69	All complications	45 (31.2)	19 (29.2)	0.769
				Mortality	2 (1.3)	1 (1.4)	1

Table 8: General surgery aggregated results

Procedure type(s)	Study	Number Procedures		Complication	Number Complications (%)		Adjusted OR (95% CI)
		NPC	Control		NPC	Control	
General surgery (various) 100% major procedures, 67% elective procedures	Beard et al.	944	750	Wound infection	75 (9.9)	41 (6.4)	0.81 (0.5 - 1.31)
				Reoperation	27 (3.6)	16 (2.5)	1.15 (0.51 - 2.6)
				Readmission	22 (2.9)	21 (3.3)	0.56 (0.24 - 1.33)
				All complications	111 (17.4)	144 (19)	0.89 (0.62 - 1.3)
				Mortality	16 (1.7)	11 (1.5)	0.73 (0.25 - 2.1)
General surgery (various) 23% major procedures, 31% elective	Vaz et al.	10,258	0	All complications	377 (3.2)	n/a	
				Mortality	31 (0.3)		
Emergency general surgery	Vaz et al.	3178	0	Mortality	3 (0.094)		
Elective general surgery	Vaz et al.	7080	0	Mortality	28 (0.4)		p value
Pediatric general surgery (various) 57% major procedures, 67% elective procedures	Tyson et al.	378	507	Complications requiring reoperation	15 (4)	23 (4.5)	0.7
				Reoperations	64 (17)	36 (7.1)	<0.001
				Length of stay (days)	24 (+/-29)	10 (+/-30)	<0.001
				Mortality (when outcome data available)	4/188 (2.1)	5/200 (2.5)	0.8
				Major case complication rate	14/264 (5.3)	16/302 (5.3)	0.998
				Minor case complication rate	1/114 (0.9)	6/203 (3)	0.2

Male circumcision results

I found 7 studies including 5 papers and 2 abstracts reporting on the outcomes of male medical circumcision when performed by NPCs. All studies were from sub-Saharan Africa; countries represented included Comoros, Kenya (3 studies), Nigeria, and Uganda (2 studies). In total these studies reported on 14,248 procedures, with 12,238 performed by NPCs and 2,010 performed by MDs. The majority of studies (5 out of 7) were conducted on adults. Studies were published from 2004 to 2014. In addition, I located one systematic review and meta-analysis from 2012 that included 10 studies, 6 of which were pertinent to this review. All studies presenting original data were prospective cohort studies and the majority (4 out of 7) were single arm studies. Duration of follow-up ranged from 1 week to 3 months; only one study did not specify duration of follow-up. Follow-up rates were reported by three studies and ranged from 6% to 18% lost to follow-up. See Table 9 for study design details. The majority of studies (5 out of 7) included mid-level providers in their NPC surgeon cohort; 3 include nurses, 2 include midwives, and 2 include surgical aids/traditional birth attendants (TBAs). In the majority of studies NPC providers received intensive hands-on training before data collection started. See Table 10 for NPC provider details.

One of the controlled studies (Osuigwe et al.) found a significant increase in complications after procedures performed by midwives and TBAs compared to physicians. This was in the context of very elevated complication rates overall; the patients operated by NPCs had a complication rate of 30.6% compared to a 14.5% complication rate in the patients operated by MDs. The other two controlled studies found no difference in outcomes ($p=0.24$, $p=0.53$) between NPC and physician operators. In these studies, the total complication rate for NPCs ranged from 0.6% to 30.6%. Excluding the values from Osuigwe et al., the maximum complication rate was 2.7% in both operator groups. The meta-analysis found an overall pooled complication rate of 2.59% (95% CI 1.36-3.81) for circumcision when performed by NPCs.

The most frequently reported side effects were bleeding (reported in 7 studies), infection (5 studies), and problems with wound healing (4 studies).

Excluding the outlying value of 8.5% from Osuigwe et al., rate of excess bleeding ranged from 0.12% to 1.1% for NPCs and was 0.88% for physicians in the one study that reported this outcome in the MD group. Infection rates ranged from 0% to 1.5% for NPCs and was 0.41% for physicians. Finally, wound healing problems ranged from 0 – 0.22% for NPCs and was 0.7% for physicians.

Five studies commented on the prevalence of severe complications, generally defined to mean those resulting in the need for reoperation or in major disability. The most common severe complication was heavy bleeding requiring surgical repair, with rates of 0.55%, 0.57%, and < 0.5% reported in NPC groups. Frajzyngier et al. reported a 0.09% incidence of severe pain at 7 days, and Krieger et al. reported no severe complications. No cases of mortality or permanent disability were reported.

Table 9: Circumcision study design details

Study	Study type	Study group	Control group	Population and setting	Outcomes	Method of sorting patients	Lost to follow-up (%)	Stat. comparison, adjust. for confounders
Ahmed et al.	Single arm prospective cohort	Surgical aid, RN, Midwife	n/a	2-8 years screened for contraindications, circumcised in their homes by visiting teams	Infection, bleeding, meatal stenosis, urethrocuteaneous fistulae, scrotal skin necrosis, reoperation	n/a	4-11 days post-op, (NS)	n/a, n/a
Buwembo et al.	Prospective cohort	MLP	GP	12-71y recruited from control arm of RCT of MC for HIV prevention and from the general public, clinic	Infection, bleeding, wound dehiscence	Trial control participants operated by physicians, all others sorted PRCP	48 hr, 9d, and 4w, (NS)	Yes, Yes
Frajzyngier et al.	Single arm prospective cohort	RN, MLP	n/a	13-54y seeking circumcision in 6 hospitals, 4 health centers, and 1 dispensary, screened for contraindications	Infection, bleeding, delayed wound healing, injury to penis, problem with appearance, pain, excess swelling, hematoma, insufficient skin removal	n/a	7d (2) and 2m post-op (18)	Yes, No
Krieger et al.	Prospective cohort	MLP	GP	18-24y, sexually active, HIV negative admitted to clinical trial and randomized to circumcision arm, screened for contraindications, hospital	Infection, bleeding, delayed wound healing, wound dehiscence, excess swelling, anesthesia reaction, excess pain, pubic abscess, folliculitis, erectile dysfunction	NS	3d, 8d, 1m, 3m post-op, (NS)	Yes, No
Ocero et al.	Single arm prospective cohort	MLP	n/a	>12y recruited during outreach events conducted in 14 lower level health facilities	Bleeding requiring reoperation	n/a	1w post-op, (NS)	n/a, n/a
Odingo et al.	Single arm prospective cohort	RN, MLP	n/a	12-54y seeking circumcision at clinics and outreach events	Infection, bleeding, pain, swelling, delayed wound healing	n/a	7d (3.4) and 2m post-op (6)	n/a, n/a
Osuigwe et al.	Prospective cohort	Midwife, TBA	MD	Neonates presenting for circumcision at 3 hospitals	Bleeding, incomplete circumcision, meatal stenosis, urethral laceration	PRCP	NS, (13.7)	No, No
MLP=mid-level provider, GP=general practitioner, PRCP=per routine clinical protocols, NS=not specified								

Table 10: Circumcision NPC provider details

Study	Type of NPC	NPC basic clinical education	NPC practical surgical training for circumcision
Ahmed et al.	Surgical aid	NS	Intensive training before intervention
	RN		
	Midwife		
Buwembo et al.	CO	3 years	Training by urologist including performance of at least 100 circumcisions before beginning study
Frajzyngier, et al.	RN	NS	Pre-study training based on WHO/UNAIDS manual and performance of 40 circumcisions under supervision
	CO	3 years	
Krieger et al.	CO	3 years	Pre-study training, not further specified
Ocero et al.	CO	3 years	10 days of training
Odingo et al.	RN	NS	Providers had training, but not specified whether this was part of study
	CO	3 years	
Osuigwe et al.	Midwife	NS	NS
	TBA		
NS = not specified, CO = Clinical Officer, TBA = traditional birth attendant			

Table 11: Circumcision results (table continued on following page)

Study, method	Number of procedures		Complication	Number of complications (%)		p, unadjusted OR (95% CI)
	NPC	Control		NPC	Control	
Ahmed et al., <i>dorsal slit</i>	3824	-	All	87 (2.3)	n/a	n/a
			Infection	60 (1.5)		
			Bleeding	14 (0.37)		
			Meatal stenosis	2 (0.5)		
			Urethrocutaneous fistula	2 (0.5)		
			Scrotal skin necrosis	2 (0.5)		
			Reoperation (due to bleeding)	21 (0.55)		
Buwembo et al., <i>52% sleeve, 48% dorsal slit</i>	3218	1934	All	22 (0.68)	29 (1.50)	0.007, 0.45 (0.26 - 0.76), adjusted OR 0.87 (0.57 - 1.33)
			Infection	9 (0.28)	8 (0.41)	NR
			Bleeding	12 (0.37)	17 (0.88)	
			wound dehiscence	0	1 (0.15)	
Frajzyngier et al., <i>not specified</i>	RN 1384	-	All	30 (2.2)	n/a	n/a
			Infection	4 (0.29)		
			Bleeding	15 (1.1)		
			delayed wound healing	3 (0.22)		
			injury to penis	0		
			problem with appearance	5 (0.36)		
	CO 807	-	All	17 (2.0)		
			Infection	0		
			Bleeding	1 (0.12)		
			delayed wound healing	0		
			injury to penis	1 (0.12)		
			problem with appearance	2 (0.25)		

Study, method	Number of procedures		Complications	Number of complications (%)		p, unadjusted OR (95% CI)
	NPC	Control		NPC	Control	
Krieger et al., <i>forceps guided</i>	1475 circumcisions by 4 operators (3 CO,1 GP); level of training not linked to outcomes		All	Op1 5/525 (1), Op2 7/411 (1.7), Op3 3/132 (2.3), Op4 11/407 (2.7)		0.24
			Infection	6 (0.4)		NR
			Bleeding	4 (0.3)		
			delayed wound healing/dehiscence	10 (0.7)		
Ocero et al., <i>not specified</i>	175	-	bleeding requiring reoperation	1 (0.57)	n/a	n/a
Odingo et al., <i>forceps guided</i>	1290	-	All	24 (1.8)	n/a	n/a
			Infection	14 (1.1)		
			Bleeding (mild & severe)	7 (0.5)		
			delayed wound healing	3 (0.3)		
Osuigwe et al., <i>"traditional" method, plastic bell method</i>	62	76	All	19 (30.6)	11 (14.5)	NR
			Bleeding	8 (12.9)	3 (3.9)	
			incomplete circumcision	8 (12.9)	6 (7.9)	
			meatal stenosis	3 (4.8)	2 (2.6)	
			urethral fistula	3 (4.8)	0	
NR=not reported						

Emergency obstetric surgery results

I located 7 papers comparing outcomes of emergency obstetric surgery performed by NPCs compared to MDs. In total these papers reported on 18,853 interventions with 11,651 performed by NPCs and 7,202 performed by MDs. All studies were conducted in sub-Saharan Africa, including Malawi (2 studies), Mozambique, Tanzania, Ethiopia, Burkina Faso, and former Zaire. The studies were published in 1987, 1996, and 2003-2011. In addition, I located one systematic review and meta-analysis from 2011 that included 6 studies, all of which are also included in this review. All studies were cohort studies and four were retrospective. All but one study reported statistical comparisons between NPC outcomes and MD outcomes. Only one study adjusted for confounding factors. See Table 12 for study design details. Except for the Zaire study that involved nurses, all NPC surgeons were mid-level providers trained and licensed in obstetric (and in some cases, general) surgery. Practical training of these providers ranged from 6 months to 2 years. See Table 13 for NPC provider details.

Significant differences in three outcomes were found when comparing NPC providers to physician providers: maternal mortality (1 study), perinatal mortality (1 study) and superficial wound separation (1 study). The most remarkable differences were found in Hounton et al.'s 2009 study from Burkina Faso. NPCs had a 3.55% maternal mortality rate compared to 1.21% for physician operators (OR 3.55 95%CI 1.65 – 5.47). In all other studies, a difference in maternal mortality was not found between provider groups, and mortality rates ranged from 0.57% to 1.7% for NPCs and 0 to 3.5% for physicians. Meta-analysis did not find an increase in maternal mortality: combined OR of maternal mortality when an emergency operation was performed by an NPC was 1.46 (95% CI 0.78 – 2.75). Perinatal outcomes were significantly different in Hounton et al. with 19.7% mortality in the NPC provider group compared to 10.8% mortality in the physician provider group, (OR 2.03 95%CI 1.6 – 2.59). Perinatal mortality in the remainder of the studies was similar in the two operator groups and ranged from 6.3% to 18.7% for the NPCs and 3.4% to 16.8% for the MDs. Meta-analysis also found no difference in perinatal mortality; the combined OR for perinatal mortality when an NPC performed an

emergency operation was 1.31 (95% CI 0.87 – 1.95). Pereira et al.'s study from Mozambique found a significant increase in superficial wound separation among patients of NPC operators, with a 4.28% incidence in these patients compared to a 1.98% incidence in MD patients (OR 2.2 95%CI 1.3 – 3.9). Interestingly, this difference did not translate into a significant increase in wound dehiscence among NPC patients. Wound dehiscence occurred in 0.31% of patients in the NPC cohort compared to 0.18% of patients in the MD cohort, with an odds ratio of 1.8 (95% CI 0.2 – 20.9). The two other studies that reported on wound dehiscence did not find a difference in rates between providers. Two studies reported on wound infection rates, and found increased rates in both NPC cohorts, although not to the level of statistical significance. When analyzed together in the meta-analysis, however, the difference was significant (OR 1.58 95% CI 1.01 – 2.47). See Table 14 for all results.

Table 12: Emergency obstetric surgery study design details

Study	Study type	Study group	Control group	Population and setting	Outcomes	Method of sorting patients	Lost to follow-up (%)	Stat. comparison, confounding variable adjustment
Chilopora et al.	Prospective cohort	MLP	GP	Consecutive obstetric surgeries at 38 district and religious hospitals	Fever, wound infection, wound dehiscence, re-operation, neonatal outcome, maternal mortality	PRCP	To hospital discharge (NS)	Yes, No
Fenton et al.	Prospective cohort	MLP	GP, OB/GYN	Caesarean sections at 23 district and 2 central hospitals	Maternal death, perinatal death	PRCP	72 hours (NS)	Yes, Yes
Gessesew et al.	Retrospective cohort	MLP	OB/GYN	All women receiving caesarean section at 11 hospitals and 2 health centers with CEmOC status in one region	Maternal death, perinatal death	PRCP	NS (NS)	Yes, No
Hounton et al.	Retrospective cohort	MLP	MD, OB/GYN	All women receiving caesarean section at 22 public hospitals in 6 regions	Maternal death, perinatal death, hemorrhage, wound infection, wound dehiscence	PRCP	NS (NS)	Yes, No
Pereira et al.	Retrospective cohort	MLP	OB/GYN	Consecutive cases of caesarean section at a central academic hospital	Maternal death, post-operative hospitalization duration, wound dehiscence, poor wound healing, newborn condition	PRCP	NS (NS)	Yes, No
McCord et al.	Prospective cohort	MLP	GP	All operative obstetric cases at 9 district and 5 missionary hospitals in 2 regions	Maternal death, neonate death, rupture of uterus, wound infections, uterine hemorrhage after caesarean, wound dehiscence, operative vesico-vaginal fistula, ureteral injury	PRCP	NS (NS)	Yes, No
White et al.	Retrospective cohort	RN	MD	Any patient undergoing caesarean in 2 rural missionary hospitals	In-hospital mortality	PRCP	NS (NS)	No, No
MLP=mid-level provider, GP=general practitioner, PRCP=per routine clinical protocols, NS=not specified								

Table 13: Emergency obstetrics NPC provider details

Study	Type of NPC	NPC basic clinical education	NPC practical surgical training for emergency obstetric surgery (unless otherwise specified)
Chilopora et al.	CO	3 years	3 months GS, 3 months OB/GYN
Fenton et al.	CO	3 years	3 months GS, 3 months OB/GYN
Gessesew et al.	MLP	3 years	6-9 months
Hounton et al.	CO	NS	6 months
Pereira et al.	AMO	3 years	1 year (GS and OB/GYN)
McCord et al.	AMO	3 years	2 years
White et al.	RN	2 years	1-2 years
NS = not specified, CO = Clinical Officer, AMO = Assistant Medical Officer, GS = general surgery, MLP = mid-level provider			

Table 14: Emergency obstetric surgery results

Study	Number of Procedures		Complication	Number of Complications (%)		p	Unadjusted OR (95% CI), Adjusted OR (95% CI)
	NPC	Control		NPC	Control		
Chilopora et al.	1875	256	Fever	388 (20.7)	56 (21.9)	0.364	
			Wound infection	137 (7.3)	14 (5.5)	0.994	1.36 (0.77-2.40)
			Wound dehiscence	40 (2.1)	4 (1.6)	0.315	1.37 (0.49-3.87)
			Need for re-operation	28 (1.5)	5 (2.0)	0.364	
			Maternal mortality	22 (1.2)	1 (0.4)	0.292	3.03 (0.41-22.56)
			Perinatal mortality	201 (10.7)	33 (12.9)	0.709	0.81 (0.55-1.20)
Fenton et al.	5256	2814	Maternal mortality	67 (1.3)	18 (0.64)	0.4	1.8 (1.0-1.3), 1.4 (0.7-2.9)
			Perinatal mortality	682 (13.0)	224 (8.0)	0.6	1.7 (1.4-2.0), 1.1 (0.8-1.3)
Gessesew et al.	1574	1261	Maternal mortality	9 (0.57)	8 (0.63)	0.8	
			Fetal demise	294 (18.7)	212 (16.8)	0.2	
Hounton et al.	733	1572	Wound infection	14 (1.9)	15 (0.95)	-	2.02 (0.97-4.21)
			Wound dehiscence	1 (0.14)	4 (0.25)		0.54 (0.06-4.80)
			Maternal mortality	26 (3.55)	19 (1.21)		3.01 (1.65-5.47)
			Perinatal mortality	145 (19.7)	170 (10.8)		2.03 (1.60-2.59)
McCord et al.	945	143	Maternal mortality	16 (1.7)	5 (3.5)	-	0.47 (0.16-1.68)
			Perinatal mortality	49 (6.3)	4 (3.4)		1.87 (0.67-7.26)
Pereira et al.	958	1113	Superficial wound separation	41 (4.28)	22 (1.98)	-	2.2 (1.3-3.9)
			Wound dehiscence	3 (0.31)	2 (0.18)		1.8 (0.2-20.9)
			Stillbirth	68 (7.10)	91 (8.18)		0.9 (0.6-1.2)
			Early neonatal death	1 (0.10)	8 (0.72)		0.1 (0-1.1)
			Maternal mortality	7 (0.73)	10 (0.90)		0.8 (0.3-2.3)
White et al.	310	43	Maternal mortality	3 (0.97)	0 (0)	-	0.99 (0.05-19.5)

Tubal ligation results

I located 7 papers reporting the outcomes of 7,179 tubal ligations, with 6,215 performed by NPCs and 964 performed by MDs. The majority of studies were from Southeast Asia, with 4 from Thailand, 1 from Bangladesh, 1 from Iran, and 1 from Uganda. All but one of these studies were over 25 years old. The Bangladesh and Iran studies date from 1975 and 1979 while the Thailand studies were published during the 1980s. The study from Uganda (2014) was the only to represent current epidemiologic and public policy trends, but I will review all studies for the sake of completeness. Four of the studies were controlled, with one randomized controlled trial and three prospective cohort studies. No study published statistical comparisons of the two operator groups, although one reports that the calculations were done and no significant difference was found. The remainder of the studies (3 out of 7) were single arm cohort studies. When reported, duration of follow up was 1 year (2 studies) to 45 days (3 studies). Follow-up ranged from 19% to 94% at the final visit. See Table 15 for study design details. I located one systematic review from 2014 that includes 9 studies, 5 of which are also included in this review.

Nurses and nurse-midwives were the NPC operators in 5 studies, paramedics in 1, and mid-level providers (MLPs) in one. All cadres of NPC operators received intensive theoretical and hands-on training before participating in any study; the Thai nurse-midwives all received 12 weeks, as did their colleagues in Iran. Paramedics in Bangladesh and MLPs in Uganda both received a 6 week course. All operators in these studies had access to a physician on call or actively supervising them. See Table 16 for NPC provider details.

No studies reported mortality or need for hysterectomy or bowel resection. In all studies combined there were 4 uterine perforations (1 was in an NPC patient and 3 were in MD patients) and 2 bowel perforations (1 each in NPC and MD groups); all injuries were successfully repaired. Three of the four comparative studies reported lower total complication rates for NPCs compared to physicians. Dusitsin et al. reported higher rates for NPCs with a 3.5% complication rate for patients in the NPC group versus 2.0% for those in the physician group. Setting

aside Ghorbani's study from Iran which reported no complications in 24 cases but did not define follow up protocol or complications sought, total complication rates ranged from 1.4% to 6.1% for NPC operators and 2% to 8.1% for physician operators. Severe complication rates ranged from 0.4% to 2.1% for NPCs and 0.8% to 3.0% for physicians. Severe complications, when specified, included uterine perforation, intestinal perforation, intraoperative hemorrhage and complications leading to hospital admission (including incisional bleeding). Three studies reported the level of physician intervention that occurred during NPC cases; physicians physically intervened in 0.27%, 0.5%, and 1.2% of cases, and verbal assistance was given in 29% of cases in the one study that reported this metric. See Table 17 for all results.

Table 15: Tubal ligation study design details

Study	Study type	Study group	Control group	Population and setting	Outcomes	Method of sorting patients	Lost to follow-up (%)	Statistical comparisons, confounding variable adjustment
Chowdhury & Chowdhury	Prospective cohort	Paramedic	MD	Women seeking TL at rural clinics	Infection, wound dehiscence, uterine perforation, intestinal perforation, intraoperative hemorrhage, mortality	NS	NS	No, No
Dusitsin et al.	Blinded RCT	Nurse-midwife	MD	Women with no previous abdominal surgery requesting TL after a normal vaginal delivery	Mild pyrexia, wound breakdown, respiratory infection, cystitis	Randomized	5d (NS) and 6w (NS)	No, No
Ghorbani	Single arm retrospective cohort	Nurse midwife	n/a	Women presenting to Family Planning Center of Farah Maternity Hospital, Tehran	NS	n/a	NS	n/a, n/a
Gordon-Maclean et al.	Single arm prospective cohort	MLP	n/a	Women presenting to rural clinic for family planning in the setting of NGO outreach event	Pain, vasovagal, bowel perforation, heavy bleeding, fever, poor wound healing, infection, hematoma	n/a	3d (6.6), 7d (6.4), 45d (6.6)	n/a, n/a
Kanchanasinith et al.	Prospective cohort	Nurse midwife	MD	Women receiving TL at 7 rural hospitals	Intra-op. complications, incisional bleeding, healing problems, infection, pelvic pain, vaginal bleeding, scar, pregnancy	Randomized	2w (7.5) and 1y (16.5)	Yes, No
Koetsawang et al.	Prospective cohort	Nurse	MD	Women receiving TL at rural hospitals	Intraoperative complications, bleeding, pain, infection, superficial abscess, pregnancy at one year	NS	24h, 7d, 6w (81.6NPC, 63.9MD), 1y*	No, No
Satyapan et al.	Single arm prospective cohort	Nurse midwife	n/a	Women requesting TL after normal vaginal delivery at 18 rural hospitals	Mild pyrexia, puerperal sepsis, wound breakdown, respiratory infection, cystitis	n/a	Discharge, 6w (50.8)	n/a, n/a

NS=not specified, * random sample only, MLP = mid-level provider, TL = tubal ligation

Table 16: Tubal ligation NPC provider details

Study	Type of NPC	NPC basic clinical education	NPC practical surgical training for TL
Chowdhury & Chowdhury	Paramedic	At least 6 months	Variable, up to 6 weeks
Dusitsin et al.	Nurse-midwife	3y nursing, 6-8m midwifery	12 weeks, 20 TLs under supervision
Ghorbani	Nurse-midwife	NS	10-15 weeks
Gordon-Maclean et al.	CO	3 years	6 weeks, 40 TL under supervision
Kanchanasinith et al.	Nurse-midwife	3y nursing, 6-8m midwifery	12 weeks, 20 TL under supervision, 4 weeks supervised experience at rural hospital
Koetsawang et al.	RN	3 years	12 weeks, 25 supervised procedures, 6 months supervised experience at rural hospital
Satyapan et al.	Nurse-midwife	3y nursing, 6-8m midwifery	12 weeks, 20 procedures under supervision
NS = not specified, CO = Clinical Officer, TL = tubal ligation			

Table 17: Tubal ligation results

Study, method	Number of Procedures		Complication	Number of Complications (%)	
	NPC	Control		NPC	Control
Chowdhury & Chowdhury, interval	366	234	Post-operative infection	20 (5.46)	15 (6.4)
			Uterine perforation	1 (0.27)	3 (1.28)
			Intestinal perforation	0	1 (0.43)
			Intraoperative hemorrhage	1 (0.27)	0 (0)
			Total reported complications	22 (6.0)	19 (8.1)
Dusitsin et al., PP	143	149	Wound breakdown	2 (1.40)	1 (0.70)
			Post-operative fever	3 (2.10)	2 (1.30)
			Total reported complications	5 (3.5)	3 (2)
Ghorbani, PP	24	0	All complications	0	-
Gordon-Maclean et al., interval	518	0	Overall major complications	1.50%	-
			Moderate complications at day 3	10 (2)	
			Moderate complications as day 7	11 (2.2)	
			Moderate complications at day 45	2 (0.4)	
			Needed verbal assistance from physician during procedure	29%	
			Needed physical assistance from physician during procedure	6 (1.2)	
Kanchanasinith et al., PP	541	279	Intraoperative injury	1 (0.2)	1 (0.4)
			Complaints at 2 weeks (including incisional bleeding, wound infection and healing problems)	0.8%	0.8%
			Complications leading to hospital admission	0.4%	0.8%
			Pregnancies reported at 1 year	0	0
			Total reported complications	1.4%	2.0%
Koetsawang et al., PP	1074	302	Intraoperative injury	1 (0.09)	0%
			Intraoperative transfusion needed	1 (0.09)	2 (0.66)
			Incisional bleeding necessitating hospital admission	0.50%	1.30%
			Wound infection	0.80%	0.50%
			Stitch abscess	1%	0.50%
			Total reported complications	2.48%	2.93%
Satyapan et al., PP	3549	0	Puerperal sepsis	51 (1.4)	-
			Poor wound healing	6 (0.2)	
			Total reported complications	57 (1.6)	
			Needed physical assistance from physician during procedure	18 (0.5)	
PP = post-partum					

Surgical abortion results

I identified 4 studies reporting complication rates for surgical first-trimester abortion procedures when practiced by NPCs. Studies came from South Africa (2 studies), India, Vietnam, and Iran and reported on a total of 4,045 procedures, with 2,208 performed by NPCs and 1,837 performed by MDs. These studies were published in 1979, 2002, 2006, and 2011. Two studies had a single arm cohort design, and two were equivalence trials (one of which was randomized). See Table 18 for design details. All NPCs were nurses and nurse-midwives except for one doctor's assistant in Vietnam and mid-level providers in one of the South African studies. Except for the study from Iran, all NPC providers participated in government-accredited training programs. See Table 19 for NPC provider details.

No mortality or serious complications were reported in any of the studies, where serious complication included blood loss >500ml or requiring hospitalization, cervical laceration, uterine perforation and septic shock. The two equivalence trials found that NPCs and doctors in South Africa, Vietnam, and India performed abortion with equal safety. Rates of retained products of conception for NPC were similar across the studies and ranged from 1.1% to 1.2%. Physician rates were slightly lower at 0.9% to 1%. Rates of infection were also low; NPC rates ranged from 0.1% to 0.2% and physician rates ranged from 0 to 0.1%. The 2002 study from South Africa analyzed the intraoperative period only, and reported zero intra-operative complications. The single arm study from Iran reported low rates of complications similar to those documented in the two equivalence trials. Of note, Warriner et al. reported frequency of adverse symptoms at follow-up, including bleeding heavier than menses, abnormal vaginal discharge, persistent pain or cramps, raised temperature, and nausea or vomiting. Women in the NPC group in South Africa reported significantly more adverse symptoms than women in the MD group. No difference in rate of adverse symptoms between provider groups was shown in Vietnam. See Table 20 for all results.

Table 18: Abortion study design details

Study	Study type	Study group	Control group	Population and setting	Outcomes	Method of sorting patient to provider group	Follow-up (% lost to f/u)	Statistical comparisons, adjustment for confounding variables
Dickson-Tetteh & Billings	Single arm prospective cohort	Midwives	n/a	Women seeking induced first-trimester abortion at 27 public health facilities in rural SA	Intraoperative complications, mortality	n/a	NS	n/a, n/a
Ghorbani	Single arm retrospective cohort	Nurse midwife	n/a	Women presenting to Family Planning Center of Farah Maternity Hospital, Tehran	NS	n/a	NS	n/a, n/a
Jejeebhoy et al.	Prospective 2 sided equivalence	RN	MD	Women \leq 10wks GA seeking abortion at 5 reproductive health NGO clinics in 2 poorly developed states	Total complication rate (retained products of conception, need for blood transfusion or hospitalization, cervical injury, uterine perforation, bowel injury, infection); Adverse symptoms (severe pain, pyrexia, bleeding > 500ml, vaginal discharge, weakness)	One provider type assigned to given clinic on each day, patients not aware of provider type schedule (closely approximated a randomization process)	7d (3.6 NPC, 3.6 MD)	Yes, Yes
Warriner et al.	Randomized 2 sided equivalence trial	RN, MLP	MD	Women seeking induced first-trimester abortion at NGO clinics in urban and peri-urban areas.	Total complication rate (retained products of conception, blood loss > 500mL, cervical injury, uterine perforation, septic shock, death); Adverse symptoms (persistent pain, nausea/vomiting, pyrexia, bleeding > 500ml, vaginal discharge)	Randomized	10-14d	Yes, Yes
NS=not specified								

Table 19: Abortion NPC provider details

Study	Type of NPC	NPC basic clinical education	NPC practical surgical training for surgical abortion
Dickson-Tetteh & Billings	Midwife	NS	160 hours leading to government certification to provide abortion
Ghorbani	Nurse-midwife	NS	10-15 weeks
Jejeebhoy et al.	RN	NS	Gov. of India physician training for MVA: 12 days, 15 procedures under supervision, one week field placement
Warriner et al.	MLP and midwife	NS	All participants were government-accredited in abortion prior to participating in the study
Warriner et al.	Doctor assistant and midwife	NS	All participants were government-accredited in abortion prior to participating in the study
NS = not specified			

Table 20: Abortion results

Study, procedure details	Number of Procedures		Complication	Number of Complications (%)		Difference in complication rates (95% CI)
	NPC group	Control group		NPC	Control group	
Dickson-Tetteh & Billings, MVA (89%), EVA (11%)	96	-	Complications during procedure	0	n/a	
			Mortality	0	n/a	
Ghorbani, not specified	263	-	Retained placenta requiring D&C	3 (1.14)	n/a	
			Procedure failure, continuing pregnancy	2 (0.76)	n/a	
			Severe complications	0	n/a	
Jejeebhoy et al., MVA w/ IM prostaglandin analogue, plastic dilators, prophylactic antibiotics	449	448	Retained products of conception	1.20%	0.90%	0.2 (-1.1 to 1.6)
			Post-abortion infection	0.20%	0.00%	
			Total major complications rate	1.40%	0.90%	0.5 (-1.8 to 1.8)
			Adverse symptoms	7 (1.6)	6 (1.4)	
			Sought help from supervising physician	2.20%	2.50%	
			Supervising physician physically intervened in procedure	2 (0.4)	2 (0.4)	
Warriner et al. (South Africa), MVA w/ misoprostol, plastic dilators	576	577	Retained products of conception	7 (1.2)	0	1.2 (-0.7 to 0.7)
			Post-abortion infection	1 (0.2)	0	0.2 (-0.5 to 1.0)
			Total major complications rate	8 (1.4)	0	1.4 (0.4 to 2.7)
			Adverse symptoms	31 (5.5)	14 (2.4)	p=0.009
Warriner et al. (Vietnam), MVA w/ plastic dilators, prophylactic antibiotics	824	812	Retained products of conception	9 (1.1)	8 (1.0)	0.1 (-1.0 to 1.2)
			Post-abortion infection	1 (0.1)	1 (0.1)	0 (-0.6 to 0.6)
			Total major complications rate	10 (1.2)	10 (1.2)	0 (-1.2 to 1.1)
			Adverse symptoms	51 (6.2)	57 (7.0)	NR
NR = not reported						

DISCUSSION

Despite the fact that NPCs play an important role in provision of surgical care in at least seven countries, and that certain types of surgical task shifting are endorsed by international health organizations, publications reporting the outcomes of these operators are limited. Systematic reviews and meta-analyses concerning safety of circumcision, caesarean, tubal ligation, and surgical abortion have been published in recent years, but to the best of my knowledge no reviews have addressed outcomes of NPCs when performing major general surgery. Publication of NPC surgeon outcomes are on the rise, with 57% of the 28 articles I identified being published in the past 10 years, compared to the remaining 43%, which were published from 11 to 40 years ago.

The majority of studies were from sub-Saharan Africa. For the sake of completeness I have included five studies representing programs that are known to no longer be in operation (4 studies on tubal ligation by midwives in Thailand and 1 study on tubal ligation and abortion by midwives in Iran). After removing these studies, the only non-African countries represented in my data set are India (surgical abortion, 2011), Vietnam (surgical abortion, 2006), and Bangladesh (tubal ligation, 1979).

General Surgery

No significant differences were found between operator groups when performing general surgery, although these results are limited by study design. Understandably, given the difficulties of conducting clinical research in areas with scarce medical personnel, all studies were retrospective and therefore patient allocation to provider type was non-random. Beard et al. accounted for this non-random allocation by performing multivariate logistic regression and Wilhelm et al. compared patient characteristics and concluded that patient groups were comparable. Tyson et al. found significant differences in the patient characteristics of their NPC and MD cohorts; MDs performed > 75% of general surgery and congenital repairs, and > 90% of urological procedures, while NPCs performed > 95% burn surgery and > 75% of neurosurgery and ENT procedures. This resulted in NPCs having higher rates of re-operation and longer hospital stays, differences that

were no longer significant after all burn surgery was removed from the analysis. White et al. reported that critical patients were preferable allocated to physicians, which is evident in their analysis; laparotomy had a 43% mortality rate when performed by MDs, compared to a 12.5% mortality rate when performed by NPCs.

Another limitation of this data set is that all studies reported in-hospital morbidity and mortality only. In addition percent lost to follow-up was reported in only two studies and was significant (16% in Beard et al. and 50% in Tyson et al.). Adverse events are therefore almost certainly underestimated due to failure to capture complications arising after hospital discharge and complications in those patients lost to follow-up, although theoretically these factors would affect both operator groups equally in the controlled studies.

The aggregated complication rates reported in these studies are problematic because of the relative numbers of low and high risk procedures. For example, Vaz et al. reported the total number of complications for 10,258 procedures, with large numbers of low risk procedures (for example 1,008 cases of skin abscess and 1,837 uterine curettages) and small numbers of high risk procedures such as splenectomy (30 cases) and colon rupture with colostomy (16 cases). High adverse event rates for these small numbers of more complicated procedures could be masked by normal complication rates for the comparatively much larger number of low risk procedures included in the data set. This renders the data much less useful as it is precisely these more complicated procedures that must be studied in order to determine a safe scope of practice for NPC surgeons. This problem could be decreased by reporting procedure-specific complication rates, as did a number of studies in this review. However, only small numbers of procedure-specific data was available; for example 98 cases of emergency hernia repair by NPCs are compared to 49 cases by MDs across two studies. Larger data sets of procedure-specific complication rates will be needed to develop robust conclusions on the safety of NPC surgery and guide decision-making regarding the recommended scope of practice for these clinicians.

Despite these limitations, some promising conclusions can be drawn from these studies. First, NPC surgeons contribute significantly (51% of procedures in

these studies) to general surgery practice in Malawi, Mozambique and Tanzania in a variety of settings (district, central and missionary hospitals). Second, these studies have failed to show significantly worse outcomes when NPCs operate, although some differences may have been obscured by study design. On the balance, a doubling of surgical capacity by adding NPCs to the provider mix in these setting likely contributed an overall mortality and morbidity benefit to the population. These results support the continued development of NPC training for general surgery, but only in the context of rigorous research on outcomes.

Medical Male Circumcision

Of the three comparative studies in this group, Osuigwe et al.'s 2004 study from Nigeria was the only to find significantly higher complication rates in the NPC group. The complication rates from this study were outliers compared to the rest of the studies, in both the NPC group and the MD group with total complication rates of 30.6% and 14.5%, respectively. This may have been due to a number of factors. To begin with, this study was unique in that providers did not receive targeted training in circumcision as part of the study. In the majority of studies in the group (5 out of 7 studies), NPC operators were specifically trained as part of the study protocol; in the remaining study NPCs were noted to be "trained" but it was not clear whether this training occurred as part of the study or if it was training clinicians had received previously. In addition, providers in this study used a "traditional" circumcision method in 31% of cases. The specifics of this method were not described, but it was associated with a high risk of complications (40.9% complication rate compared to 15.5% complication rate for the other method used (plastic bell method)). Finally, operators in this study were performing circumcision whenever the need arose in their daily practice; they were likely practicing a lower volume of procedures compared to their colleagues in the other studies who were practicing high volumes of circumcisions in the context of outreach events and research activities. The other two controlled studies found no difference between NPC and MD operators in terms of total complication rates, suggesting that the results of Osuigwe et al. may not be representative of general trends.

Overall complication rates reported for NPC operators in these studies (0.6% to 2.7%) compare favorably with complication rates from a large retrospective trial in the United States (5.31% for males greater than 10 years) (70). Complication rates in the studies presented here may have been underestimates for a number of reasons. First, percentages of patients lost to follow-up were not reported in four studies. When reported, 2-18% of participants were lost to follow-up. In contradiction to the common assumption that patients who do not return for follow-up are less likely to have complications, a 2012 study from Kenya found that circumcision patients who did not return to clinic had higher complication rates (6.8%) when subsequently visited in their homes, compared to patients who did follow up (3.3% complication rate) (71).

Three studies reported on the effect of provider experience on complication rate. Frajzyngier et al. found that patients of providers with 6 or more years of professional experience were significantly less likely to experience a complication ($p < 0.05$) and Krieger et al. found that complication rates declined for every additional one hundred procedure performed up to 300, and that significantly fewer complications occurred after providers had accomplished 200 procedures compared to during their first 200 procedures ($p = 0.0001$). Buwembo et al. found that adverse events were less likely with increasing provider experience, but this difference was not demonstrated after adjusting for cofounders.

Possible limitations of the studies in this review include non-randomization of patients to provider groups, although this effect should be relatively small in the context of an elective procedure performed on healthy individuals. The single-arm cohort design of 4 out of 7 studies is also a limitation, but attenuated by the fact that complication rates are lower than those experienced by patients operated on by physicians in the United States, keeping in mind that complications in these studies may have been underestimated due to loss of patients to follow-up. Short duration of follow-up (not reported or less than or equal to one month in 4 studies) and failure to report percentage of patients seen at follow-up are other possible sources of error in these studies. Ford et al.'s systematic review and meta-analysis reported

that the literature on safety of task shifting for male circumcision is of moderate quality.

These studies demonstrate that NPCs can perform male circumcision with outcomes similar to MDs under certain circumstances. Specifically, they should have been trained recently, be practicing recommended surgical techniques, and have the opportunity to practice their skills regularly. Within these limits, performance of circumcision by NPCs can be recommended in the context of continued research with a focus on improving and standardizing follow-up protocols. Increasing the ability of a medical system to offer circumcision is especially desirable in regions with high HIV prevalence, as circumcision has a high benefit to individuals receiving the procedure and the population as a whole in these contexts.

Emergency obstetric surgery

Patients needing emergency obstetric interventions are a heterogeneous population anywhere in the world. In low resource environments this heterogeneity is increased by extreme presentations due to delays in obtaining care and the additional complexity of caring for critical patients in facilities with limited capacity for high dependency care. In this setting, creating an unbiased study is difficult, if not impossible. This was the case in the studies included in this review. Wilson et al.'s meta-analysis, which included six of the seven articles in this review, assessed studies for risk of bias and found that on average, studies had a medium risk of selection bias, a medium to high risk of comparability bias, and a high risk of outcome assessment bias. While randomized allocation of patients to different provider groups would likely be impossible due to problems with availability of providers, important limitations found across the majority of studies that could potentially be remedied were short duration of follow-up, failure to report percent of patients lost to follow-up, failure to control for confounding factors, and non-standardized outcomes reporting.

Wilson et al.'s meta-analysis reported a significant increase in wound dehiscence in NPC patients. It should be noted that when calculating the combined odds ratio for wound dehiscence, Wilson et al. included cases of superficial wound separation in the total number of wound dehiscence cases from Pereira et al. Pereira

et al. reported 3 cases of wound dehiscence and 41 cases of superficial wound separation; Wilson et al. included 44 cases of wound dehiscence for Pereira et al. in the combined odds ratio calculation. If we consider the number of cases of wound dehiscence in Pereira et al. to be 3, no significant difference in wound dehiscence was found between operator groups in this study. A difference in wound dehiscence rates was not found in the two other studies that reported this outcome. Pereira et al. did find a significant increase in superficial wound separation, and meta-analysis found an increase in wound infections in patients of NPCs. Therefore, it seems reasonable to conclude that NPCs demonstrate some inferiority in terms of incision closure or post-operative care, although not to the point of resulting in more cases of complete wound dehiscence compared to physicians. Studies did not report on protocols for post-operative care or whether it differed according to provider.

Clearly these results must be interpreted with caution, but some conclusions can be drawn. First, no evidence of increased maternal or perinatal morality in NPC patients was found outside of Hounton et al.'s study from Burkina Faso. This study and the small study from former Zaire were the only studies conducted in regions without well-established obstetric surgery training programs for NPCs. In addition, these two studies were the only ones where NPCs were former nurses rather than mid-level providers. The differences found in this study may therefore represent a need for improved training rather than indicate an inherent inferiority of NPC surgeons. Differences in superficial wound separation and wound infections demonstrated in these studies were modest and suggest a need for improved training on surgical technique and post-operative care among NPCs. Given that obstetric emergencies are highly morbid in the absence of surgical interventions and that there is a high unmet need for caesarean in sub-Saharan Africa, adding clinicians with outcomes similar to those demonstrated by the NPCs in these studies would be of undeniable benefit at the population level (72).

Tubal ligation

Complication rates in both NPC and MD provider groups in these studies were elevated compared to a large retrospective study conducted in Switzerland. While this may be expected when comparing complication rates in high and low

resource areas, interestingly this was not the case with circumcision and abortion, where rates in the studies included in this review were similar to those reported in the United States. The total rate of major and minor perioperative complications⁴ from the Swiss study for post-partum minilaparotomy tubal ligation was 1.21% with 0.39% major complication and 0.82% minor complications (73). In comparison, total complication rates (excluding pain, as this was not included as a complication in the Swiss study) ranged from 1.4% to 6.1% for the NPC group and from 2% to 8% for the MD group in the studies included in this review. These elevated rates were mostly accounted for by increased rates of infection and bleeding and not severe complications such as uterine or bowel perforation. In this group of studies, complication rates of NPC patients were on average lower than those of MD patients. Reasons for this trend are unclear but may be due to the fact that the NPCs in these studies received pre-study training, whereas the physician operators did not.

These studies are limited by a number of factors, especially non-controlled design, lack of statistical comparisons, non-standardized outcomes reporting and low follow-up rates or failure to report these rates. Rodriguez et al.'s systematic review concluded that there was insufficient evidence to determine whether tubal ligation may be performed safely by NPCs. Interestingly, the WHO considers tubal ligation to be within the normal scope of practice of mid-level providers and did not review evidence before recommending that tubal ligation may be provided by NPCs in its 2012 guidelines (40).

Several conclusions can be drawn concerning performance of tubal ligation by NPCs in LMICs. First, there is very little evidence on the subject, and even less (1 study) on the current generation of NPC providers. The limited evidence that is available failed to show NPC performance of tubal ligation to be of inferior quality

⁴ Major complications included unintended major surgery, intra-operative blood loss >500 ml, fever, life-threatening event (cardiopulmonary arrest, MI, PE, DIC, anaphylaxis). Minor complications included uterine injuries, abdominal wall hematoma, ileus, wound dehiscence, and UTI. 40 WHO. WHO recommendations: optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. 2012.

compared to that of physicians. The relatively low level of complexity of tubal ligation suggests that it may very well be practiced safely by NPCs. However, at this time there is not a base of quality evidence to support this hypothesis. Keeping in mind that pregnancy is a morbid condition in many low income countries and that reliable access to effective birth control often cannot be guaranteed, for some women tubal ligation can be desirable and life-saving. Further research to document the safety of tubal ligation by NPC providers could be an important part of efforts to decrease morbidity and mortality and improve quality of life for women during their childbearing years.

Surgical Abortion

Two of the four studies in this review are limited significantly by study design. Dickson-Tetteh et al.'s 2002 study from South Africa reports on intra-operative complications only in 96 abortion procedures. While it is certainly encouraging that no complications occurred, small data sample and restriction of outcomes reported to the intra-operative period limit the conclusions that can be drawn from this data. Ghorbani's 1979 study from Iran reports on a larger cohort of patients (263) and includes post-operative complications, but does not specify duration of follow, percentage of patients lost to follow-up or method of pregnancy termination. In contrast, Jejeebhoy et al. and Warriner et al. present high quality data to support the safety of first trimester abortion when performed by NPCs. These studies demonstrated equivalence in NPC and MD outcomes, and NPC results compared favorably to those of PAs and MDs in the United States (63). With two studies reporting on 1,849 NPC procedures in three countries, this is a small dataset that will need to be expanded. In addition, more studies on procedures performed during the third month of pregnancy are needed, as the majority of procedures in these studies were performed during the first two months of gestation (about 85%) and complications are more likely to occur as the pregnancy advances.

Unsafe abortion remains a major threat to women's health. Every year 19 to 20 million unsafe abortions result in 68,000 deaths, with 97% of these procedures occurring in developing countries. This gives unsafe abortion a case-fatality rate (CFR) of 367 per 100,000 procedures, which should be compared to a CFR of <1 per

100,000 for legal abortions performed in developed countries. Only 26% of the world's population lives in countries where abortion is illegal, so for the majority of women, access to safe abortion is obstructed not by laws but by an inability to access a safe procedure (74). A major expansion of trained abortion providers is a necessary step to prevent morbidity and mortality from unsafe abortion; the data presented in this review firmly supports continued efforts to train NPCs in abortion as a strategy to achieve this goal. As programs are implemented in new areas research on outcomes will be vital to ensure safety and identify areas for improvement.

CONCLUSION

The data presented in this literature review failed to show significantly worse outcomes when NPCs perform major general surgery, circumcision, emergency obstetric surgery, tubal ligation and first-trimester abortion. This review supports the development of NPC training programs as a method to decrease morbidity and mortality from surgical conditions in LMICs by increasing access. It should be emphasized that NPCs should not be expected to replace MD surgeons within the medical system and that efforts to train and retain MD surgeons must also be intensified. The context within which NPCs can operate with maximal safety remains to be defined; other research has called into question the capacity of NPCs to perform other roles of the surgeon including deciding when an operation is the best option for an individual patient, and caring for the patient in critical condition after an operation. Further research is needed to answer these questions and continue to monitor the quality of NPC surgery.

REFERENCES

- 1 Kitamura T, Obara H, Takashima Y, et al. World Health Assembly agendas and trends of international health issues for the last 43 years: analysis of World Health Assembly agendas between 1970 and 2012. *Health policy (Amsterdam, Netherlands)*. 2013 May;**110**(2-3):198-206.
- 2 DCP3. Essential Surgery. In: “Debas HTD, Peter; Gawande, Atul; Jamison, Dean T.; Kruk, Margaret E.; Mock, Charles N., editor. *Disease Control Priorities, Third Edition*. Washington, D.C.: World Bank; 2015.
- 3 Organization WH. *Surgical Care at the District Hospital*. Malta: World Health Organization 2003
- 4 Meara JG, Leather AJM, Hagander L, et al. Global Surgery 2030: evidence and solutions for achieving health, welfare, and economic development. *The Lancet*. //;**386**(9993):569-624.
- 5 Henry JA, Bem C, Grimes C, et al. Essential surgery: the way forward. *World journal of surgery*. 2015 Apr;**39**(4):822-32.
- 6 Luboga S, Macfarlane SB, von Schreeb J, et al. Increasing access to surgical services in sub-saharan Africa: priorities for national and international agencies recommended by the Bellagio Essential Surgery Group. *PLoS Med*.**6**(12):e1000200.
- 7 Debas H, Gosselin, R., McCord, C., Thind A. . *Surgery. Disease control priorities in developing countries, 2nd edn* New York: Oxford University Press; 2006. p. 1245-60.
- 8 Shrimpe MG, Bickler SW, Alkire BC, Mock C. Global burden of surgical disease: an estimation from the provider perspective. *Lancet Glob Health*. 2015 Apr 27;**3 Suppl 2**:S8-9.
- 9 Weiser T.G. L, S. . Global volume of surgery and its relationship ot caesarean delivery and life expectancy. *Lancet Global Health* (in press).
- 10 Rose J, Weiser TG, Hider P, Wilson L, Gruen RL, Bickler SW. Estimated need for surgery worldwide based on prevalence of diseases: a modelling strategy for the WHO Global Health Estimate. *Lancet Glob Health*. 2015 Apr 27;**3 Suppl 2**:S13-20.
- 11 Alkire BC, Shrimpe MG, Dare AJ, Vincent JR, Meara JG. Global economic consequences of selected surgical diseases: a modelling study. *Lancet Glob Health*. 2015 Apr 27;**3 Suppl 2**:S21-7.
- 12 Higashi H, Barendregt JJ, Kassebaum NJ, Weiser TG, Bickler SW, Vos T. Surgically avertable burden of obstetric conditions in low- and middle-income regions: a modelled analysis. *BJOG : an international journal of obstetrics and gynaecology*. 2015 Jan;**122**(2):228-36.
- 13 Higashi H, Barendregt JJ, Kassebaum NJ, Weiser TG, Bickler SW, Vos T. Surgically avertable burden of digestive diseases at first-level hospitals in low and middle-income regions. *Surgery*. 2015 Mar;**157**(3):411-9; discussion 20-2.
- 14 Higashi H, Barendregt JJ, Kassebaum NJ, Weiser TG, Bickler SW, Vos T. Burden of injuries avertable by a basic surgical package in low- and middle-income regions: a systematic analysis from the Global Burden of Disease 2010 Study. *World journal of surgery*. 2015 Jan;**39**(1):1-9.
- 15 Ologunde R, Maruthappu M, Shanmugarajah K, Shalhoub J. Surgical care in low and middle-income countries: burden and barriers. *Int J Surg*. 2014;**12**(8):858-63.

- 16 Grimes CE, Law RS, Borgstein ES, Mkandawire NC, Lavy CB. Systematic review of met and unmet need of surgical disease in rural sub-Saharan Africa. *World journal of surgery*. 2012 Jan;**36**(1):8-23.
- 17 Shrimel MG, Dare AJ, Alkire BC, O'Neill K, Meara JG. Catastrophic expenditure to pay for surgery worldwide: a modelling study. *Lancet Glob Health*. 2015 Apr 27;**3 Suppl 2**:S38-44.
- 18 Kouo-Ngamby M, Dissak-Delon FN, Feldhaus I, Juillard C, Stevens KA, Ekeke-Monono M. A cross-sectional survey of emergency and essential surgical care capacity among hospitals with high trauma burden in a Central African country. *BMC health services research*. 2015;**15**:478.
- 19 Holmer H, Lantz A, Kunjumen T, et al. Global distribution of surgeons, anaesthesiologists, and obstetricians. *Lancet Glob Health*. 2015 Apr 27;**3 Suppl 2**:S9-11.
- 20 Holmer H, Shrimel MG, Riesel JN, Meara JG, Hagander L. Towards closing the gap of the global surgeon, anaesthesiologist, and obstetrician workforce: thresholds and projections towards 2030. *The Lancet*. 2015 4/27/;**385, Supplement 2**:S40.
- 21 Petroze RT, Nzayisenga A, Rusanganwa V, Ntakiyiruta G, Calland JF. Comprehensive national analysis of emergency and essential surgical capacity in Rwanda. *The British journal of surgery*. 2012 Mar;**99**(3):436-43.
- 22 Sani R, Nameoua B, Yahaya A, et al. The Impact of Launching Surgery at the District Level in Niger. *World journal of surgery*. 2009 Oct;**33**(10):2063-8.
- 23 Sohler N, Frejacques L, Gagnayre R. Design and implementation of a training programme for general practitioners in emergency surgery and obstetrics in precarious situations in Ethiopia. *Annals of the Royal College of Surgeons of England*. 1999 Nov;**81**(6):367-75.
- 24 White S, Thorpe R, Maine D. EMERGENCY OBSTETRIC SURGERY PERFORMED BY NURSES IN ZAIRE. *The Lancet*. 1987 9/12/;**330**(8559):612-3.
- 25 Chowdhury S, Chowdhury Z. Tubectomy by paraprofessional surgeons in rural Bangladesh. *Lancet*. 1975 Sep 27;**2**(7935):567-9.
- 26 Chu K, Rosseel P, Gielis P, Ford N. Surgical task shifting in Sub-Saharan Africa. *PLoS Med*. 2009 May 19;**6**(5):e1000078.
- 27 Chu KM, Ford NP, Trelles M. Providing surgical care in Somalia: A model of task shifting. *Confl Health*. 2011;**5**:12.
- 28 Ahmed A. Childhood circumcision: a planned approach. *Tropical doctor*. 2007 Oct;**37**(4):239-41.
- 29 Otero A LJ, Ciccio J. . Scaling up male circumcision in Northern Uganda: results from a start-up campaign Rome: 6th IAS Conference on HIV Pathogenesis, Treatment and Prevention 2011.
- 30 Mullan F, Frehywot S. Non-physician clinicians in 47 sub-Saharan African countries. *The Lancet*. 2007 12/22/;**370**(9605):2158-63.
- 31 Kouanda S, Coulibaly A, Ouedraogo A, Millogo T, Meda BI, Dumont A. Audit of cesarean delivery in Burkina Faso. *International Journal of Gynaecology & Obstetrics*.**125**(3):214-8.
- 32 Cobb NM. *Zambian Associate Clinicians 2014* [cited 2016 2/17/16]; Available from: <http://whoeducationguidelines.org/content/zambian-associate-clinicians>

- 33 Warriner IK, Meirik O, Hoffman M, et al. Rates of complication in first-trimester manual vacuum aspiration abortion done by doctors and mid-level providers in South Africa and Vietnam: a randomised controlled equivalence trial . *Lancet*.**368**(9551):1965-72.
- 34 Gibson JO. Personal Communication. 2016.
- 35 Milland M, Bolkan H. Surgical task shifting in Sierra Leone: a controversial attempt to reduce maternal mortality. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2014;**122**(2):155.
- 36 Milland M, Bolkan HA. Enhancing access to emergency obstetric care through surgical task shifting in Sierra Leone: confrontation with Ebola during recovery from civil war. *Acta Obstet Gynecol Scand*. 2015;**94**(1):5-7.
- 37 Ystgaard B, Bolkan H. Surgery and task shifting in the rainforest. *Tidsskrift for den Norske laegeforening : tidsskrift for praktisk medicin, ny raekke*. 2013 Aug 20;**133**(15):1618-20.
- 38 Cometto G, Belgrano E, De Bonis U, et al. Primary surgery in rural areas of southern Sudan. *World journal of surgery*. 2012 Mar;**36**(3):556-64.
- 39 Bergstrom S. Training non-physician mid-level providers of care (associate clinicians) to perform caesarean sections in low-income countries. *Best practice & research Clinical obstetrics & gynaecology*. 2015 Nov;**29**(8):1092-101.
- 40 WHO. WHO recommendations: optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. 2012.
- 41 WHO. Healthcare worker roles in providing safe abortion care and post-abortion contraception: Recommendations 2015.
- 42 UNAIDS. Joint Strategic Action Framework to Accelerate Scale-Up of Voluntary Medical Male Circumcision for HIV Prevention in Eastern and Southern Africa; 2011.
- 43 Beard JH, Oresanya LB, Akoko L, Mwanga A, Mkony CA, Dicker RA. Surgical task-shifting in a low-resource setting: outcomes after major surgery performed by nonphysician clinicians in Tanzania. *World journal of surgery*. 2014;**38**(6):1398-404.
- 44 Buwembo DR, Musoke R, Kigozi G, et al. Evaluation of the safety and efficiency of the dorsal slit and sleeve methods of male circumcision provided by physicians and clinical officers in Rakai, Uganda. *BJU international*. 2012 Jan;**109**(1):104-8.
- 45 Chilopora G, Pereira C, Kamwendo F, Chimbiri A, Malunga E, Bergstrom S. Postoperative outcome of caesarean sections and other major emergency obstetric surgery by clinical officers and medical officers in Malawi. *Human resources for health*. 2007;**5**:17.
- 46 Dickson-Tetteh KaB, D.L. Abortion care services provided by registered midwives in South Africa. *International Family Planning Perspectives* 2002;**28**(144).
- 47 Dusitsin N, Chalapati S, Varakamin S, Boonsiri B, Ningsanon P, Gray RH. Post-partum tubal ligation by nurse-midwives and doctors in Thailand. *Lancet*. 1980 Mar 22;**1**(8169):638-9.
- 48 Fenton PM, Whitty CJ, Reynolds F. Caesarean section in Malawi: prospective study of early maternal and perinatal mortality. *Bmj*. 2003 Sep 13;**327**(7415):587.

- 49 Ford N, Chu K, Mills EJ. Safety of task-shifting for male medical circumcision: a systematic review and meta-analysis. *AIDS (London, England)*. 2012 Mar 13;**26**(5):559-66.
- 50 Frajzyngier V, Odingo G, Barone M, Perchal P, Pavin M. Safety of adult medical male circumcision performed by non-physician clinicians in Kenya: a prospective cohort study. *Glob*.**2**(1):93-102.
- 51 Gessesew A, Barnabas GA, Prata N, Weidert K. Task shifting and sharing in Tigray, Ethiopia, to achieve comprehensive emergency obstetric care. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics*. 2011 Apr;**113**(1):28-31.
- 52 Ghorbani FS. The use of paramedics in family planning services in Iran. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics*. 1979 Sep-Oct;**17**(2):135-8.
- 53 Gordon-Maclean C, Nantayi LK, Quinn H, Ngo TD. Safety and acceptability of tubal ligation procedures performed by trained clinical officers in rural Uganda. *International Journal of Gynaecology & Obstetrics*.**124**(1):34-7.
- 54 Hounton SH, Newlands D, Meda N, De Brouwere V. A cost-effectiveness study of caesarean-section deliveries by clinical officers, general practitioners and obstetricians in Burkina Faso. *Human resources for health*. 2009;**7**:34.
- 55 Jejeebhoy SJ, Kalyanwala S, Xavier AJ, et al. Can nurses perform manual vacuum aspiration (MVA) as safely and effectively as physicians? Evidence from India. *Contraception*. 2011 Dec;**84**(6):615-21.
- 56 Kanchanasinith K, Piyapinyo P, Pitaktepsombati P, et al. Postpartum Sterilization by Nurse-Midwives in Thailand. *International Family Planning Perspectives*. 1990;**16**(2):55-8.
- 57 Koetsawang S, Varakamin S, Satayapan S, Srisupandit S, Apimas SJ. Postpartum sterilization by operating-room nurses in Thailand. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics*. 1981 Jun;**19**(3):201-4.
- 58 Krieger JN, Bailey RC, Opeya JC, et al. Adult male circumcision outcomes: experience in a developing country setting. *Urologia internationalis*. 2007;**78**(3):235-40.
- 59 McCord C, Mbaruku G, Pereira C, Nzabuhakwa C, Bergstrom S. The quality of emergency obstetrical surgery by assistant medical officers in Tanzanian district hospitals. *Health affairs (Project Hope)*. 2009 Sep-Oct;**28**(5):w876-85.
- 60 Odingo G, Perchal P, Pavin M, Mumba F, Ndede F, Mbayaki R, Were R. . Comparing adverse event rates of male circumcision services performed in static and outreach public health facilities in Nyanza, Kenya. XVIII International AIDS Conference. 2010;**Vienna**:abstract MOPE0341.
- 61 Osuigwe A OP. Circumcision-related complications in the male: experience amongst the Igbo's of Southeast Nigeria. *Afr J Urol*. 2004;**4**:246-51.
- 62 Pereira C, Bugalho A, Bergstrom S, Vaz F, Cotiro M. A comparative study of caesarean deliveries by assistant medical officers and obstetricians in Mozambique. *British journal of obstetrics and gynaecology*. 1996 Jun;**103**(6):508-12.
- 63 Renner RM, Brahmi D, Kapp N. Who can provide effective and safe termination of pregnancy care? A systematic review*. *BJOG : an international journal of obstetrics and gynaecology*. 2013 Jan;**120**(1):23-31.

- 64 Rodriguez MI, Gordon-Maclean C. The safety, efficacy and acceptability of task sharing tubal sterilization to midlevel providers: a systematic review. *Contraception*. 2014 Jun;**89**(6):504-11.
- 65 Satyapan S, Varakamin S, Suwannus P, Chalapati S, Onthuam Y, Dusitsin N. Postpartum tubal ligation by nurse--midwives in Thailand: a field trial. *Studies in family planning*. 1983 Apr;**14**(4):115-8.
- 66 Tyson AF, Msiska N, Kiser M, et al. Delivery of operative pediatric surgical care by physicians and non-physician clinicians in Malawi. *Int J Surg*. 2014;**12**(5):509-15.
- 67 Vaz F, Bergstrom S, Vaz Mda L, Langa J, Bugalho A. Training medical assistants for surgery. *Bull World Health Organ*.**77**(8):688-91.
- 68 Wilhelm TJ, Thawe IK, Mwatibu B, Mothes H, Post S. Efficacy of major general surgery performed by non-physician clinicians at a central hospital in Malawi. *Tropical doctor*. 2011 Apr;**41**(2):71-5.
- 69 Wilson A, Lissauer D, Thangaratinam S, Khan KS, MacArthur C, Coomarasamy A. A comparison of clinical officers with medical doctors on outcomes of caesarean section in the developing world: meta-analysis of controlled studies. *Bmj*.**342**:d2600.
- 70 El Bcheraoui C, Zhang X, Cooper CS, Rose CE, Kilmarx PH, Chen RT. Rates of adverse events associated with male circumcision in U.S. medical settings, 2001 to 2010. *JAMA pediatrics*. 2014 Jul;**168**(7):625-34.
- 71 Reed J, Grund J, Liu Y, et al. Evaluation of loss-to-follow-up and post-operative adverse events in a voluntary medical male circumcision program in Nyanza Province, Kenya. *Journal of acquired immune deficiency syndromes (1999)*. 2015 Jan 23.
- 72 Cavallaro FL, Cresswell JA, Franca GV, Victora CG, Barros AJ, Ronsmans C. Trends in caesarean delivery by country and wealth quintile: cross-sectional surveys in southern Asia and sub-Saharan Africa. *Bull World Health Organ*.**91**(12):914-22D.
- 73 Huber AW, Mueller MD, Ghezzi F, Cromi A, Dreher E, Raio L. Tubal sterilization: complications of laparoscopy and minilaparotomy. *Eur J Obstet Gynecol Reprod Biol*.**134**(1):105-9.
- 74 Grimes DA, Benson J, Singh S, et al. Unsafe abortion: the preventable pandemic. *The Lancet*.**368**(9550):1908-19.