

**A SURVEY OF ANAESTHETIC DRUG AVAILABILITY:
IMPACT ON PRACTICE OF ANAESTHESIA AND PATIENT
CARE IN HARARE**

DR GERALD. T. NYAKATAWA [MBChB, DA (UZ)]

**A thesis submitted in partial fulfillment of the requirements for the degree of
Masters in Medicine (Anaesthetics).**

University of Zimbabwe

Department of Anaesthetics and Critical Care Medicine

College of Health Sciences

June 2015

RELEASE FORM

I, **Dr Gerald T. Nyakatawa**, declare that this submission is my own work. In submitting it for my Masters Degree in Medicine (Anaesthetics), I attest that it has not been submitted in part or whole to any university or other institution of higher learning.

Signature.....Date.....

We.....

.....

.....

Having supervised and read this dissertation are satisfied that this is an original work of the author under whose name it is being presented. We confirm that the work has been completed satisfactorily and is ready for presentation to the examiners.

Signatures:

Supervisor.....Date.....

Supervisor.....Date.....

Chairman.....Date.....

Abstract

Objectives:

To investigate how common anaesthetic drug shortages are, how they affect the practice of anaesthesia and patient care in Harare.

Methodology:

A multicentre prospective observational study of anaesthetic drug availability was carried out involving a self-administered questionnaire completed by anaesthetists working in 3 Public hospitals and 6 Private hospitals in Harare daily over the period; 1 August 2014 to 31 October 2014. A total of 422 completed questionnaires were collected out of 619 that had been distributed. In the last week of October 2014, a once off survey of the hospitals' chief pharmacists was done using a different questionnaire.

Results:

The incidence of reporting at least an anaesthetic drug shortage by anaesthetists was 79.86% and 100% for pharmacist. There is a statistically significant difference in the availability of drugs between private and public hospitals, $p < 0.001$. Private hospitals tend to have less drug shortages compared to public hospitals. Anaesthetic drug shortages are associated with a high frequency of negative adverse effects on the practice of anaesthesia and patient care.

Conclusion:

Anaesthetic drug shortages are common in Harare and they are associated with high incidences of adverse effects on anaesthesia practice and patient care.

Acknowledgements

I am extremely grateful to my supervisors Dr S. Shumbairerwa and Dr F. D. Madzimbamuto who assisted me tirelessly from the beginning to the end of this project. Many thanks to all the anaesthetists, pharmacists and nurses in Harare and Chitungwiza, and departmental staff members who helped make this project a success.

I am also greatly indebted to my mentor; Dr E Mgano for her support throughout the study.

Finally, I would like to thank my beloved wife; Gracious and my beautiful daughter;

Tanyaradzwa for their everlasting love, constant prayers and tremendous support during the time of the study.

Table of Contents	Page
Release Form	ii
Abstract	iii
Acknowledgements	iv
Table of contents	v
List of tables	vii
List of figures	viii
List of appendices	ix
Abbreviations	x
Introduction	1
Literature Review	7
Methodology	31
Results	38
Discussion	54
Conclusion	59
Recommendations	60
Study limitations	60

References	62
Appendix 1	68
Appendix 2	71
Appendix 3	74
Appendix 4	76

List of Tables

Table 1:	Drugs most frequently available in Sub-Saharan French-speaking Africa
Table 2:	Comparison of drug prices: Zimbabwe against UK
Table 3:	Distribution of responses/questionnaires collected from anaesthetist according to designation
Table 4:	Distribution of responses according to duration of practice in anaesthesia
Table 5:	Distribution of Questionnaires in the hospitals
Table 6:	Association between frequency of drug shortage and whether reported in public or private hospital
Table 7:	Hospital pharmacy anaesthetic drug stock-outs reported by pharmacist
Table 8:	Frequency of advance notices of drug shortages
Table 9:	Frequency of who notifies pharmacist about drug shortages
Table 10:	Do drug shortages increase the cost of anaesthesia care
Table 11:	Frequency of pharmacists who experienced at least a drug shortage
Table 12:	Causes of drug shortages as cited by pharmacists

List of Figures

- Figure 1: USA National drug shortages from January 2001 to September 15, 2001
- Figure 2: AHA drug shortage analysis
- Figure 3: Respondent Experience with drug shortages in the ISPE survey, June 2013
- Figure 4: The state of SADC member states Pharmaceutical manufacturing
- Figure 5: Causes of drug shortages in the USA in 2013
- Figure 6: The basis of drug shortages
- Figure 7: Hospital involvement in the study
- Figure 8: Frequency of all types of anaesthetic drug shortages in all hospitals
- Figure 9: Frequency of Intravenous and Inhalational Anaesthetic drug shortages
- Figure 10: Frequency of Anaesthetic gases, neuromuscular blockers and reversal drug shortages
- Figure 11: Frequency of Opioids & Antagonists, and Antimuscarinic& Antiemetic drug shortages
- Figure 12: Frequency of Sedative and Local Anaesthetic drug shortages
- Figure 13: Frequency of Vasopressor/Inotropic drug shortages
- Figure 14: Response on how anaesthetic drug shortages affected anaesthesia practice
- Figure 15: Responses on how anaesthetic drug shortages affect patient care

List of Appendices

Appendix 1: Anaesthetist's Questionnaire

Appendix 2: Pharmacist's Questionnaire

Appendix 3: Consent Form

Appendix 4: Hospital Authorisations

Abbreviations

AHA	American Heart Association
AIDS	Acquired Immunodeficiency Syndrome
APIs	Active Pharmaceutical Ingredients
ASA	American Society of Anesthesiologists
ASHP	American Society of Health System Pharmacists
CAS	Canadian Anesthesiologists Society
CPhA	Canadian Pharmacists Association
COMESA	Common Market East and Southern Africa
DA	Diploma in Anaesthetics
DALYs	Disability-Adjusted Life Years
DSP	Drug Shortage Program
FDA	Food and Drug Association
GAO	Government Accountability Office
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
MCAZ	Medicines Control Authority of Zimbabwe

MoHCC	Ministry of Health & Child Care
MMED	Masters in Medicine
SADC	Southern African Development Community
SSC	Surviving Sepsis Campaign
USA	United States of America
UUHC	University of Utah Health Care
WHO	World Health Organisation
ZAA	Zimbabwe Anaesthetic Association

Introduction

The world over, drug shortages have increasingly become a hindrance to the delivery of quality health care. These shortages affect almost every medical specialty. A commentary in a Belgian pharmacy journal reported that the problem of drug shortages is global, describing it as stretching “from Afghanistan to Zimbabwe”, listing 21 countries affected by a variety of supply problems.¹ In March 2012, 97.6% of anesthesiologists surveyed by the American Society of Anesthesiologists (ASA) reported experiencing at least one current anaesthetic drug shortage.² These drug shortages may have far reaching consequences to hospitals, patients and the medical practitioners concerned.

Unavailability of a needed drug signifies a drug shortage, which may result in challenges in the delivery of anaesthesia. There is no standard definition of a drug shortage in literature. For the purposes of this study an **anaesthetic drug shortage** is defined as “the unavailability of any contemporary drug, when required for use in conducting anaesthesia”.

Generic injectable drugs have the highest risk for shortage. These drugs are more likely than brand-name drugs to be in short supply because they are produced by fewer manufacturers, probably because of their lower profit margins. Jensen and Rappaport reported that “although shortages can occur with any drug, sterile injectable drugs such as propofol are particularly susceptible.”³ Anaesthesia is among the medical specialties most affected by drug shortages because most of the drugs used in this specialty are injectable drugs. Anaesthetic and central nervous system drugs were reported to have the highest number of shortages in a summary of critical drug shortages produced from June 2011 to June 2013 in the United States of America (USA).⁴

Drug shortages negatively impact on patient care by forcing substitution of safe and effective therapies with alternative treatments thereby compromising or delaying medical and surgical procedures, and causing medication errors. Ventola reported that the USA is experiencing a rapidly increasing frequency of drug shortages, which has posed a variety of challenges for doctors, nurses, health care facilities, patients and federal regulators.⁵ Health care facility finances and personnel are also significantly burdened by drug shortages. They have to work harder, sometimes overtime to acquire the drugs or alternatives at usually higher prices. When anaesthetists are faced with drug shortages it may be difficult to deal with anaesthesia complications such as hypotension, hypertension, delayed awakening, nausea & vomiting, resulting in postponement of surgical procedures and even death.³

The causes of drug shortages are multi-factorial; hence management strategies with clear policies and procedures are required for information gathering, decision-making, collaboration, and timely communication.⁶ In developed countries the collection and analysis of data relating to drug shortages is now standard practice. This is exemplified by the Food and Drug Administration (FDA), and the American Society of Health-system Pharmacists (ASHP) Drug Shortage Resource Centre in the USA. The new law requires the FDA to maintain an updated list of critically needed drugs in short supply on its website for easy public access.⁷

The World Health Organisation (WHO) launched its Safe Surgery Saves Lives Campaign in 2007. The three pillars of which are clean surgery, safe anaesthesia and safe surgeons.⁸ Provision of safe anaesthesia is hampered by drug shortages in resource poor settings.⁸ The WHO also recommends an essential drug list for anaesthesia. It has developed a Guide to Anaesthetic Infrastructure and Supplies at various levels of health care facilities. Enright commented that many hospitals in low-income countries do not meet these WHO requirements.⁹ A reliable

supply of anaesthetic drugs is essential for the safe practice of anaesthesia and it is important for every player in the health delivery system to understand the negative effects of drug shortages.⁹ It is important to study the types of drug shortages and their impact on anaesthesia practice and patient care in Zimbabwe, a very low income country.

In Zimbabwe health care is provided by public facilities, nonprofit groups, church organizations, company-operated clinics and profit-making private facilities. The for-profit private sector is mainly found in urban areas. There is also a traditional medicine sector which provides treatment for a variety of illnesses to a largely unknown but significant portion of the population. Public health services are decentralized, with health care provided at primary, secondary, tertiary and quaternary levels. However, the public health system is centralized for policy and administrative governance, resource allocation and coordination of responses to national health. Quaternary or central care comprises two central hospitals in Harare, two in Bulawayo, and one in Chitungwiza that have the most advanced equipment, specialist staff and clinicians, and pharmaceuticals for dealing with the most complicated clinical cases.¹⁰

The procurement and drug licensing bodies in Zimbabwe are semi-autonomous and must fund their services based on their own revenue reserves in addition to a treasury grant. This system is intended to create sustainability and lessen the country's reliance on outside donors.

Pharmaceutical management in the public sector is done by two organizations¹⁰:

- The National Pharmaceutical Company of Zimbabwe (NatPharm): a state owned company that procures, stores, and distributes medical supplies for the country's public health institutions. It also provides for mission health facilities that are part of the public health system and private health centres that are willing to purchase from them.

- The Medicines Control Authority of Zimbabwe (MCAZ): a statutory body, and the sole regulator for the pharmaceutical industry. MCAZ controls the registration of pharmaceuticals to be used in Zimbabwe and licensing of pharmaceutical manufacturers, wholesalers, pharmacies, and other organizations and individuals that deal with pharmaceuticals. This agency also has laboratories which can be used for testing pharmaceuticals, prior to their registration.

Zimbabwe's health care system was satisfactory until the mid-1990s. The 90's were characterised by deterioration of most health indicators. When the country was at its lowest in 2008, all of its WHO's six building blocks for health systems strengthening were seriously compromised. The building blocks are; human resources for health, health financing, health information, health service delivery, medicines or vaccines and medical technology, leadership and governance.¹¹

In the face of all the economic challenges, the national budgetary allocation to health has been low at 6.7% in 2010, 9.3% in 2011, 8.6% in 2012 and 9.9% in 2013 but dropped in 2014 to 8.2%. All these figures are below the Abuja Declaration recommendation of 15%.¹¹ In 2013 the budget compliance was only 62%, which was consumed by salaries and allowances.¹¹ The Ministry of Health and Child Care's capacity to meet its mandates like providing 100% of essential medicines, remains constrained as seen by no grant to NatPharm between 2009 and 2013. This has resulted in more than 40% of the essential medicines being provided by donors, leaving a deficit of 60%. Currently about 98% of NatPharm's medical supplies stocks are being provided by donors with the National AIDS Council providing the remaining 2%.¹¹ The National AIDS Council is funded via 3% levy from all taxpayers.

There is some awareness that anaesthetic drug shortages are encountered daily in the theatres and critical care areas in Harare. This is evident in nurses', doctors', and pharmacists' reports, and critical incident reports in the Department of Anaesthesia covering the two referral hospitals in Harare. Journalists, politicians and health workers alike have blamed the shortages entirely on inadequate funding.¹² However, without evidence, it may be difficult to justify that lack of monetary resources is the sole reason for drug shortages.

The Zimbabwean health delivery system has been dominated by donor funded vertical programmes of health intervention, mostly related to HIV/AIDS, tuberculosis, malaria, and maternal and child health over the last 2 decades. Little attention has been given to areas such as surgery and anaesthesia. The emerging global discussion on surgical diseases and public health is yet to grip Zimbabwe. The overlooked factors are the burden of surgical disease and the importance of safety in anaesthesia. The WHO estimates that 11% of the global burden of diseases can be treated surgically.¹³ Surgical conditions also account for approximately 25 million disability-adjusted life years (DALYs) in Africa, the region with the highest concentration of surgical DALYs (38/1000 population). Despite a significant burden of disease, surgical conditions apart from obstetric emergencies are not included in the Millennium Development Goals.¹⁴ Recent cost-effectiveness studies show that basic surgical services are more cost-effective than antiretroviral therapy; (US\$11 – US\$33/DALY averted) vs (US\$300-US\$500/DALY averted), even if assuming low-cost production, high HIV prevalence and high compliance.¹⁴

The Zimbabwean anaesthetic drug availability situation has not been formally studied but observations and anecdotal reports suggest anaesthetists and pharmacists are battling with drug shortages daily. There is no drug shortage surveillance system in place in the MoHCC or the

MCAZ to constantly monitor, inform and advise the nation on management strategies for drug shortages in general, especially anaesthetic drugs. This study seeks to identify anaesthetic drugs in short supply and assess the impact of the shortages on the practice of anaesthesia, and impact on patient care in Harare.

Literature Review

The end of the last millennium saw drug shortages emerging to be a major global problem, although this was reported more in the developed world.⁵ Historically, drug shortage reporting started in 1999 in the USA with the formation of the Drug Shortage Program under the FDA, whose mandate is to address potential and actual drug shortages in the whole country. Media reports of drug shortages date as far back as the World War II, but heightened concern began at the turn of the millennium. These shortages have been traced by the FDA and the American Society of Health-System Pharmacists (ASHP) partnered by The Drug Information Service at University of Utah Health Care as shown by Figure 1 below.⁵

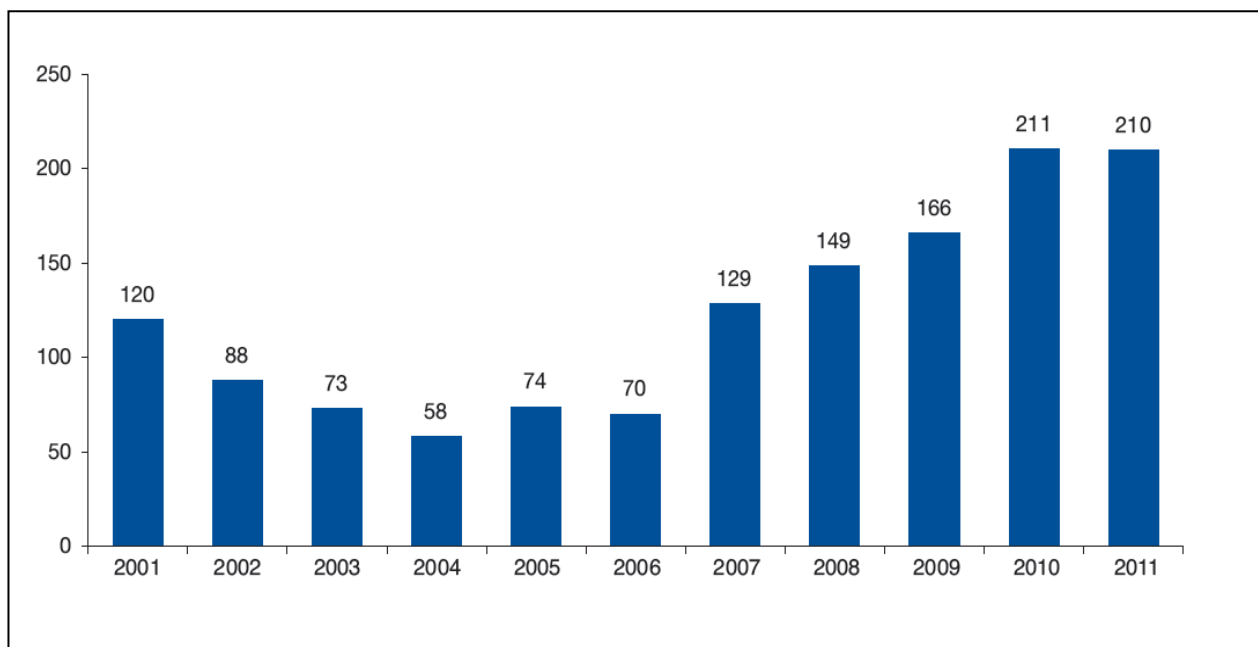


Figure 1: USA National drug shortages from January 2001 to September 15, 2011. Each column represents the number of new shortages noted during that year. Source: C. Lee Ventola. The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies. P&T. 2011; 36 (11): 740 - 757.

In North America drug shortages are treated seriously to the extent that there are several institutions that monitor drug shortages. These include the FDA, ASHP, ASA and Canada Health. These bodies together with the pharmaceutical manufacturers form an efficient drug shortage surveillance and notification system that monitors drugs in their region.

Such is the magnitude of drug shortages that in June 2013 delegates from around the world converged in Toronto to attend the historical and first-ever “International Summit on Medicine Shortages” co-hosted by the International Pharmaceutical Federation (FIP) and the Canadian Pharmacists Association.¹⁵ The summit ushered a platform to discuss the causes, impacts, and solutions to the global issue of drug shortages by representatives from governments, healthcare practitioners and professional bodies, industry and patients. The summit delegates came up with the following recommendations:

- Each country should establish a publicly accessible means involving the ministry of health, medicines regulatory authority or professional bodies, of providing full information on drug shortages.
- A global process to determine the list of critical or vulnerable products should be developed then each country could adapt the list to local conditions.
- All procurers of drugs are encouraged to move towards active procurement processes that assure the continuity of supply of quality drugs.
- All countries are encouraged to remove unnecessary variability of regulatory practices within and between countries.
- All countries should investigate the potential to establish a national body charged with gathering and sharing information about demand for and supply of medicines within their jurisdiction.

- All countries are encouraged to develop evidence-based risk mitigation strategies which might include strategic buffer stocks and stock piles, contingency planning, pandemic planning and capacity redundancy, appropriate to their national needs.

Issues concerning anaesthetic drug shortages, initially echoed by the media fraternity have recently been corroborated by scientific studies mainly in the developed world.

Definition of a drug shortage

Currently there is no harmonized, universal definition for a drug shortage and there is need for one.¹⁶ Different institutions and authorities have come up with definitions that suit their circumstances. Each study done has crafted a definition relevant to its main objectives and setting. Some of the definitions of drug shortages in literature are:

- **FDA:** “A situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level”.¹⁷
- **American Society of Health-System Pharmacists (ASHP):** “A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent”.¹⁸
- **International Society for Pharmaceutical Engineering (ISPE):** “A situation in which the total supply of an approved (by the appropriate Health Authority) drug is inadequate to meet the current or projected demand at the user level. A near miss - as a situation in

which a company had reason to be concerned that the total supply of an approved drug might become inadequate to meet the current or projected demand at the user level.¹⁹

▪ **European Federation of Pharmaceutical Industries and Association (EFPIA):**

“describes a potential drug shortage as the occurrence of internal or external situations (single or in a combination of both) which could result in an interruption of supplies of a medicinal product, if not properly addressed and controlled”.¹⁶

One thing in common with these definitions is that authorities are primarily concerned with drug shortages that affect patient care. In general, the focus is on shortages of medically necessary products that have a significant effect on public health.

Drug shortages in developed countries and their impact

Drug shortages have been extensively studied in the developed countries, particularly in North America and Europe. This was after the realization that drug shortages pose a serious public health problem and have far-reaching consequences for healthcare providers and their patients.²⁰ Developed countries are ahead in the understanding of the drug shortage problem and they have adopted most of the recommendations from the International Summit on Medicine Shortages. All the stakeholders; governments, healthcare practitioners and professional bodies, industry, and patients have come together in the fight against drug shortages.

Premier Healthcare, a private health care company, conducted two surveys on drug shortages in 2010 and 2014 in the USA. In the first survey, 311 pharmacy experts representing 228 hospitals and multiple other centres were involved. Drug shortages were reported in the study.

Consequences of drug shortages on the patients were delays or cancellation of their therapeutic interventions and medication safety issues or errors in their care. These shortages also resulted in increased costs to the hospitals which were eventually transferred to the patients.²¹

The 2014 Premier Healthcare survey had almost similar results. It revealed that shortages may result in a delay or cancellation of crucial medical procedures, increased time and expense in protecting against errors or adverse effects because of the substitution of alternative medications. This is a problem if prescribers are not as familiar with alternative dosing and potential interactions with other drugs. Results suggest shortages remain a patient safety risk, with 90% of respondents experiencing at least one shortage in the last six months that may have caused a medication safety issue or error in patient care, compared to 91.4% in 2010. However, the prevalence of shortages that affect patient care seemed to be decreasing.²² Data from the FDA drug shortage program also show a similar trend. USA drug shortages peaked in 2011, with 251 new reported drug shortages then in 2012 the figure came down to 117 new shortages and in 2013 the numbers were more promising at 44 new shortages. However, sterile injectable drugs, including anaesthetic drugs remain at the top of the shortages.²⁰

The American Hospital Association (AHA) carried out an electronic drug shortage survey in 2011 across 820 non-federal healthcare facilities. Anaesthesia and emergency care drugs had the highest frequency of shortages. The impact of the drug shortages were; delay or cancellation of treatment and increased cost on anaesthesia borne by the hospitals and patients.²³

Percent of Hospitals Experiencing a Drug Shortage in the Last Six Months by Treatment Category

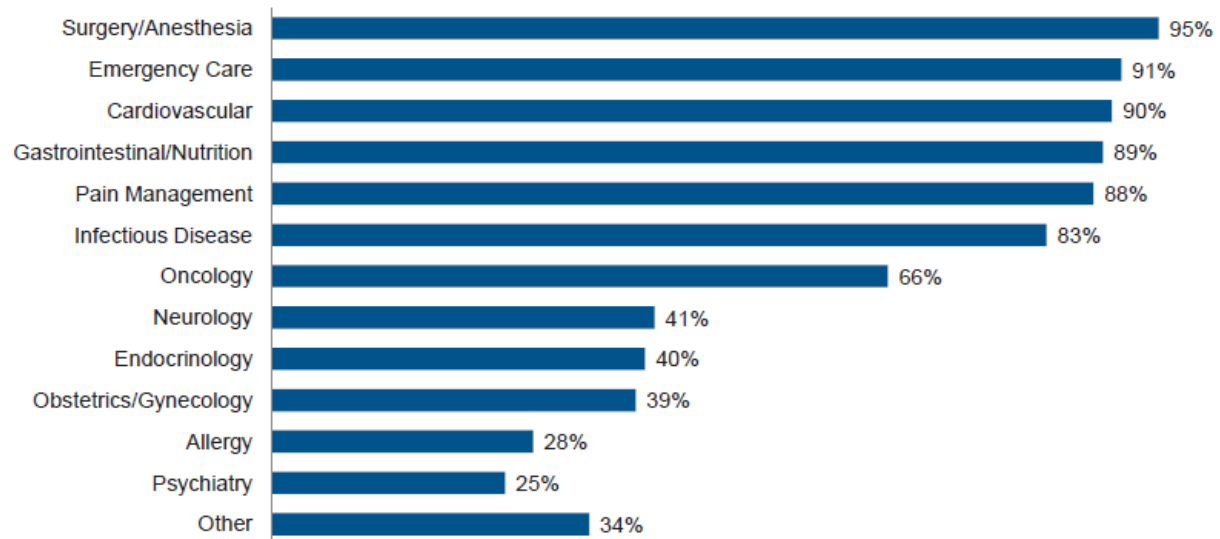


Figure 2: AHA analysis of survey from 820 non-federal, short-term care hospitals in 2011. (<http://www.aha.org/content/11/drugshortagesurvey.pdf>)

The 2012 ASA Drug Shortages Survey revealed serious shortages in the USA. About 97.6% of respondents reported they were currently experiencing a shortage of at least one anaesthesia drug.² The anesthesia drugs with the highest frequency of reported current shortage were fentanyl (66.3%), thiopental (40.3%), succinylcholine (21.1%), propofol (19.2%) and pancuronium (15.2%). This was a survey done involving a total of 3063 anaesthesiologists representing 50 states, the District of Columbia, Puerto Rico and six nations. Respondents reported that drug shortages had the following significant impact on their patients:

- Patients experienced a less optimal outcome (for example; post-op nausea and vomiting) (66.7% of the respondents)
- Patients experienced longer recovery times (52.8%)
- Patients complained (27.5%)

- Resulted in death of a patient (0.2%)

Respondents reported that drug shortages had the following impact on their anaesthesia practice:

- Use of alternative drugs (96.3% of the respondents)
- Change of the procedure in some way (50.2%)
- Postponement of cases (7.0%)
- Cancellation of cases (4.1%)

The results of The 2012 ASA Drug Shortages Survey supported data from the Government Accountability Office (GAO) report on drug shortages. The GAO report contained analysis that found anaesthetic and central nervous system drugs to be the worst hit by shortages.²

A national survey done by Hall *et al* in 2013 showed that anaesthetic drug shortages are common in Canadian anaesthesia. This was a self-administered national survey of anesthesiologists in Canada using the membership list of the Canadian Anaesthesiologist Society (CAS). Most respondents, 65.6% described a current shortage of one or more anaesthetic or critical care drugs. The survey also revealed that the shortages may negatively affect how anaesthetists practise; some had to give what was considered an inferior anaesthetic technique or postpone the procedure. According to the study adverse patient outcomes such as prolonged recovery or death may be associated with anaesthetic drug shortages.²⁴ The strengths of this study were that it involved a diversity of respondents; 1932 anaesthesiologists across the whole country, giving a national scope, with an acceptable 66% response rate. However, caution was expressed in the interpretation of four reports of perioperative deaths attributed in part to drug shortages. Respondents remained anonymous hence there was no means to confirm the details of such incidents. The study was also limited by being a convenience sample of about two-thirds of the

membership of the CAS, and it may not reflect the views of the other one-third of the membership or non-members. The study was also subject to recall bias as respondents who have experienced a drug shortage are more likely to remember and report a reoccurrence than doctors without such an experience.²⁴

In response to the 2013 Canadian Anaesthesiologist Society survey, some Zimbabwean authors; Nyakatawa *et al* suggested that the Zimbabwean anaesthetic drug shortage situation had not received as much scrutiny as was the case in Canada and North America. Anaesthetic and related drug shortages in Zimbabwe may be similar or greater than those in Canada and North America and may include most drug classes.²⁵

The Canadian Anaesthesiologist Society (CAS) study was preceded by a survey by the Canadian Pharmacists Association (CPhA) in 2010 on drug shortages in Canada. This was a broader study looking at all the classes of drugs on the Canadian pharmaceutical market. The results confirmed that drug shortages were real and were having negative impacts on the health and well being of patients. This was an on-line survey of the membership of the association. Questions were developed, based partially on a similar survey that the CPhA had done in 2004.²⁶ The final report on the study came up with recommendations on how to address drug shortages which were presented to government, regulatory agencies, manufacturers, distributors, pharmacy corporations and pharmacists.

Drug shortages are not only a North American problem as revealed by the June 2013 International Society for Pharmaceutical Engineering (ISPE) survey.²⁷ This was a global survey involving individuals and companies in the pharmaceutical industry. Out of the 264 respondents 212 of them experienced an actual drug shortage or a near miss. The survey also unraveled some

of the causes of drug shortages. The survey was such that the design could not allow the investigation of the impact of drug shortages on patients and medical practitioners.

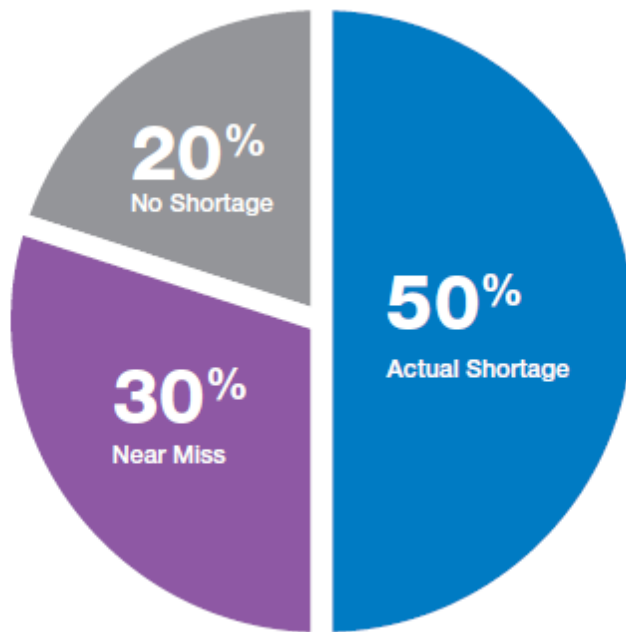


Figure 3: Respondent Experience with Drug Shortages in the ISPE survey, June 2013

Source:International Society for Pharmaceutical Engineering (ISPE) Report on the ISPE Drug Shortages Survey.2013.www.ispe.org/drugshortages/2013JuneReport(Accessed 10/02/2015)

Further confirming the global and universal nature of drug shortages is the European Association of Hospital Pharmacists (EAHP) 2014 pan-European survey of hospital pharmacists from 36 countries. EAHP's 2014 survey of medicines shortages in European hospitals was the largest (online and paper-based) investigation of its kind, with over 600 responses, from 36 European countries.²⁸ The survey done from the 19th March 2014 to the 7th May 2014, showed that:

- 86% of pharmacists reported that drug shortages were a current problem in the hospital they work in, in terms of providing the best care to patients and/or operating the hospital pharmacy

- 66% of participants reported that drug shortages affected their hospital pharmacy on a daily or weekly basis
- Antimicrobial agents, oncology products, emergency medicines, cardiovascular medicines and anaesthetic agents were the most affected
- 75.4% of pharmacists either agreed or strongly agreed with the statement *"medicines shortages in my hospital are having a negative impact on patient care."*
- Impact on patients included delayed or interrupted chemotherapy treatment, unnecessary side effects on patients, heightened clostridium difficile risk and deterioration in patients' conditions.

Studies done in developed countries; North America and Europe have demonstrated that drug shortages are common and negatively impact on patients and medical practitioners.

Drug shortages in middle- and lower-income countries and their impact

Epidemiological data on drug shortages, especially anaesthetic drugs is almost non-existent in the less developed countries, particularly in Africa. This is noted by Andy Gray who cited North America as the only region with publicly accessible data on shortages of medicines.²⁹ Drug shortages in Africa have not been adequately studied in a manner as comprehensive as in the developed world but there are reports of drug shortages in a few papers and commentaries by some authors. Media reports of drug shortages are rife, almost on a daily basis in South Africa, Kenya, Zimbabwe and the war-torn zones in Africa and the middle-east.^{30, 31, 32} However, these reports cannot be entirely relied upon; and so there is immediate need for scientific studies to investigate issues surrounding drug shortages in these areas.

Developing countries are faced with a plethora of challenges which may be social, cultural, political and financial. Local governments may not always recognize health as one of the cornerstones for national development. One current major debate in the provision of anaesthesia in Sub-Saharan Africa is that of the “sophistication syndrome” loosely taken as the hurried movement towards safe, modern and expensive anaesthesia, which is unsustainable in a particular setting.³³ This is the transition from halothane to isoflurane and sevoflurane, atracurium to cisatracurium or ketamine to propofol. This has been cited by one author as contributing to drug shortages as more money is required to pursue these modern drugs.⁵ Anaesthesia in developed countries is sophisticated by “fancy” techniques and modern drugs that have significantly improved the safety of anaesthesia which is excellent but the million dollar question is; is Africa ready for this?

Van Houwe commented that provision of anaesthesia in Africa relies on the overall framework of the healthcare system, which in turn is also closely linked to the obtaining socio-cultural and political environment.³³ He cautioned that the “sophistication syndrome” should be minimized, allowing developing countries to depend and develop on home-grown systems indigenous to their local circumstances.³³ Withdrawal of Halothane has been described as a “disaster for paediatric anaesthesia” because half of humanity’s anaesthesia practitioners have neither the means nor knowledge to use sevoflurane.³⁴

In 2007, in a paper of an Overview of anaesthesia in French-speaking Sub-Saharan Africa, Lokossou *et al* reported that basic anaesthetic drugs (Table 1) were easily available in most of the countries.³⁴ However, the procurement and supply chains of drugs were quite intricate and depended on a variety of factors. They commented; “Broadly speaking the essential drugs to deliver anaesthesia can be found, but their provisioning is irregular”. They noted however that

traditional antidotes used in anaesthesia were generally non-available. In their paper the major problem bedeviling anaesthesia provision was generally more of unavailability of competent anaesthesiologists than anaesthetic drug shortages.³⁴

Drugs most frequently available in sub-Saharan French-speaking Africa	
Anesthetics	Thiopental, Ketamine, and seldom Propofol
Opiates	Pethidine, Fentanyl, and inconstantly Morphine
Myorelaxants	Gallamine, Pancuronium bromide, Succinylcholine (rare)
Benzodiazepines	Diazepam, and seldom Midazolam
Halogenated vapors	Isoflurane ; Halothane being in the process of withdrawal
Local anesthetics	Lidocaine 1 to 2% (5% still exists) ; Bupivacaine 0,5%
Hemodynamic drugs	Adrenalin, Atropine, Ephedrine, Clonidine, Nicardipine

Table 1: Drugs most frequently available in sub-Saharan French-speaking Africa. Source: Lokossou et al. Anesthesia in French-speaking Sub-Saharan Africa: An overview. Acta Anaesth. Belg. 2007; 58: 197-209.

Procurement and Supply of Drugs in Southern Africa

In the Southern African Development Community (SADC) region, a 15 member regional block of which Zimbabwe is a member, the majority of the country members have a documented public sector procurement policy. Most of the countries have a procurement board which uses an international competitive tender system and also have some means to guarantee the quality of medicines procured. All countries try to prioritise local manufacturers, suppliers or importers and wholesalers but no country gives priority to suppliers from the regional block. The majority of the countries have no manufacturing capacity for pharmaceuticals. Most of the region's pharmaceutical manufacturers have very minimal export capacity. South Africa has 42 domestic

pharmaceutical manufacturers, making up 40% of the region, which is the largest. The second largest is DRC with 22 followed by Zimbabwe with 14 local manufacturers.³⁵ Zimbabwe's pharmaceutical manufacturing industry capacity utilization is very low and production of intravenous agents is almost non-existent. This is because machinery and equipment in the country's generic pharmaceutical industry is fairly antiquated. The sector is in dire need of equipment and machinery refurbishment, preferably new installations.³⁶ CAPS Pharmaceuticals, one of the major and oldest manufacturers which used to produce opioids and intravenous fluids has virtually closed due to undercapitalization.

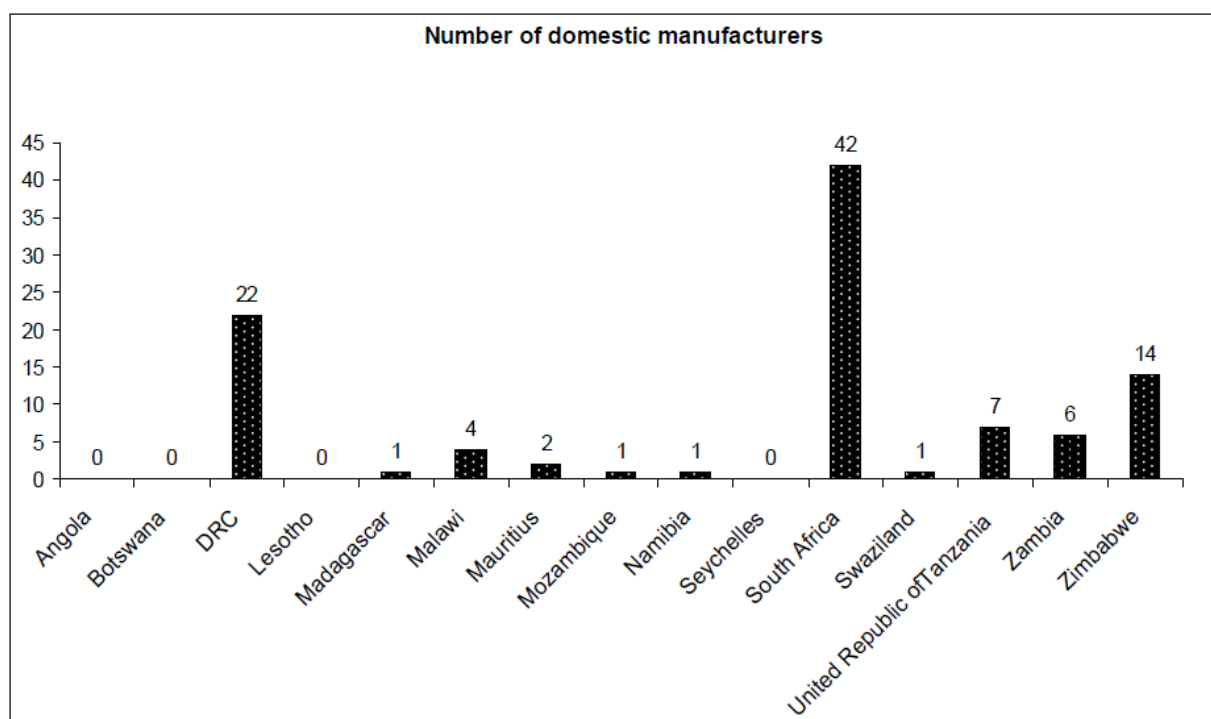


Figure 4: The state of pharmaceutical manufacturing present in SADC member states. Source: World Health Organisation. Baseline assessment of the Pharmaceutical situation in Southern African Development Community countries Fact Book 2009.

2011. www.who.int/medicines/areas/coordination/sadc_final.pdf (accessed 23/02/15)

In a brief report on medicines shortages in the KwaZulu-Natal province of South Africa between July 2012 and June 2013, Gray²⁹ noted a number of drug shortages, their causes, some of their effects and the way the shortages were handled. He mentioned that in September 2012 there was a global shortage of glycopyrrolate with no alternative supplier to turn to, which resulted in their anaesthetists using alternative anticholinergic agents. This was also accompanied by a shortage of haloperidol injections and the sole manufacturer had sent out a message that they were not able to confirm when stock would be available but had warned that supplies would restart in 18 months. In this report a number of reasons for the shortages of the various drugs were given. A common reason was that of a sole manufacturer and supplier who would just terminate supplies with no reason given and without any available alternatives. Sometimes a manufacturer would cite a business decision or rationalisation of the product portfolio as the reason for termination of supplies. In this paper the impact of the drug shortages on the patients or medical practitioners were not given.²⁹

In sub-Saharan Africa drug shortages that have been studied are antiretroviral and antituberculosis drugs which have essentially caused a crisis. With more than 2.4 million people on antiretroviral therapy (ART) and over 300,000 people treated for tuberculosis (TB) every year, South Africa's HIV treatment programme is probably the largest in the world. In September and October 2013 the Stop Stock Outs Project (SSP) in South Africa carried out the Stockouts National Survey³⁷ which mainly focused on antiretroviral and antituberculosis drugs including some vaccines. The most shocking and worrying finding was the severity of the problem, affecting at least one in every five health facilities, with 459 out of 2139 (21.4%) facilities reporting a shortage of ARV and/or TB medicines within the three months before the

survey. The stock-outs resulted in some patients being switched to other regimens, sent away or referred to other facilities and in some, defaulting treatment.

In 2006 a study was carried out in Uganda to assess anaesthesia services in developing countries.³⁸ The study looked at several aspects of anaesthesia such as availability of anaesthetists, anaesthesia equipment and drugs. They reported critical anaesthetic drug shortages. In the study most of the drugs were not easily available except ketamine. Only 54% of the anaesthetists had pethidine or morphine available on a continuous basis. It is worrying to realize that 30% of the anaesthetists stated that they never had local anaesthetic solution for a subarachnoid block in their hospitals, in an era when regional anaesthesia is being advocated for obstetric anaesthesia the world over. Suxamethonium supplies were erratic, always available to only 54% of anaesthetists and non-depolarising neuromuscular blockers were never available to 69% of anaesthetists. It is disturbing to note that 10% of the anaesthetists in Uganda always worked without an oxygen source in the twenty-first century.³⁸ However, the study did not investigate the impact of the drug shortages on the patients and medical practitioners.

In a 2011 study on the availability of critical resources to implement the guidelines for the Surviving Sepsis Campaign (SSC) in Africa, Baelani et al showed that drugs, amongst other resources were available less frequently in Sub-Saharan Africa than in high income countries. The study reported that 20.1% and 26.3% of the African respondents stated that they never had dopamine and noradrenaline, respectively, while 13.8% and 6.9% never had propofol and a nondepolarising neuromuscular blocker, respectively. The results of this self reported survey suggest that some of the SSC guidelines cannot be readily implemented, particularly in Sub-Saharan Africa, in part due to drug shortages.³⁹ It can therefore be assumed that septic patients who potentially could be saved, succumb to their illnesses due to these shortages.

Causes of Drug Shortages

Drug shortages occur as a result of a variety of causes. In the developed countries, reasons cited for drug shortages include quality and manufacturing operating systems, economic factors, competing priorities and inadequate supply of finished drug or active pharmaceutical ingredient (API).¹⁹ In 2012 and 2013 quality-related issues were the most prominent reason for drug shortages in the USA according to the FDA drug shortage program.

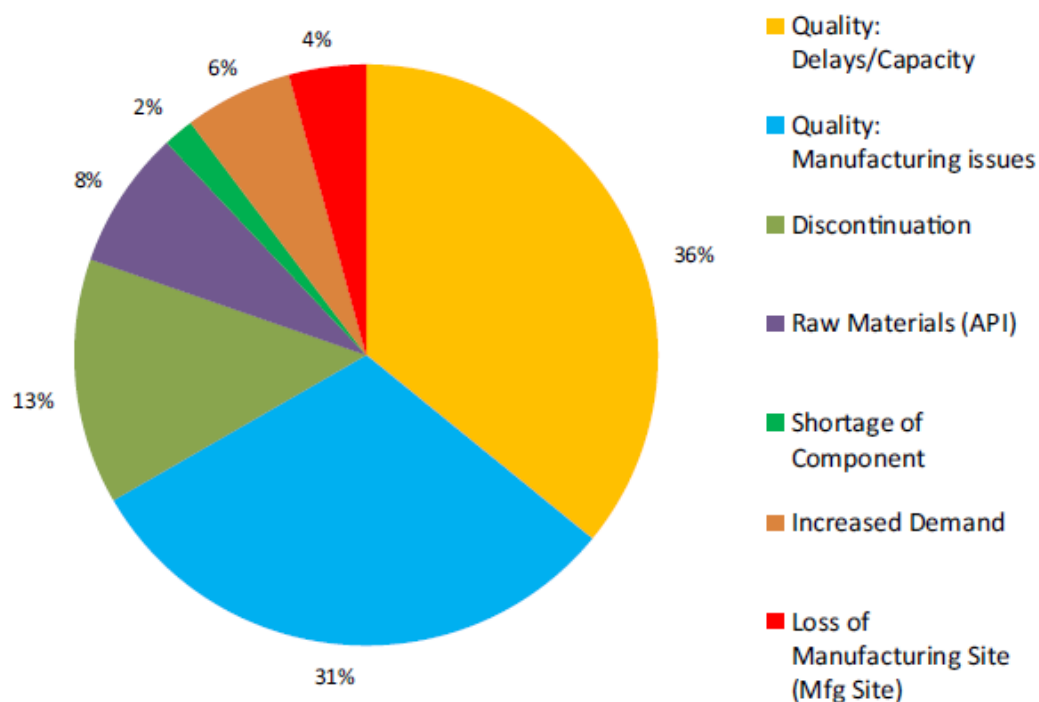


Figure 5: Causes of drug shortages in USA in 2012. Data from FDA drug shortage staff. Source: Dill S and Ahn Jin. Drug shortages in developed countries – reasons, therapeutic consequences, and handling. European Journal of Clinical Pharmacology 2014;70:1405 – 1412.

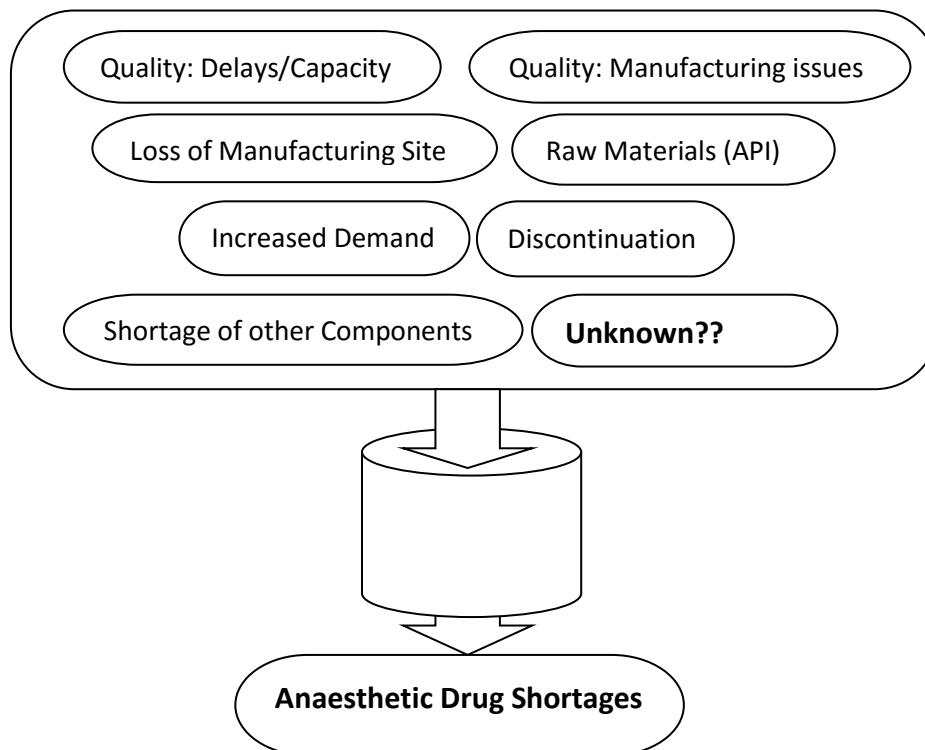


Figure 6: Basis of Anaesthetic drug shortages.

Quality concerns may arise during routine quality or maintenance check by a manufacturer or regulatory authority. These may relate to product impurities: potentially toxic heavy metals, product degradation, compromised product sterility: microbial contamination, particulate matter: glass, metal or fiber in vials and precipitate formation: unforeseeable chemical reactions with container or stopper. Quality issues can also be associated with production line breakdown and shut-down for repairs.

Increase in drug demand may result in apparent shortages. Most of the times the manufacturing of a drug is characteristically confined to a specific production line such that there is no room for

expansion, should there be an increase in demand when operating at full capacity. This usually applies to injectable drugs which require highly sophisticated production processes.

In undeveloped and developing countries the dynamics of pharmaceutical procurement and distribution are quite intricate. Most drugs are manufactured far away from the user as noted by Nyakatawa *et al.*²⁵ In the regional block of Common Market for Eastern and Southern Africa (COMESA), the major pharmaceutical producers are in Egypt and Kenya according to a survey of existing profiles of pharmaceutical industries in the 19 member states.⁴⁰ In Zimbabwe none of the 14 pharmaceutical manufacturers has any measurable production of anesthetic drugs.

Natpharm the only public pharmaceutical procurer and distributor, is facing serious financial constraints. Most of the stocks in its warehouses are donated drugs but some of the drugs get to expire in the warehouses because they are obsolete drugs or unfamiliar drugs. Anaesthesia drugs make a very small proportion of the donations and unfortunately it is the old drugs such as pancuronium, ketamine or halothane. The legal frame-work by which these drugs come into the country is too weak to protect the recipients and the pharmaceutical industry.³⁶

Currently, Zimbabwe's pharmaceutical supplies are dependent completely on private pharmaceutical companies which import most drugs, anesthetic drugs included from manufacturers across the whole globe. This long supply chain is complicated by "middle men", who push the prices of drugs high. Private pharmaceutical companies' prices for anaesthetic drugs in Zimbabwe are more than double the prices of the same drugs in the United Kingdom (Table 2).

Drugs	Average Zimbabwe Price (US\$)	UK Price from BNF⁴¹ March – September 2013 edition (GB£)	UK Price (US\$) at RBZ⁴² \$:£ exchange of 1:1.54 (on 18/2/15)
Propofol 1%, 20ml vial	15.00	4.18	6.45
Atracurium 10mg/ml, 2.5ml vial	7.00	1.80	2.78
Midazolam 1mg/ml, 5ml vial	6.00	0.60	0.93

Table 2: Comparison of drug prices: Zimbabwe vs. UK (UK - United Kingdom, GB - Great Britain, RBZ – Reserve Bank of Zimbabwe, BNF – British National Formulary)

Manufacturing difficulties and voluntary recalls

Drug manufacturing difficulties will result in drug shortages if they are not rectified. These can arise from a number of reasons such as loss of production, a shift of a company's resources from manufacturing to research, development or antiquated equipment. In Zimbabwe antiquated equipment was the main reason why Datlabs Pharmaceuticals stopped manufacturing intravenous fluids at their Bulawayo Belmont Plant. This resulted in a serious shortage of intravenous fluid during the cholera disaster of 2007.^{36,43} Drug shortages can be triggered by major drug recalls, particularly when the drug involved is produced by a sole manufacturer. Recalls usually arise as a result of lack of confidence in the safety of the particular drug. This is a

common problem reported in developed countries where regulations on quality assurance are tight and frequent inspections are done on manufacturing plants and products.

Shortage of raw materials

Unavailability of raw materials may be responsible for drug shortages. It is usually the case that there is only a sole-source supplier of a raw material so any problem that arises with the supplier results in reduced or no production downstream. Pharmaceutical manufacturers frequently import raw materials from other countries. The supplies then depend on global supply chains. About 80% of the raw materials used in drug manufacturing in the USA are imported from abroad.⁵ The few Zimbabwean manufacturers import 100% of their raw materials or APIs at high import tariffs. This makes their products more expensive than imported finished products.^{36,44}

Natural Disasters

When a natural disaster strikes in an area it can destroy finished drug products, sources of raw materials and the manufacturing plants themselves resulting in drug shortages. Natural disasters can come in the form of fires, hurricanes, tornadoes, floods and earthquakes. In 1998, a shortage of several drugs occurred when hurricane George damaged pharmaceutical manufacturing plants in Puerto Rico.⁵

Business and Economic issues

A manufacturer's business decisions may influence drug supplies in the market. These may be based on a variety of factors such as insufficient profits, introduction of generic products, market

share, anticipated clinical demand, patent expiration or drug-approval status. This becomes an issue of competing priorities and is common when a number of drugs share a common manufacturing line. In difficult economic times, there is usually a trade-off amongst the products in the same production line and the manufacturer is forced to decide on which product to dominate production so as to maximize profits. Most of the drugs in short supply tend to be generics, which are usually not very profitable. So manufacturers usually shun them.²⁰ This was suspected to be the reason why CAPS initially stopped producing morphine and atropine. These drugs are very cheap on the international market, with one ampoule priced less than 1 GB£.⁴¹

Regulatory issues

The legal frame-work in the pharmaceutical industry regarding manufacturing, packaging and distribution, importing and exporting of products and raw materials can result in drug shortages. Regulatory authorities need to constantly review their standards and policies to avoid drug shortages. In the USA, some industry representatives blame the drug shortages on increased oversight by the FDA. This is because the FDA has prioritised drug safety after being criticized for being too lax.⁵ In Zimbabwe the Pharmaceutical Manufacturing Association of Zimbabwe bemoans the unfavourable prevailing legal framework. Recommendations were issued to the Government in July 2009 on measures essential to resuscitate the pharmaceutical industry. These included 25 per cent local products preference, removal of duties and value added tax on pharmaceutical raw and packaging materials, tax allowances and rebates and import bans on products which are manufactured locally.³⁶

In Zimbabwe the pharmaceutical industry and medical practitioners decry MCAZ's regulations on registration of drugs. The registration of new drugs involves a lengthy process with high tariffs. Yearly retention tariffs for registered drugs are also unreasonably high. These tariffs are borne by the various pharmaceutical manufacturers and or importers involved. A crucial drug such as naloxone is not on the MCAZ register because no manufacturer or importer would want to pay for its registration because it does not make any business sense since it does not move in terms of volumes.

It is clear that epidemiological data on anaesthetic drug shortages is lacking in poor countries. There is need for properly structured studies to unravel the problems in this area so as to come up with suitable solutions. The availability of drugs is also compounded by the lack of drug shortages surveillance and stock level monitoring systems. In Zimbabwe's public hospitals, drug stock level monitoring systems are still poor, involving manual stock cards, whereas private hospitals use advanced computerised systems which offer real-time data.

Statement of the problem

Anecdotal reports and observations suggest that anaesthetists and pharmacists may be facing significant anaesthetic drug shortages commonly at Harare's Government referral Hospitals, which may be compromising the conduct of anaesthesia and patient care. Anaesthetic drug shortages have been associated with adverse effects in patient care and changes in practice by anaesthetists in North America and Europe.

Aims of the study

The purpose of this study is to investigate how common anaesthetic drug shortages are at hospitals in Harare and how the shortages affect the practice of anaesthesia and patient care. The results of the study will be useful in coming up with management strategies to improve anaesthetic drug supplies and better ways of handling anaesthesia in the face of shortages.

Research Questions

1. Which anaesthetic drugs are frequently in short supply in Harare's hospitals?
2. How do anaesthetic drug shortages impact on the practice of anaesthesia?
3. How do anaesthetic drug shortages affect patient care?
4. What do pharmacists find as the causes of anaesthetic drug shortages in Harare?

Main Objectives

1. To investigate how common anaesthetic drug shortages are in Harare.

2. To assess how anaesthetic drug shortages change the way anaesthetists deliver anaesthesia care.
3. To assess how anaesthetic drug shortages affect patient care.

Secondary objectives

1. To investigate what pharmacists find as the causes of anaesthetic drug shortages in Harare.
2. To use the results to come up with an anaesthetic drug shortage protocol for anaesthesia staff if necessary, to be presented to the Department of Anaesthesia and the Zimbabwe Anaesthetic Association
3. To come up with the necessary recommendations that can improve the availability of anaesthetic drugs in hospitals to be presented to the relevant authorities.

Specific Null Hypotheses

1. H^0 : There are no shortages of anaesthetic drugs in Harare.
2. H^0 : Anaesthetic drug shortages do not negatively affect anaesthesia practice and patient care.

Methodology

Authorisation

Authorisation was sought to carry out the study from Joint Parirenyatwa and College of Health Sciences Research Ethics Committee (JREC) and the hospital authorities in which the study was carried out. Nine out of twelve hospitals consented and got involved in the study. The hospitals in which the study was carried out are listed below (the first 3 are public central hospitals).

- Parirenyatwa Group of Hospitals
- Harare Central Hospital
- Chitungwiza Central Hospital
- Westend Hospital
- Westend Clinic
- Baines Avenue Clinic
- Belvedere Maternity Hospital
- Citimed Hospital (Southmed)
- Suburban Medical Centre

(Authorization letters from the hospitals can be found in the Appendix 4)

Inclusion criteria

This was a self-administered questionnaire survey involving:

1. Specialist Anaesthetists, Trainee Anaesthetists (MMed and DA students) and Nurse Anaesthetists working in both private and public hospitals in Harare.
2. Hospital pharmacists in Harare working at hospitals which offer anaesthetic and surgical services regularly.

Participation in the survey by the subjects was purely voluntary after signing consent once; but would be eligible to participate repeatedly throughout the 3 month study period. They were however, not eligible to complete more than one questionnaire per day.

Setting

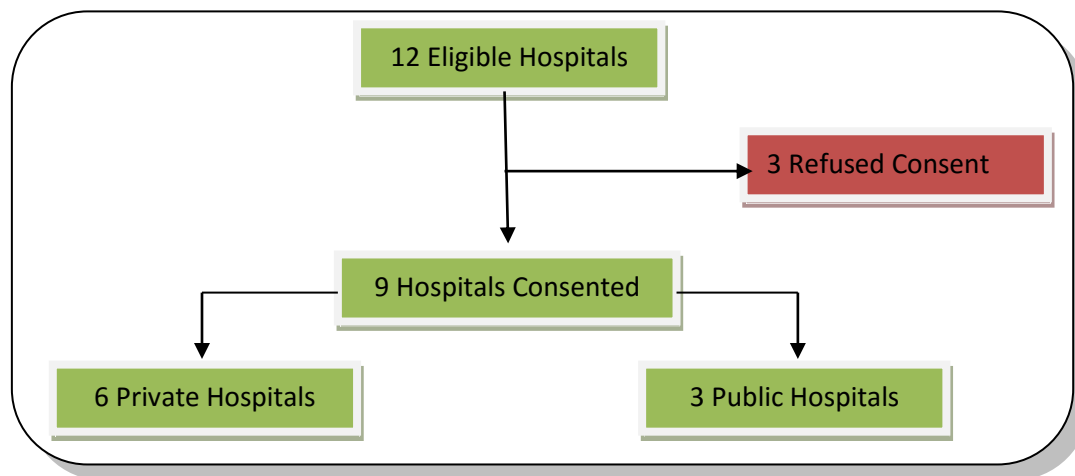


Figure 7: Hospital involvement in the study

The study was carried out at hospitals in Harare and the neighbouring Chitungwiza, which is about 27km southwards. About 99% of physician anaesthetists in Zimbabwe work in these 2 cities, where three of the country's five central hospitals are located. The rest of the country is

covered by nurse anaesthetists. Parirenyatwa Group of Hospitals and Harare Central Hospital are the Zimbabwean Government's quaternary and tertiary level hospitals respectively. A total of 17 consultant anaesthetists from the University of Zimbabwe (UZ) and public service as well as 4 senior registrars were working in the two Government hospitals at the time of the study. The two hospitals had 17 junior registrars (MMed students), 8 Diploma in anaesthetics students and 10 nurse anaesthetists.

At the time of the study Parirenyatwa Group of Hospitals had 13 functional operating theatre suites and Harare Central Hospital had 10 functional operating theatre suites. Chitungwiza hospital had 3 functional operating theatre suites covered by 3 consultant anaesthetists, 2 senior house officers and 5 nurse anaesthetists at the time of the study. Each of the private hospitals involved had at least 2 functional operating theatre suites. These hospitals were covered by various consultant anaesthetists and nurse anaesthetists, some of whom also worked at the 3 public central hospitals.

Study Design

The study was a multicentre prospective observational study involving the users of anaesthetic drugs; the anaesthetists and hospital pharmacists. Two different study questionnaires were designed, one for the anaesthetists and the other for the pharmacists.

Questionnaire Development

Key domains were identified in the area of drug shortages from the information obtained in previous studies such as the Canadian Anaesthesia Drug Shortage national survey, American Society of Anaesthesiology and the Canadian Pharmacists survey. The domains included the types of drugs, the impact on the ability of anaesthetists to provide anaesthesia care, the impact on patient outcomes and the causes of anaesthetic drug shortages.

A content and validity check was done by asking the senior registrars, three consultant anaesthetists and two pharmacists to assess the comprehensiveness of the domains and items addressed in the questionnaire and to comment on the survey. The Anaesthesia Medicines section of the 6th Essential Medicines List and Standard treatment Guidelines for Zimbabwe was used to draw up the list of drugs that were to be considered in the survey. A few important drugs were added to that list.

Sample Size

The minimum required sample size for the anaesthetist survey was determined using the Dobson formula for a single proportion as shown below:

$$n = \left(\frac{Z_{\alpha}}{\Delta} \right)^2 p(1 - p)$$

n = minimum required sample size

Z_{α} = critical value for the two sided 95% confidence level (=1.96),

P = expected true proportion of anesthetic drug shortage (=0.5)

Δ = desired precision (half desired CI width)(=0.05).

Using the Dobson's formula above, the minimum required sample size was 385 and was calculated based on the assumption that an expected proportion of anesthetic drug shortage was 50%, a 95% confidence interval and a desired precision of 5%.

Survey Administration and Data Collection

1. Data on drug shortages were collected from the theatres daily from 1 August 2014 to 31 October 2014.
2. In the 3 Public Hospitals, questionnaires were distributed in the theatres to the anaesthetists daily, with the aid of 2 research assistants. They were collected at the end of every theatre day, over the period of 3 months.
3. Private hospitals were coded A,B,C,D,E and F. Anaesthetists questionnaires were distributed in each private hospital once a week over the period of 3 months, 1 August 2014 to 31 October 2014. Hospitals remained anonymous throughout the time of the study.
4. Reminders about the study were sent out to all anaesthetists at the beginning of the study and once midway through the study period via emails and verbally at the regular Departmental Wednesday meetings.

5. Pharmacists' questionnaires were distributed once at the end of the study period, in the last week of October 2014. Questionnaires could not be distributed repeatedly due to lack of manpower.
6. A response rate equal or above 60% the target in this study, as noted in the Canadian Medical Association Journal's (CMAJ) editorial policy, "Except for in unusual circumstances, surveys are not considered for publication in *CMAJ* if the response rate is less than 60% of eligible participants".⁴⁵ I intend to submit my work for publication in the CMAJ or Canadian Journal of Anesthesia.
7. The researcher was assisted by staff from the Department of Anaesthesia and the nurses in the various theatres.

Data entry and Analysis

Data entry was done using Epi infor version 3.5.3. Data cleaning and analysis was done using Stata version 12 with the assistance of a statistician.

Ethical considerations

1. Participation in the study by anaesthetists, pharmacists and hospitals was voluntary.
2. Research subjects and hospitals remained anonymous and the information given on the questionnaires was held confidential.
3. There were no potential risks or dangers posed to anaesthetists, pharmacists, patients and hospitals, since it was a prospective observational study.

Consent

Only an English version of the consent was available since the subjects were professionals with a good command of the English language (see appendix 3).

Results

Anaesthetists Survey

Eighty-five (85) anaesthetists participated in the study as shown by 85 signed consent forms.

Anaesthetists' responses were anonymous throughout the study. Junior registrars and senior house officers worked in the public hospitals only.

Table 3: Distribution of responses/questionnaires collected from anaesthetist according to designation

Designation	Number of responses	(%) Percentage of responses
Consultant	129	30.57
Senior Registrar	14	3.32
Junior Registrar	134	31.75
Nurse Anaesthetist	87	20.62
SHO	52	12.32
Unknown	6	1.42

Table 3 above summarizes the participation frequency of the anaesthetists in terms of the number of questionnaires they contributed, according to their designation in the study. Junior registrars had the highest participation frequency contributing 31.75% of the responses/questionnaires, followed by the consultant anaesthetists at 30.57%. "Unknown" represents the responses in which the level of qualification was not given, contributing 1.42% of the questionnaires.

Demographic characteristics of anaesthetists

Table 4: Demographic factors associated with reporting of anesthetic drug shortages

Independent variables	No drug shortage	At least one drug shortage	OR (CI)	P- Value
Hospital type				
Private	59 (69.41)	69 (20.47)		
Public	26 (30.59)	268 (79.53)	8.81 (5.18-15)	<0.001
Gender				
Female	59 (34.12)	152 (45.10)		
Male	42 (49.41)	175 (51.93)	0.79 (0.47- 1.33)	0.388
Qualification level				
Consultant	46 (54.12)	83 (24.63)		
Registrars	30 (35.29)	118 (35.01)	2.18 (1.27- 3.74)	0.005
SHO	0	52 (15.43)		
Nurse Anaesthetist	9 (10.59)	78 (23.15)	4.80 (2.21- 10.46)	<0.001
Duration in anesthetic practice				
Less than 5 years	27 (31.76)	212 (62.91)		
6 to 10 years	29 (34.12)	59 (17.51)	0.26 (0.14-0.47)	<0.001
Above 10 years	27 (31.76)	61 (18.10)	0.29 (0.16-0.53)	<0.001

Type of hospital, qualification level and duration in anesthetic practice are the variables which were significantly associated with reporting of at least one drug shortage. However, gender was not significantly associated with reporting of drug shortage. Public hospital anesthetists were 8.81 times more likely to report a drug shortage when compared to those in private hospitals (OR=8.81, p<0.001). Registrars when compared to consultants were 2.18 times more likely to report a drug shortage (OR=2.18, p=0.005). Nurse anesthetist when compared to consultants were 4.8 times more likely to report a drug shortage (OR=4.8, p <001). Those with 6 to 10 years in anesthetic practice were 74% less likely to report a drug shortage when compared to those with less than 5 years (OR=0.26, p<0.001). Those with above 10 years in anesthetic practice

were 71% less likely to report a drug shortage when compared to those with less than 5 years (OR=0.29, $p<0.001$).

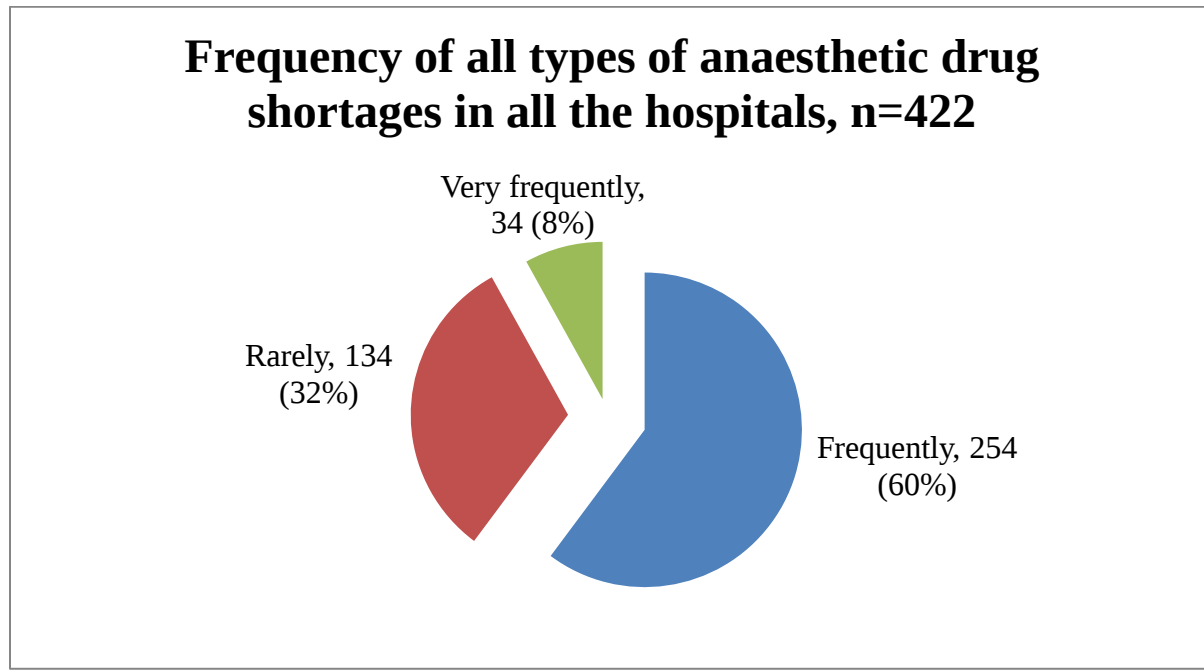
Table 5: Distribution of Questionnaires in the hospitals

Hospital type	Responders	Non-responders	Total distributed	% Response rate
Public	294	101	395	74.4
Private	128	96	224	57.1
Grand Total	422	197	619	68.2

Table 4 above shows the distribution of the questionnaires in the hospitals. The total number of responses/questionnaires collected for the whole survey was 422, with 294 coming from the public hospitals. Non-responders represent the number of questionnaires that came back uncompleted or that were never recovered during the study. The total number for the non responders was 197 of which 96 were from the private hospitals. The response rate of 68.17% was statistically acceptable for analysis.

Frequency of all types of anaesthetic drug shortages in all hospitals

Figure 8: Frequency of all types of anaesthetic drug shortages in all hospitals



Of all responses from private and public hospitals, 60% reported that anaesthetic drug shortages were frequent in the hospital in which they were working on the day of reporting as shown in Figure 7 above. Those who reported drug shortages as rare were mainly from the private hospitals.

Association between frequency of drug shortage and whether reported in public or private hospital

Table 6: Association between frequency of drug shortage and whether reported in public or private hospital

Drug shortage frequency	Public hospital, n=294	Private hospital, n=128	P - value
Rarely	22 (7.48)	16 (12.50)	
Frequently	238 (80.95)	112 (87.50)	
Very frequently	34 (11.56)	0	<0.001

There is an association between frequency of drug shortage and whether it is in public or private hospital. There is a statistically significant difference in the availability of drugs between private and public hospitals ($p < 0.001$). Private hospitals tend to have less drug shortages compared to public hospitals.

In the survey the number of questionnaires in which at least a drug shortage was reported was 337 (79.86%) and the number of questionnaires in which no drug shortage was reported was 85 (20.14%). The majority of the questionnaires 79.86% reported at least one anaesthetic drug shortage in this survey.

Please note: Figure 9 to 15 are bar graphs showing drug shortage frequencies. The total for each drug class in the graphs does not necessarily have to be 422 (n=422) because the response options on the questionnaire were not mutually exclusive, see Appendix 1.

Intravenous and Inhalational Anaesthetic drug shortages

Figure 9: Frequency of Intravenous and Inhalational Anaesthetic drug shortages

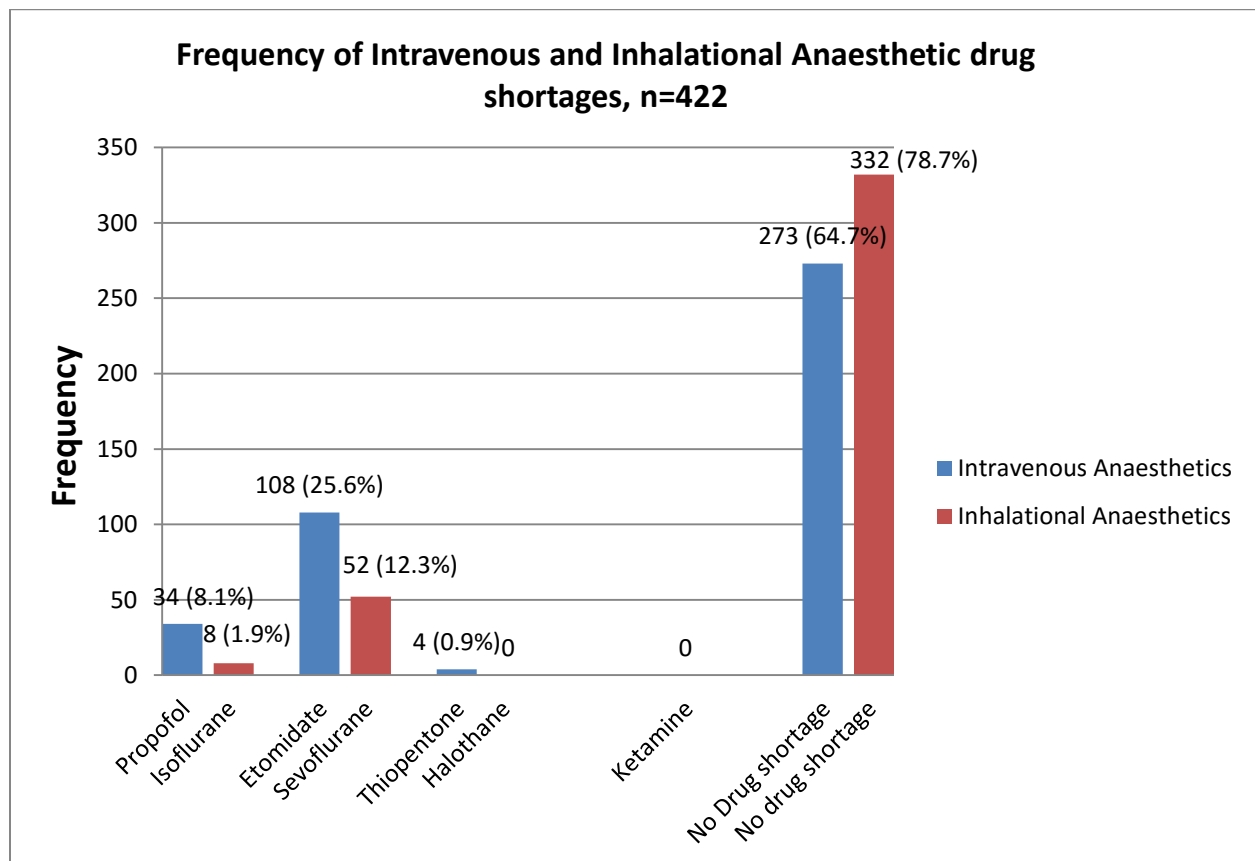
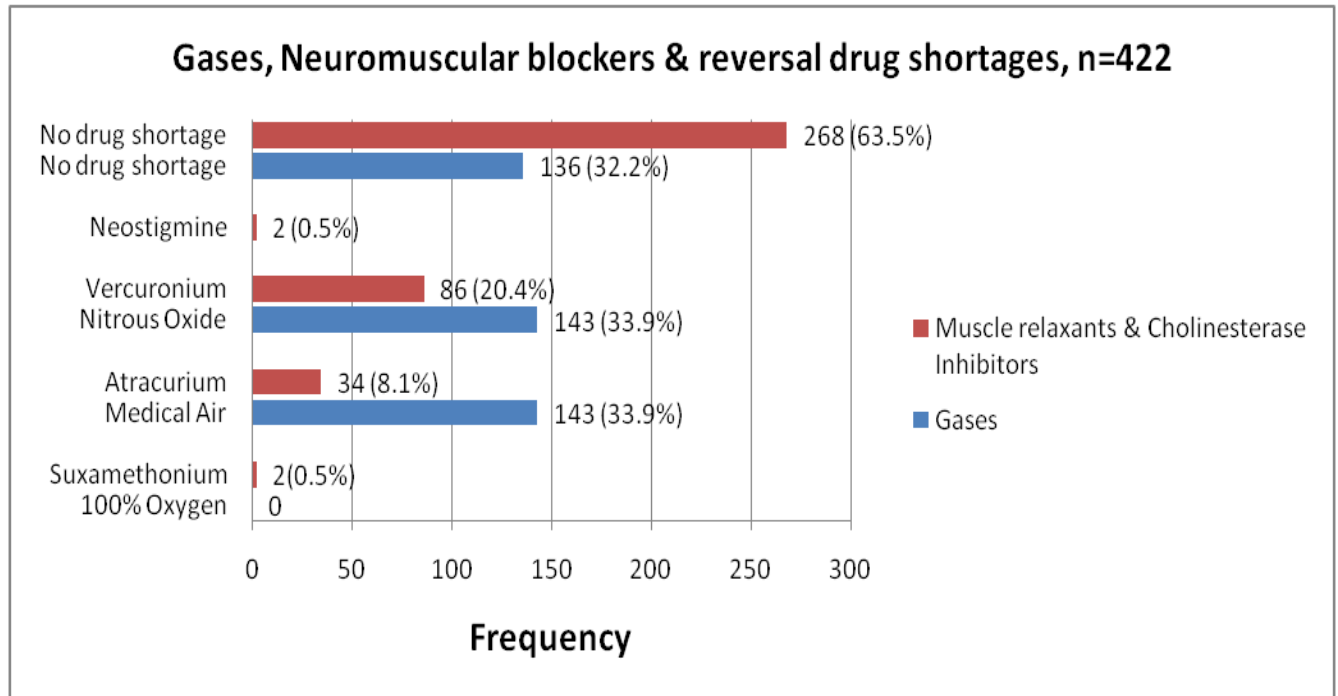


Figure 9 above summarizes the frequency of intravenous and inhalational anaesthetic shortages reported. Amongst the intravenous anaesthetic agents, the highest frequency of shortages was reported for etomidate, 108 (25.6%) and none for ketamine. No shortages of intravenous anaesthetics were reported in 64.7% of the questionnaires. For inhalational anaesthetics, sevoflurane reported the highest frequency of shortages with none reported for halothane.

Frequency of Gaseous, Neuromuscular blockers and Reversal drug shortages

Figure 10: Frequency of Anaesthetic gaseous, neuromuscular blockers and reversal drug shortages



In Figure 10 above, in the gaseous drug category, shortages of medical air and nitrous oxide were high with a frequency of 286 (67.8%) shared equally between them and no shortages reported for 100% oxygen. One hundred and thirty-three responses reported no shortages of anaesthetic gases. Amongst neuromuscular blockers and reversal drugs the highest frequency of shortages was recorded with vecuronium followed by atracurium with 268 responses indicating no shortages in these classes of drugs.

Frequency of Opioids & Antagonists, and Antimuscarinic & Antiemetic drug shortages

Figure 11: Frequency of Opioids & Antagonists, and Antimuscarinic & Antiemetic drug shortages

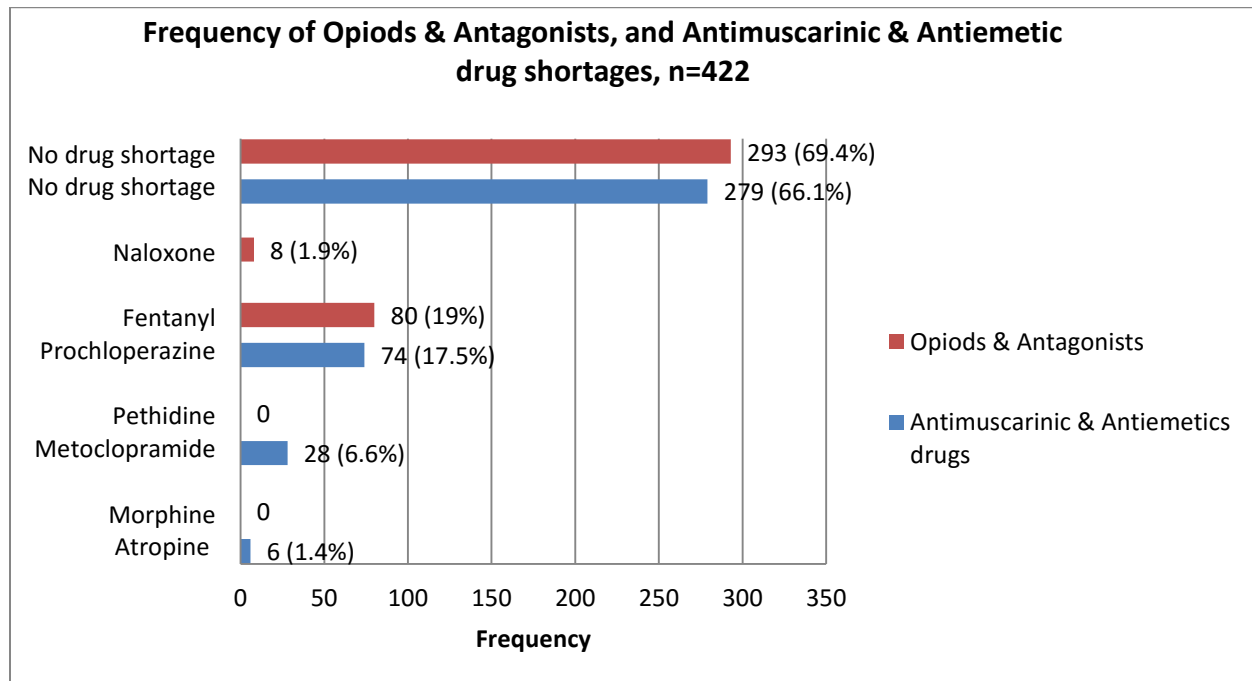
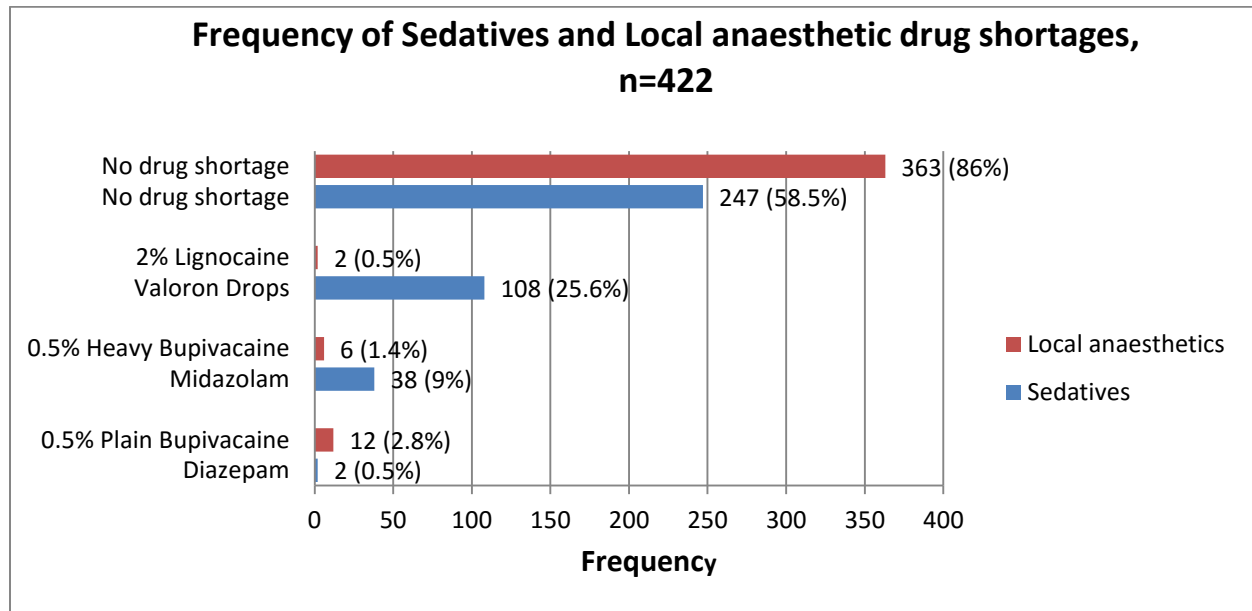


Figure 11 above shows the frequency of Opioids & Antagonists, and Antimuscarinic & Antiemetic drug shortages. In the opioids and antagonists category, shortages were reported for fentanyl and naloxone as 80 and 8 responses respectively. No shortages were recorded for pethidine and morphine. A total of 293 (69.4%) responses did not report any opioids & antagonists shortages. Prochlorperazine shortage reports were 74 and 28 for metoclopramide in the antimuscarinic and antiemetic group of drugs. Only 6 responses indicated atropine shortages. Two hundred and seventy-nine (279) responses did not report any shortage of antimuscarinic and antiemetic drugs hospitals.

Frequency of Sedative and Local Anaesthetic drug shortages

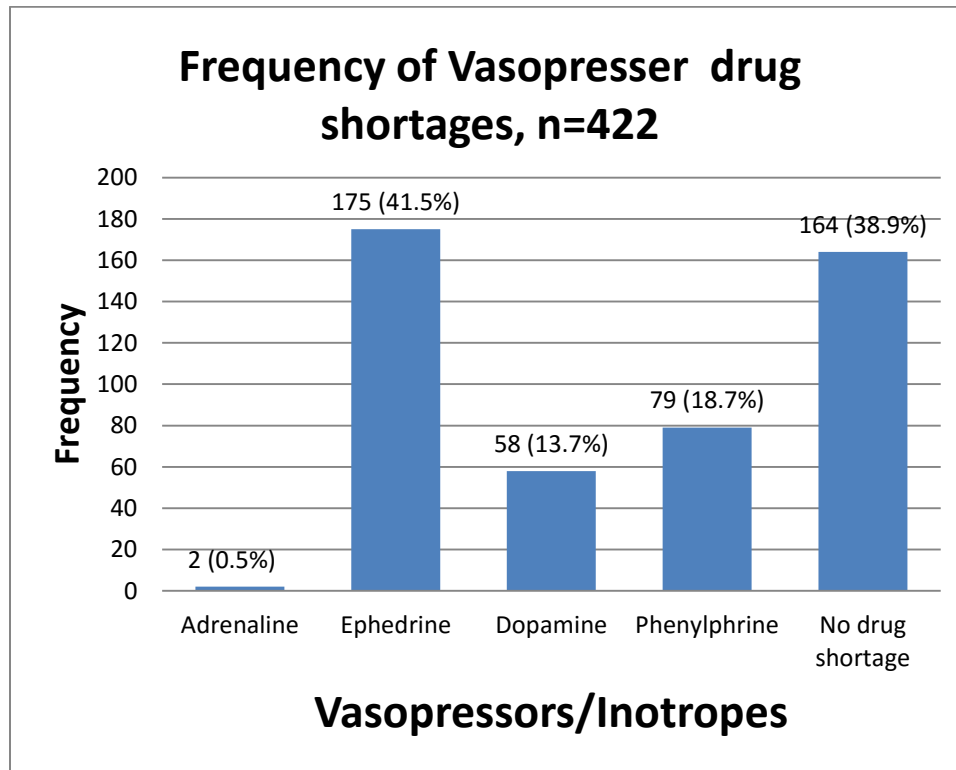
Figure 12: Frequency of Sedative and Local Anaesthetic drug shortages



For sedatives, valoron (Tilidine) drops had the highest frequency of shortages of 108 and 247 of the responses did not indicate shortages in the sedatives category. Valoron (tilidine) drops shortages occurred both in public and private hospitals. Trimeprazine was not included in the study because it did not meet the criteria for the investigation. Local anaesthetic drug shortages were relatively low, 12 reports for 0.5% plain bupivacaine and 6 for 0.5% heavy bupivacaine. Figure 12 above summarizes the frequency of sedative and local anaesthetic drug shortages

Frequency of Vasopressor drug shortages

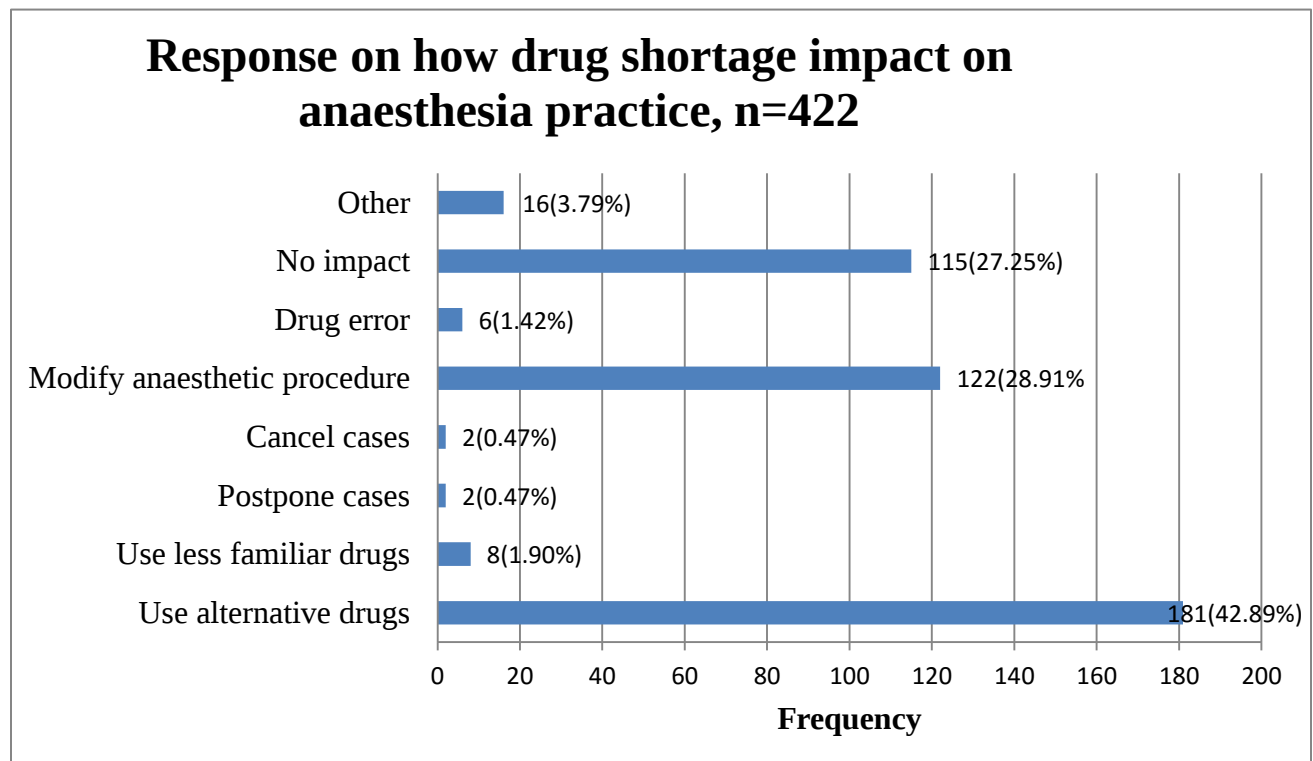
Figure 13: Frequency of Vasopressor/Inotropic drug shortages



The highest frequency of shortages was recorded for ephedrine, 175(41.47%) and 164 responses did not indicate any shortages of vasopressors as shown in Figure 13. The 2 reports of adrenaline shortage were recorded at 2 different private hospitals on 2 separate days. The ephedrine and phenylephrine shortages were reported in both public and private hospitals.

Response on how anaesthetic drug shortages affected anaesthesia practice.

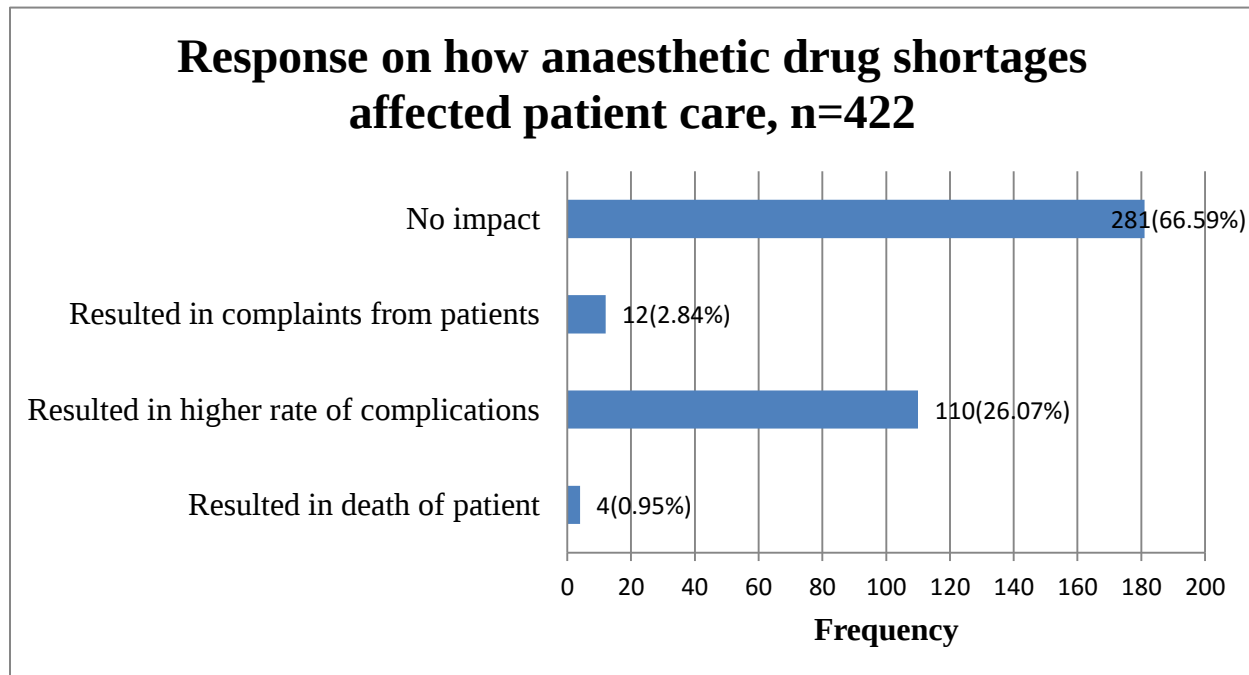
Figure 14: Response on how anaesthetic drug shortages affected anaesthesia practice



The majority of responses indicated that they had to modify the anaesthetic procedure or use alternative drugs. Use of alternative drugs was the most frequent impact recorded when anaesthetists were faced with shortages. One hundred and fifteen responses did not report any impact. “Other” included additional comments made by some anaesthetists for example; “I had to do without”, “I suffered” etc. The graphical form is shown in Figure 14 above.

Responses on how anaesthetic drug shortages affected patient care

Figure 15: Responses on how anaesthetic drug shortages affected patient care



Sixty-six percent reported that there was no impact on patients as shown in Figure 15. This number includes some of those responses that did not report any anaesthetic drug shortage. One hundred and twenty-six 126 (29.86%) of the responses reported at least a negative impact on patient care. Four deaths were reported. Drug shortages adversely affected patient care in this study at an unacceptably high frequency of 29.86%.

Pharmacists Survey results

Nine (9) questionnaires were given to the chief hospital pharmacists for each of the hospitals involved in the survey. One pharmacist did not respond.

Table 7: Hospital pharmacy anaesthetic drug shortages reported by pharmacists.

Responses on drugs shortages in hospital pharmacies	Number (n=8)
<u>Intravenous Anaesthetics</u>	
Propofol	2 (25%)
Etomidate	5(62.5%)
Sodium Thiopentone	1(12.5%)
Ketamine	0
<u>Inhalational Anaesthetics</u>	
Isoflurane	0
Sevoflurane	2 (25%)
Halothane	1(12.5%)
<u>Muscle Relaxants & Cholinesterase Inhibitors</u>	
Suxamethonium	0
Atracurium	1(12.5%)
Vercuronium	4 (50%)
Neostigmine	0
<u>Antimuscarinics & Antiemetics</u>	
Atropine	1(12.5%)
Metochlopramide	0
Prochlorperazine	1(12.5%)
<u>Opioids & Antagonists</u>	
Morphine	0
Pethidine	1(12.5%)
Fentanyl	3(37.5%)
Naxolone	1(12.5%)
<u>Sedatives</u>	
Diazepam	0
Midazolam	0
Valoron (Tilidine) drops	6 (75%)
<u>Local Anaesthetics</u>	
0.5% Plain Bupivacaine	2 (25%)
0.5% Heavy Bupivacaine	1(12.5%)
2% Lignocaine	0
<u>Vasopressors/Inotropes</u>	
Adrenaline	0
Ephedrine	7(87.5%)
Dopamine	1(12.5%)
Phenylephrine	4(50%)

In table 5 above, drugs for which no shortages were reported by pharmacists were ketamine, isoflurane, suxamethonium, neostigmine, metoclopramide, morphine, diazepam, midazolam, lignocaine and adrenaline. Valoron drops, etomidate, phenylephrine, ephedrine and vecuronium were reportedly out of stock at some point by at least 50% of the pharmacists.

Table 8: Frequency of advance notices of drug shortages

Do you receive any advance notice of drug shortages, (n=8)	
Never	1 (12.50%)
Sometimes	7 (87.50%)
Always	0
Unknown	0

The majority (87.50%) reported that they sometimes received advance notice of drug shortages.

Only 1 out of 8 reported that he had never received a notice of drug shortages.

Table 9: Frequency of who notifies pharmacist about drug shortages

Who notifies you about drug shortages? (n = 8)	
manufacturer	1 (12.50%)
other pharmacies/pharmacists	3 (37.50%)
wholesaler	4 (50%)

Half of the pharmacists received warnings about drug shortages from their wholesalers. Only one reported having received a notice from the manufacturer. Three out of eight of the pharmacists reported being notified by their colleagues about drug shortages.

Table 10: Do drug shortages increase the cost of anaesthesia care

Do drug shortages increase the cost of anaesthesia care patient (n=8)	
Yes	8 (100%)
No	0

All the pharmacists interviewed thought that anaesthetic drug shortages increase the eventual cost of anaesthesia care. The cost is transferred to the patients in private hospitals but borne by the hospitals in public hospitals.

Table 11: Frequency of pharmacists who experienced at least a drug shortage

Ever experienced anaesthetic drug shortage in your practice, n=8	
Yes	8 (100%)
No	0

All the pharmacists reported that they had experienced some kind of anaesthetic drug shortage.

Table 12: Causes of drug shortages as cited by pharmacists

Causes of Anaesthetic drug shortages cited by Pharmacists	n=8
Lack of local/regional manufacturing	3(37.50%)
Financial constraints resulting in huge debts with suppliers	3(37.50%)
Problems with MCAZ registration issues	2(25%)
Hospital bureaucratic procurement process	2(25%)
Section 75 instrument takes too long to deliver drugs	1(12.5%)

Several reasons were cited by the pharmacists as contributing to anaesthetic drug shortages, with no one cause, particularly being the leading problem. Opinions were varying amongst the group of 9 as shown in Table 12. The Section 75 instrument is a facility provided by the Medicines Control Authority of Zimbabwe (MCAZ), intended to ensure availability of essential, life saving, medicines where there are no registered alternatives. The authority is empowered to issue such authorisation in terms of Section 75 of the Medicines and Allied Substances Control Act, Chapter 15:03.

Discussion

To achieve the set objectives this study combined data obtained from anaesthetists and pharmacists surveys. No study in the past has involved anaesthetists and pharmacists at the same time. Traditionally pharmacists have always done their own surveys involving all types of drugs that they handle.^{21,22,26,28} Anaesthetists have done studies concentrating on anaesthetic drugs separately.^{2,24,38}

In this study 79.86% of the questionnaires reported at least one anaesthetic drug shortage over the 3 month period; August through October 2014. This is comparable to results of previous studies done in other areas.^{2,21,22,23,24,26,27,28,29,38} Hall R *et al* revealed that about 65.6% of Canadian anaesthetists reported drug shortages of some sort in the first third of 2012.²⁴ The ASA 2012 Drug Shortage Study estimated that 97.6% of the respondents reported they had encountered a shortage of at least one anaesthesia drug in their practices.² The Premier Healthcare surveys showed that at least 90% of the respondents had experienced at least one drug shortage in the previous 6 months.^{21,22} In the closest study to Harare, Hodges *et al* revealed a gloomier picture of anaesthetic drug shortages in Uganda, where 10% of anaesthetists had no oxygen available in the year 2006.³⁸ Baelani *et al* in their survey also demonstrated shortages of inotropes (noradrenaline and dopamine) and propofol in Africa in a study they were investigating the feasibility of the Surviving Sepsis Campaign.³⁹ My study demonstrates that anaesthetic drug shortages are as common in Harare as they are in other areas studied previously.^{2,21,22,23,24,26,27,28,29,38}

The types of stock-outs noted in my study are almost the same as those reported in previous studies. Shortages of drugs such as propofol, ephedrine, fentanyl, vecuronium and antiemetics recorded outstanding shortages in a similar manner as the North American studies^{2,21,22,23,24,28,38} and

the Ugandan study.³⁸ However, this study reported significant shortages of medical air and nitrous oxide which have not been reported elsewhere. This means that most of the times patients use 100% oxygen in Harare for which there was no shortage reported. Drug shortages are dynamic over a period of time depending on the cause of the shortages.²⁴ However it was not possible to follow the trend of drug shortages in my study because most of the questionnaires came back without showing dates on which they were filled in. In my study there was an association between type of hospital (public or private) and reporting of anaesthetic drug shortages. Public hospital anaesthetists were 8.81 times more likely to report a drug shortage when compared to those in private hospitals (OR=8.81, $p<0.001$). No association was reported between the type of hospital and reporting of at least a shortage by Hall *et al* or any other studies. In Hall *et al*'s study, the majority of the anaesthetists worked at either a community hospital or academic medical centre and the rest at private medical clinics or "other", of which about 70 had not indicated their place of work.²⁴

The impact of anaesthetic drug shortages on anaesthesia practice in my study was varied. The majority of the anaesthetists reported that they had to modify the anaesthetic procedure, maybe from a local or regional to a general anaesthetic or sedation and use of alternative drugs which were considered to be inferior to the indicated drugs. This result was similar to results of studies by Hall *et al* and the ASA drug shortage survey.^{2,24} However no impact was reported by some anaesthetists in my study and the majority of the responses in this category had also not recorded a single drug shortage. Drug errors were recorded by a few anaesthetists possibly because of use of unfamiliar drugs, in terms of their packaging, dosing and reconstitution methods.

In my study the designation and duration of experience in anaesthetic practice were statistically associated with reporting of at least one drug shortage. The more junior the anaesthetist was

hence the lower the experience, the higher was the chance to report an anaesthetic drug shortage and adverse patient effects. Registrars when compared to consultants were 2.18 times more likely to report a drug shortage (OR = 2.18, $p=0.005$). Nurse anesthetist when compared to consultants were 4.8 times more likely to report a drug shortage (OR=4.8, $p <0.001$). Those with 6 to 10 years of experience in anaesthetic practice were less likely to report a drug shortage and adverse patient outcome when compared to those with less than 5 years (OR=0.26, $p<0.001$). Those with above 10 years in anesthetic practice were less likely to report a drug shortage when compared to those with less than 5 years (OR=0.29, $p<0.001$). The reason maybe that as anaesthetists get more experienced, they may get used to drug shortages and develop coping mechanism to the shortages. These data are almost similar to the findings of Hall *et al*, who also reported that junior members of their profession had reported more anaesthetic drug shortages and more adverse consequences on patients.

Other findings from my study were that anaesthetists were not able to carry out awake intubations (6 reports), peripheral nerve blocks (4 reports), epidural and subarachnoid blocks (14 reports) because of drug shortages. This forced them to modify the anaesthetic procedures and may have resulted in adverse patient outcomes.

As shown by previous studies,^{2,24,26,28} drug shortages and anaesthetic drug shortages in particular may result in several adverse effects on patient care. In my study a significant number of responses/questionnaires (29.86%) indicated at least some negative impact on patient care which was comparable to the 21% revealed by Hall *et al*. The similarities in this outcome, between these two studies may stem from the fact that the majority of basic anaesthetic drugs are almost similar despite geographical location. In both studies (Hall *et al* and mine) drug shortages resulted in higher rates of perioperative complications, patient complaints and deaths were

recorded. Interestingly the same number of deaths; 4 were reported in both studies. In my study there was no way to verify how these deaths were directly linked to anaesthetic drug shortages, as the reporting anaesthetists remained anonymous throughout the study. The same reason was also given by Hall *et al.* My study's methodology was such that it was impossible to get a denominator to calculate the mortality rate over the 3 month study period. In my study the bulk of the adverse effects were reported by public hospital anaesthetists with only 12 reports from private hospital anaesthetists.

As for the hospital pharmacists' survey, in my study the results were similar again to results from previous studies done in the high income countries^{21,22,26,28} although my sample size was limited by the number of hospitals that participated in the survey. Only 9 hospitals consented to the study but I was only able to interview 8 of the chief hospital pharmacists. All of the pharmacists (8, 100%) whether from the private or public hospitals, reported that they had experienced at least an anaesthetic drug shortage in the preceding 3 months of the interview. All of the pharmacists also reported that they thought anaesthetic drug shortages increase the cost of anaesthesia care. Previous surveys done in the high income countries showed high rates of drug shortages in which anaesthetic drug shortages ranked highest. The shortages negatively impacted on patient care.^{21,22,26,28}

There are some irregularities noted with certain drugs, where data provided by anaesthetists and that provided by pharmacists did not tally. Examples that stand out are that of drugs such as isoflurane, neostigmine, midazolam and metoclopramide. No pharmacist ever reported shortages of these drugs but anaesthetists reported their shortages. This could be explained by the fact that some of the hospitals do not have real-time drug stock control systems and that only chief

hospital pharmacists were interviewed, dispensary assistants were not. Data collected from pharmacists was subject to recall, since they had to use recall to complete the questionnaires.

In my study the causes of drug shortages cited by the pharmacists who play the leading role in drug procurement and dispensing in our hospitals were somewhat different from the causes cited in high-income countries in North America and Europe.^{19,20, 21, 22 23,24,26,27,28} In my study reasons given by pharmacists as causes of shortages were mainly:

- Financial constraints resulting in huge debts with suppliers
- Lack of local/regional manufacturing
- Problems with MCAZ registration issues
- Hospital bureaucratic procurement processes

I have to express caution that this data was gathered from pharmacists through an open-ended question on the questionnaire and was poorly responded to by the respondents. Two of the respondents did not answer the question. Leading causes of drug shortages in the West are mainly to do with:

- Quality issues relating to delays/capacity/manufacturing concerns,
- Shortages of raw materials
- Increased demand.

Anaesthetic drug shortages in Harare are almost similar in many respects to those experienced in developed countries. This may not be the same for the rest of the country; in the provincial, district missionary and rural hospitals not included in the study.

One of the secondary objectives was to come up with an anaesthetic drug shortage protocol for anaesthesia staff if necessary. This was not done because I realized that it was not necessary, instead a recommendation was made to encourage awareness of anaesthetic drug shortages and their consequences. Regular drug shortage meetings to facilitate planning and the creation of a drug shortage intranet site to improve communication were recommended.

Conclusion

- Anaesthetic drug shortages are common in Harare spanning almost the entire drug classes for example injectable agents like propofol, etomidate, fentanyl and inhalational agents such as sevoflurane and nitrous oxide.
- There is an association between public hospitals and the reporting of anaesthetic drug shortages. Public hospitals experience more anaesthetic drug shortages than private ones.
- Anaesthetic drug shortages do not only adversely impact on the way anaesthetists carry out their work but also negatively affect the care of patients.
- Financial constraints resulting in huge debts with suppliers, lack of local or regional manufacturing, problems with MCAZ registration and hospital bureaucratic procurement processes were cited by pharmacists as the major causes of anaesthetic drug shortages.

Recommendations

- A concerted effort from the Government, MCAZ, healthcare funders, pharmacists, anaesthetists and hospital administrators is required to come up with efficient drug procurement protocols and increased funding for anaesthetic drugs.
- Junior anaesthetists may require supervision when caring for patients particularly, in the face of anaesthetic drug shortages, to avoid adverse outcomes on patients.
- A bigger national study is recommended to investigate the national anaesthetic drug availability and anaesthesia care situation, where the majority of the country has only the nurse anaesthetist to provide anaesthetic services.
- Consider regular drug shortage meetings to facilitate planning and the creation of a drug shortage intranet site to improve communication in hospitals.

Study limitations

This study was limited by the following:

- The poor response rate of 57.1% from the private hospital anaesthetists, which resulted from the fact that some of them were very busy and they would be rushing to the next hospital for the next case. However some of them complained that they were tired of the questionnaires. This may have skewed data of the shortages.
- Participation frequency of anaesthetists was only restricted to completing one questionnaire per day per hospital. The risk of recycling anaesthetists' views was very high leading to bias.

- Certain information given on the questionnaires could not be verified, particularly the death reports described earlier on, as anaesthetists remained anonymous.
- Pharmacists' data relied more on recall than real-time status of drug availability, as such the risk of bias could be high.

References:

1. Beerten E, Bonheure F. “Autour du monde – des indisponibilités de médicaments.”
Annales Pharmaceutiques Belges 2011; 15:11-14.
2. American Society of Anesthesiologists. 2012 ASA Drug Shortage Survey Results.
www.asahq.org (accessed 16/02/15).
3. Jensen V, Rappaport BA. The reality of Drug Shortages – The Case of the Injectable
Agent Propofol. The New England Journal of Medicine 2010; 363: 806-7 doi:
[10.1056/NEJMp1005849](https://doi.org/10.1056/NEJMp1005849) pmid: [20554977](https://pubmed.ncbi.nlm.nih.gov/20554977/).
4. Woodcock J, Wosiska M. Economic and technological drivers of generic sterile
injectable drug shortages. Clin Pharmacol Ther 2013; 93(2): 133 – 135.
5. Ventola CL. The Drug Shortage Crisis in the United States: Causes, Impact, and
Management Strategies. P&T 2011; 36(11): 740- 757.
6. Fox E, Birt A, James KB *et al*. ASHP guidelines on managing drug product shortages in
hospitals and health systems. Am J health Syst Pharm 2009; 66: 1399-1406.
7. FDA. Current Shortages. FDA Drug shortage Program.
www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm (accessed 16/02/15)
8. World Health Organization. Meeting Summary. First Consultation. Safe Surgery Saves
Lives. WHO Headquarters, Geneva 2007.
http://www.who.int/patientsafety/events/07/safer_surgery_summary_notes.pdf (accessed
09/02/15).
9. Enright A. Review article: safety aspects of anesthesia in under-resourced locations.
Canadian Journal of Anesthesia. 2013; 60: 152-158.
10. Osika J, Altman D, Ekblad L, *et al*. Zimbabwe Health System Assessment 2010; 11- 84.
http://pdf.usaid.gov/pdf_docs/pnaeb916.pdf (accessed 16/02/15)

11. United Nations Zimbabwe. Zimbabwe Country Analysis Working Document Final Draft. 2014; 71 – 72.
http://www.zw.one.un.org/sites/default/files/Publications/UNZimbabwe/Country%20Analysis_FinalReview_3Oct2014.pdf (accessed on 22/02/15)
12. ShamisoYikoniko. Drug shortages hit hospitals. The Sunday Mail 2015 April 5.
www.sundaymail.co.zw (accessed on 05/04/15)
13. Ozgediz D, Jamison D, Cherian M, *et al.* The burden of surgical conditions and access to surgical care in low- and middle-income countries. Bulletin of the World Health Organization 2008. <http://www.who.int/bulletin/volumes/86/8/07-050435/en/>(accessed 29/02/2014).
14. Ozgediz D, Riviello R. The ‘other’ neglected diseases in Global Public Health: Surgical conditions in Sub-Saharan Africa. PLoS Medicine 2008; 5(6): e121.
doi:10.1371/journal.pmed.0050121.
15. International Pharmaceutical federation. Report on The International Summit on Medicines Shortage 2013; 1 – 18
http://www.fip.org/files/fip/publications/FIP_Summit_on_Medicines_Shortage.pdf
(accessed on 22/02/15)
16. Ramnarine E, Ronninger S. Preventing and Managing Drug Shortages. Parental Drug Association2014. <http://www.pda.org/publications/pda-publications/pda-letter/latest-news/2014/04/29/preventing-and-managing-drug-shortages> (accessed on 23/02/15)
17. FDA. A Review of FDA’s Approach to Medical Product Shortages2011; 8.
<http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/reports/ucm277755.pdf>
(accessed 23/02/15)

18. American Society of Health-System Pharmacists. ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems. American Journal of Health-System Pharmacy 2009; 66:1399-1406.
19. The International Society for Pharmaceutical Engineering. Drug Shortage Survey Questionnaire 2013; 1 – 30. <http://www.ispe.org/2013-ispe-drug-shortages-survey-questions.pdf> (accessed 23/02/5)
20. Dill S, Ahn J. Drug shortages in developed countries – reasons, therapeutic consequences, and handling. European Journal of Clinical Pharmacology 2014; 70: 1405 – 1412.
21. Premier Healthcare Alliance. Navigating Drug Shortages in American Healthcare: A Premier healthcare alliance analysis 2011. <https://legacy.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf> (accessed 23/02/15)
22. Premier Healthcare Alliance. Drug shortages 2014: A Premier healthcare alliance update 2014. <http://seagatealliance.com/Portals/0/DrugShortage%20Survey%20White%20Paper.pdf> (accessed 23/02/15)
23. American Hospital Association (AHA). AHA Survey on Drug Shortages 2011. <http://www.aha.org/content/11/drugshortagesurvey.pdf> (accessed 23/02/15)
24. Hall R, Bryson GL, Flowerdew G, *et al.* Drugs shortages in Canadian anesthesia: a national survey. Canadian Journal of Anesthesia 2013; 60: 539-551.
25. Nyakatawa GT, Chifamba HN, Madzimbamuto FD. Drug shortages in Canadian anesthesia: a national survey; *Correspondence*. Canadian Journal of Anesthesia 2013; 60 (11): 1158-59.

26. Canadian Pharmacists Association. Canadian drug Shortages Survey Final Report 2010.
<http://www.pharmacists.ca/cpha-ca/assets/File/cpha-on-the-issues/DrugShortagesReport.pdf> (accessed 23/02/15)
27. International Society for Pharmaceutical Engineering (ISPE). Report on the ISPE Drug Shortages Survey 2013. www.ispe.org/drugshortages/2013JuneReport (Accessed on 10/02/2015)
28. European Association of Hospital Pharmacists (AEHP). Medicines shortages 2014.
<http://www.eahp.eu/practice-and-policy/medicines-shortages> (Accessed 23/02/15)
29. Gray A. Medicine shortages - unpicking the evidence from a year in South Africa. *Australasian Medical Journal* 2014; 7(5) 208-212.
30. SAPA. Drug shortage at Baragwanath. *iolnews* 2014 Nov 21.
http://www.iol.co.za/news/south-africa/gauteng/drug-shortage-at-baragwanath-1.1784447#.VOr9xS4e_fw (accessed 23/02/15)
31. Inter Press Service News Agency. Kenya: People dying because of lack of anaesthetics 2011 Jul 4. <http://www.ipsnews.net/2011/07/kenya-people-dying-because-of-lack-of-anaesthetics/> (accessed 23/02/15)
32. Patrick Chitumba. Patients stranded: Mpilo Hospital suspends ops. *Chronicles* 2014 May 24. <http://www.chronicle.co.zw/patients-stranded-mpilo-hospital-suspends-ops/> (accessed 23/02/15)
33. Van Houwe P. Anesthesia in Africa: quo vadis? *Acta Anaesthesiol Belg* 2007; 58: 161-2.
34. Lokossou T, Zoumenou E, Secka G, *et al*. Anesthesia in French-speaking Sub-Saharan Africa: an overview. *Acta Anaesth. Belg* 2007; 58: 197-209

35. World Health Organisation. Baseline assessment of the pharmaceutical situation in Southern African Development Community countries. WHO/EMP/MPC/2011.2; 1 – 72. www.who.int/medicines/areas/coordination/sadc_final.pdf (accessed 23/02/15)
36. United Nations Industrial Development Organization (UNIDO). Pharmaceutical Sector Profile: Zimbabwe. Global UNIDO Project: Strengthening the Local Production of Essential Generic Drugs in Least Developed and Developing Countries 2011. <http://apps.who.int/medicinedocs/en/d/Js18701en/> (accessed 23/02/15)
37. Stop Stock Outs Project (SSP). Stock-outs National Survey 2013. https://www.msf.org.za/sites/msf.org.za/files/Publication/Documents/stop_stockouts_report_2013pdf.pdf (accessed 23/02/15)
38. Hodges SC, Mijumbi C, Okello M, *et al*. Anaesthesia services in developing countries: defining the problems. *Anaesthesia* 2007; 62: 4-11.
39. Baelani I, Jochberger S, Laimer T, *et al*. Availability of critical care resources to treat patients with severe sepsis or septic shock in Africa: a self-reported, continent-wide survey of anaesthesia providers. *Crit Care* 2011; 15: R10.
40. COMESA Member States - Seminar Series Paper. Implementation of the WTO Decisions on TRIPS Public Health- Survey of Pharmaceutical Industry 2011; 4 – 14. www.comesabusinesscouncil.org/attachments/article/31/5.%20Survey%20of%20Pharmaceutical%20Industry%2031.10.2010.pdf (accessed 16/02/2014).
41. British National Formulary (BNF). March – September 2013.
42. Reserve Bank of Zimbabwe. Interbank Foreign Currency Exchange rates 2014. <http://www.rbz.co.zw> (accessed 18/02/15).

43. Central Emergency Relief Fund (CERF). Zimbabwe Annual Report of the Humanitarian/Resident Coordinator on the Use of CERF Grants 2007; 1 – 15.
https://docs.unocha.org/sites/dms/CERF/ANNUAL%20REPORT-%20Zimbabwe_FINAL_WEB.pdf (accessed 23/02/15).
44. Musundire H, Pharmaceuticals Zimbabwe. Zimtrade 2012; 1 – 7.
<http://www.zimtrade.co.zw/pdf/sector%20right-ups/Pharmaceuticals.pdf> (accessed 23/02/15).
45. Huston P. Reporting on surveys: information for authors and peer reviewers. Canadian Medical Association Journal. 1996;154:1695–8

Appendix 1: Anaesthetist Questionnaire

A Survey of Anaesthetic Drug Availability: Impact on Anaesthesia Practice and Patient Care in Harare

Researcher: Dr Gerald T Nyakatawa [MBChB (UZ), DA (UZ)]

For the purposes of this study an **anaesthetic drug shortage** is defined as “the unavailability of any contemporary drug, when required for use in the conduct of anaesthesia”.

May you please complete this questionnaire at the end of your theatre list today.

Demographics

Q1. Qualification Level:

Consultant ☐ Snr Registrar ☐ Jnr Registrar ☐ SHO ☐ Nurse Anaesthetist ☐

Q2. Male ☐ Female ☐

Q3. For how long have you been in anaesthetic practice?

A ☐ ≤ 5 years C ☐ 11 - 15 years E ☐ >20 years
B ☐ 6 - 10 years D ☐ 16 - 20 years

Current status with respect to Anaesthetic Drug Availability

Q4. How frequent do you experience anaesthetic drug shortages in this hospital?

☐ Never ☐ Frequently
☐ Rarely ☐ Very frequently

Q5. Which of the following drugs were **NOT** available to you to give the anaesthetic of your choice to your patients **TODAY**? (Check all that apply)

a) Intravenous Anaesthetics

☐ Propofol ☐ Etomidate ☐ Thiopentone ☐ Ketamine ☐ None

b) Inhalational Anaesthetics

☐ Isoflurane ☐ Sevoflurane ☐ Halothane ☐ None

c) Gases

☐ 100% Oxygen ☐ Medical Air ☐ Nitrous Oxide ☐ None

d) Muscle Relaxants & Cholinesterase Inhibitors

☐ Sux ☐ Atracurium ☐ Vecuronium ☐ Neostigmine ☐ None

e) Antimuscarinic Drugs & Antiemetics

☐ Atropine ☐ Metoclopramide ☐ Prochlorperazine ☐ None

f) Opioids & Antagonists

☐ Morphine ☐ Pethidine ☐ Fentanyl ☐ Naloxone ☐ None

g) Sedatives

☐ Diazepam ☐ Midazolam ☐ Valeron drops ☐ None

h) Local Anaesthetics

☐ Plain Bupivacaine ☐ Heavy Bupivacaine ☐ Lignocaine ☐ None

i) Vasopressors/Inotropes

☐ Adrenaline ☐ Ephedrine ☐ Dopamine ☐ Phenylephrine ☐ None

j) Other Drugs, Please indicate

The impact of TODAY'S drug shortages on your practice and patients

Q6. How have anaesthetic drug shortages impacted on your practice? (Check all that apply)

- ☐ I had to use alternative drugs considered to be inferior for the indicated anaesthetic
- ☐ I had to use less familiar drugs
- ☐ I had to postpone cases
- ☐ I had to cancel cases
- ☐ I had to modify the anaesthetic procedure
- ☐ I witnessed drug error as a result of substitution of "look alike" drugs from alternate suppliers

☐ No impact

☐ Other – please specify

Q7. How have drug shortages affected your patient(s) **TODAY?** (Check all that apply)

☐ Have resulted in death of a patient

☐ Have resulted in a higher rate of intra- and post-operative complications (e.g. **hypotension, delayed awakening, aspiration, pain, postoperative nausea and vomiting** etc)

☐ Have resulted in complaints from patients

☐ No impact

☐ Other – please specify

Q8. Which anaesthetic procedures have you not been able to do **TODAY**, because of anaesthetic drug shortages? (Please indicate the drug(s) that you would have used against the procedure)

☐ Sub-Arachnoid Block/Spinal_____

☐ Epidural Block_____

☐ Peripheral Nerve Block_____

☐ Awake Intubation_____

☐ Central Venous Cannulation_____

☐ None

Others_____

Q9. Do you believe that drug shortages increase the cost of care in anaesthesia?

☐ Yes

☐ No

☐ Do not know or unsure

The End! Thank you for your participation in this survey today.

Appendix 2: Pharmacist Questionnaire

A Survey of Anaesthetic Drug Availability: Impact on Anaesthesia Practice and Patient Care in Harare

For the purposes of this study an **anaesthetic drug shortage** is defined as “the unavailability of any contemporary drug, when required for use in the conduct of anaesthesia”.

Demographics

Q1. Qualification

☐

Pharmacist

☐

Pharmacy Technician

Q2. Male ☐

Female ☐

Q3. In which hospital/clinic do you work?

☐

Private hospital/clinic

☐

Public hospital

Q4. For how long have you been in this hospital?

A ☐

< 5 years

E ☐

>20 years

B ☐

6 - 10 years

C ☐

11 - 15 years

D ☐

16 - 20 years

Anaesthetic drug availability in your practice

Q5. How do you source your anaesthetic drug supplies? (Check all that apply)

☐

From local pharmaceutical manufacturers

☐

From local pharmaceutical wholesalers

☐

From foreign suppliers

☐

From donors

Q6. Have you experienced any **Anaesthetic drug shortages** in your practice in the **last 3 months?** (Refers to the Anaesthetic drugs listed in Q7)

☐

Yes

☐

No

Q7. Which of the following anaesthetic drugs have been out of stock in your pharmacy at any given time in the last 3 months?

a) Intravenous Anaesthetics

☐ Propofol ☐ Etomidate ☐ Sodium Thiopentone ☐ Ketamine

b) Inhalational Anaesthetics

☐ Isoflurane ☐ Sevoflurane ☐ Halothane ☐ 100% Oxygen

c) Muscle Relaxants & Cholinesterase Inhibitors

☐ Suxamethonium ☐ Atracurium ☐ Vecuronium ☐ Neostigmine

d) Antimuscarinic & Antiemetic Drugs

☐ Atropine ☐ Metoclopramide ☐ Prochlorperazine

e) Opioids & Antagonists

☐ Morphine ☐ Pethidine ☐ Fentanyl ☐ Naloxone

f) Sedatives

☐ Diazepam ☐ Midazolam ☐ Valeron drops

g) Local Anaesthetics

☐ Plain Bupivacaine ☐ Heavy Bupivacaine ☐ Lignocaine

h) Vasopressors/Inotropes

☐ Adrenaline ☐ Ephedrine ☐ Dopamine ☐ Dobutamine

i) Other Drugs, Please indicate

Q8. Which of the drugs listed in Q7 have been in erratic supply or have been difficult to acquire in the last 3 months from your suppliers? List the drugs below

Q9. What were the causes of the **anaesthetic** drug shortages in your practice in the last 3 months? List below

Q10. What are the measures that can be taken to improve anaesthetic drug supply in your practice?

Q11. Do you receive any advance notice of drug shortages?

☐ Never ☐ Sometimes ☐ Always ☐ Unknown

Q12. Who notifies you of drug shortages?

☐ Wholesaler ☐ No one ☐ Manufacturer ☐ Other pharmacies/Pharmacists
☐ Head office ☐ Unknown

Q13. Do you believe that drug shortages increase the cost of anaesthesia care to the patient?

☐ Yes ☐ No ☐ Do not know or unsure

Q14. By how much does a single drug shortage increase the cost of patient anaesthesia care?

☐ <5% ☐ 5 to 20% ☐ 20 to 50% ☐ >50%

The End! Thank you for your participation in this survey

Appendix 3: Consent Form

DEPARTMENT OF ANAESTHESIA AND CRITICAL CARE MEDICINE

Mazowe Street, P O Box A 178
Avondale, HARARE, Zimbabwe
Telephone: 263-4-791631
Fax: 263-724912/791995/795019



COLLEGE OF HEALTH SCIENCES UNIVERSITY OF ZIMBABWE

CONSENT FORM

Project Title:

A Survey of Anaesthetic Drug Availability: Impact on the Practice of Anaesthesia and Patient Care in Harare

Principal Researcher: Gerald Tapiwa Nyakatawa, [MBChB (UZ), DA (UZ)]

Purpose of this research study

I am doing this research as part of the requirements for the MMed (Anaesthesia) degree. I want to study the impact of anaesthetic drug shortages on the practice of anaesthesia and patient care in Harare.

Background information

Drug shortages have been reported as a global problem. Previous studies on anaesthetic drug shortages in particular, have shown that shortages negatively impact on the conduct of anaesthesia, in turn adversely affecting patient outcomes. The Zimbabwean situation has not been formally studied but observations and anecdotal reports suggest anaesthetists and pharmacists may be battling with drug shortages on a daily basis.

What will the study involve?

The study will involve interviewing anaesthetists and pharmacists in Harare through questionnaires. The interview is to assess how anaesthetists are affected by drug shortages, in their day to day practice of anaesthesia and how this impacts on their patients' outcomes. I also want to find out how pharmacists view and manage anaesthetic drug shortages in Harare hospitals.

Aim of the study

The research seeks to find out how common anaesthetic and critical care drug shortages are, how these shortages change the way anaesthetists deliver anaesthesia care and how in turn patient

outcomes are affected in Harare. The study also aims to investigate the causes of these shortages and how pharmacists manage them.

Procedure

If you agree to take part in this study I kindly ask you to complete the questionnaire attached to the best of your knowledge. It will take about 5 minutes of your precious time.

Results of the study

The data from the questionnaire will be kept confidential for the duration of the study. Upon completion of my thesis they will be retained for another six months and then destroyed thereafter. The results will be presented in the thesis and will be seen by my supervisor and my examiners. The study will also be presented to the Department of Anaesthesia, Zimbabwe Pharmaceutical Association and the Ministry of Health and Child Care

Possible risks or benefits

There is no risk involved in this study except your valuable time. There is no direct benefit to you also. However, the results of the study will help us to define the severity of the problem and formulate guidelines or recommendations on how to manage it.

Right of refusal to participate and withdrawal

You are free to choose to participate in the study. You may refuse to participate or refuse to answer some or all the questions if you don't feel comfortable with those questions.

Confidentiality

The information provided by you will remain confidential. Your name and identity will also not be disclosed at any time. However the data may be seen by the ethical review committee and may be published in a journal and elsewhere without giving your name or disclosing your identity.

Available Sources of Information

For more information contact the Researcher Dr. G. T. Nyakatawa, Department of Anaesthetics and Critical Care Medicine, UZCHS. Cell: +263 773 253 018. Email: gtnyakatawa@yahoo.co.uk

AUTHORIZATION

I have read and understood this consent form, and I volunteer to participate in this research study. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable state, or local laws.

PARTICIPANT

Signature_____

Date_____

RESEARCHER

Signature_____

Date_____

Appendix 4: Hospital Authorisations



Parirenyatwa
Group of Hospitals

Joint Research Ethics Committee For The University of Zimbabwe, College of Health Sciences and Parirenyatwa Group of Hospitals

JREC Office No.4, 5th Floor College of Health Sciences Building
Telephone: +263 4 708140/ 791631 Exts 2241/2242

Email: jrec.office@gmail.com/ jrec@medsch.uz.ac.zw, website: www.jrec.uz.ac.zw



University of Zimbabwe
College of Health Sciences

APPROVAL LETTER

Date: 15th July 2014

JREC Ref: 137/14

Names of Researchers: Dr Gerald Tapiwa Nyakatawa

Address: University of Zimbabwe, Department of Anaesthetics

Re: A Survey of Anaesthetic Drug Availability: Impact on Anaesthesia Practice and Patient Care in Harare.

Thank you for your application for ethical review of the above mentioned research to the Joint Research Ethics Committee. Please be advised that the Joint Research Ethics Committee has reviewed and approved your application to conduct the above named study. You are still required to obtain MRCZ approval and if required by the nature of your study, RCZ approval as well, before you commence the study.

- APPROVAL NUMBER: JREC/137/14
- APPROVAL DATE: 15th July 2014
- EXPIRY DATE: 14th July 2015

This approval is based on the review and approval of the following documents that were submitted to the Joint Ethics Committee:

- a) Completed application form
- b) Full Study Protocol
- c) Informed Consent in English and/or appropriate local language
- d) Data collection tool version:

After this date the study may only continue upon renewal. For purposes of renewal please submit a completed renewal form (obtainable from the JREC office) and the following documents before the expiry date:

- a. A Progress report
- b. A Summary of adverse events.
- c. A DSMB report

- **MODIFICATIONS:**

Prior approval is required before implementing any changes in the protocol including changes in the informed consent.

- **TERMINATION OF STUDY:**

On termination of the study you are required to submit a completed request for termination form and a summary of the research findings/ results.

Yours faithfully,



Professor M.M Chidzonga
JREC Chairman

Telephone: 621100-19
Fax: 621157



Reference: 190514/32

HARARE CENTRAL HOSPITAL
P. O. Box ST 14

SOUTHERTON

Harare

29 May 2014

Dr. Gerald T. Nyakatawa
Parirenyatwa Hospital Flat E3
Mazowe Street
HARARE

Dear Dr. Nyakatawa,

**REF: A SURVEY OF ANAESTHETIC DRUG AVAILABILITY IN HARARE: IMPACT ON ANAESTHESIA
PRACTICE & PATIENT CARE**

I am glad to advise you that your application to conduct a study entitled: **A Survey of Anaesthetic Drug Availability in Harare: Impact on Anaesthesia Practice & Patient Care**, has been approved by the Harare Hospital Ethics committee.

This approval is premised on the submitted protocol. Should you decide to vary your protocol in any material way please submit these for further approval.

You are advised to avail the results of your study whether positive or negative to the hospital through the committee for our information.

Yours sincerely,

A blue ink signature of Dr. C. Pasi is written over a rectangular stamp. The stamp contains the text 'HARARE CENTRAL HOSPITAL', 'DEPARTMENT OF MEDICINE', and 'MAY 2014'. Below the signature, the text 'PO DR. C. Pasi SOUTHERTON' is visible.

DR. C. Pasi
Chairman Harare Central Hospital Ethics Committee

BAINES AVENUE CLINIC

66 Baines Avenue
P.O. Box BE 190
Belvedere
HARARE

Telephone : 705011 ; 707489 ; 705062
Fax : 704850
Email:- secretary@bainesclinic.co.zw

15.05.14

Att:- Dr Farai D. Madzimbamuto
Department of Anaesthesia and Critical Care
Mazoe Street
P.O.Box A178
Avondale
HARARE

Dear Dr Madzimbamuto

RE: PERMISSION TO CONDUCT A RESEARCH ON ANAESTHETIC DRUG SHORTAGES BY DR. GERALD NYAKATAWA.

Permission to conduct a study on **ANAESTHETIC DRUG SHORTAGES:- IMPACT ON THE PRACTICE OF ANAESTHESIA AND PATIENT OUTCOME IN HARARE** is hereby granted to Dr Gerald Nyakatawa.

Please be advised that the clinic will not be liable to any harm or infection that Dr Gerald Nyakatawa could get during his study.

Please note that all information collected during his study should be treated strictly private and confidential and to should be used solely for the purpose of the research only.

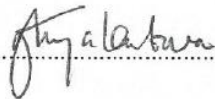
Please advise Dr Nyakatawa to sign below as acknowledgement of the above mentioned conditions.

Yours faithfully



Dr. Riaz Ahmed
MANAGING DIRECTOR

Signed by :Dr. G.Nyakatawa



Date

21/5/14

Time

14:30 hrs



BELVEDERE HOSPITAL

17 Princess Road, P. O. Box BE 268, Belvedere, Harare

Tel: 778011, 778040, 778085, 778060, 741137

Fax: 778451, 740740, 778450

Email: maternitybelvedere19@gmail.com

06 June 2014

Attention: Dr G.T.Nyakatawa

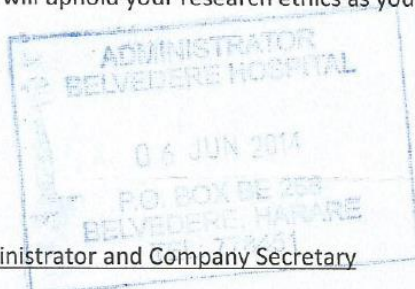
Permission to carry out research: Belvedere Maternity Hospital

Permission has been granted to you to carry out your research at this institution on the topic:
Anaesthetic Drug Shortages:- Impact on Anaesthesia Practice and Patient Care in Harare.

We trust you will uphold your research ethics as you carry out the research.

J Makamure

Hospital Administrator and Company Secretary



HOSPITAL APPLICATION FOR RESEARCH

Name of Applicant	Dr Gerald Tapiwa Nyakatawa
Address	Dept Anaesthesia & CCM, UZCHS Mazowe St, Belgravia, Harare. Zimbabwe.
Institution	University of Zimbabwe College of Health Sciences
Supervisor	Dr F.D. Madzimbamuto Dr S. Shumbairerwa and Dr H.N. Chifamba
Project Proposal Title	A Survey of Anaesthetic Drug Availability: Impact on Anaesthesia Practice and Patient Care in Harare
Objectives	1. To investigate how common anaesthetic drug shortages are in Harare's hospitals 2. To assess how anaesthetic drug shortages change the way anaesthetist deliver anaesthesia care 3. To assess how anaesthetic drug shortages affect patient care 4. To investigate the causes of anaesthetic drug shortages in Harare's hospitals
Methodology	Population: Anaesthesia care givers and hospital pharmacists in Harare's hospitals. Design: Cross-sectional study. 1. Two different study questionnaires have been designed, one for the anaesthetists and the other for the pharmacists. 2. Data on drug shortages will be collected from the theatres daily over a period of three months. The Zimbabwean essential drug list for anaesthesia will be considered 3. Anaesthetists' questionnaires will be placed in each theatre, on every anaesthetic machine for the anaesthetists to complete daily. They will be collected at the end of every theatre day, over a period of 3 months. 4. Private hospitals will be coded A,B,C.... Anaesthetist questionnaires will be administered in the theatres once a week in a blinded and randomized manner over the period of 3 months. Hospitals will remain anonymous throughout the time of the study. 5. Reminders about the study will be sent out to all anaesthetists at least once a month at the Department of Anaesthesia Wednesday meetings. 6. Pharmacists' questionnaire shall be administered at the end of the study period. 7. At least 60% response rate is the target in this study. 8. The researcher will be assisted by staff from the Department of Anaesthesia and the nurses working in the theatres. 9. Data on drug shortages collected from the anaesthetists will be reconciled with pharmacy data/stock levels regularly Data concerning drug shortages and stock levels will be collected from each hospital pharmacy records at the end of the study period

	17. COMESA Member States - Seminar Series Paper. Implementation of the WTO Decisions on TRIPS Public Health- Survey of Pharmaceutical Industry, 2011. Available from URL: www.comesabusinesscouncil.org/attachments/article/31/5.%20Survey%20of%20Pharmaceutical%20Industry%2031.10.2010.pdf (accessed 16/02/2014). 18. American Society of Health-System Pharmacists. Drug Shortages Summit Report. Available at: www.ashp.org/drugshortages/summitreport (accessed 16/02/2014).
--	---

I promise to forward conclusions of this study to the CLINICAL DIRECTOR

Name: Musainyana G. S. Signature: [Signature]

**STATION
PERMISSION
(ANAESTHESIA & CRITICAL
CARE)**

1. Clinical Director

Name/Signature [Signature]

Agree / Do Not Agree ☒

SOUTH MEDICAL
CHITUNGWIZA HOSPITAL

2014 -05- 28

CELL: 0774 733 316
P.O BOX 300, CHITUNGWIZA

2. Theatre Matron/Sister in Charge

Name/Signature D.S. Mukahira

Agree / Do Not Agree ☒

SOUTH MEDICAL
CHITUNGWIZA HOSPITAL
NURSING SERVICES MANAGER

28 MAY 2014

CELL: 0779 768 649
P.O BOX 300, CHITUNGWIZA

**STATION
PERMISSION
(PHARMACY)**

1. Chief Pharmacist

Name/Signature Musainyana G. S.

Agree / Do Not Agree ☒

SOUTH MEDICAL
CHITUNGWIZA HOSPITAL
(CITIMED) PHARMACY

28 MAY 2014

CELL: 0774 733 316
P.O BOX 300, CHITUNGWIZA

	17. COMESA Member States - Seminar Series Paper. Implementation of the WTO Decisions on TRIPS Public Health- Survey of Pharmaceutical Industry, 2011. Available from URL: www.comesabusinesscouncil.org/attachments/article/31/5.%20Survey%20of%20Pharmaceuticl%20Industry%2031.10.2010.pd (accessed 16/02/2014). 18. American Society of Health-System Pharmacists. Drug Shortages Summit Report. Available at: www.ashp.org/drugshortages/summitreport (accessed 16/02/2014).
--	--

I promise to forward conclusions of this study to the General Manager

Name: MAKATAWA G. T Signature [Signature]

STATION PERMISSION	1. General Manager Name/Signature <u>[Signature]</u> Agree / Do Not Agree	PSMI WEST END HOSPITAL 22 MAY 2014 14 BAINES AVENUE HARARE TELEPHONE : 251730-3
	2. Theatre Matron/Sister in Charge Name/Signature <u>M Mutede (M MUTEDE)</u> Agree / Do Not Agree	
STATION PERMISSION (PHARMACY)	3. Chief Pharmacist Name/Signature <u>[Signature] KAREN</u> <u>GABRIEL KARAN</u> Agree / Do Not Agree	

	17. COMESA Member States - Seminar Series Paper. Implementation of the WTO Decisions on TRIPS Public Health- Survey of Pharmaceutical Industry, 2011. Available from URL: www.comesabusinesscouncil.org/attachments/article/31/5.%20Survey%20of%20Pharmaceutical%20Industry%2031.10.2010.pdf (accessed 16/02/2014). 18. American Society of Health-System Pharmacists. Drug Shortages Summit Report. Available at: www.ashp.org/drugshortages/summitreport (accessed 16/02/2014).
--	---

I promise to forward conclusions of this study to the ~~CLINICAL DIRECTOR~~ **MANAGER**

Name: MYRA RUTANDA LIAT Signature: [Signature]

STATION
PERMISSION
(ANAESTHESIA
& CRITICAL
CARE)

1. ~~Clinical Director~~ **MANAGER**

Name/Signature: P. MACHERA

Agree / ~~Do Not Agree~~

THE CLINIC MANAGER
WEST END MEDICARE
TEL: (04) 706313/012 871975
FAX: (04) 706288
E-mail: medicare @mweb.co.zw

2. Theatre ~~Matron~~/Sister in Charge

Name/Signature: [Signature]

Agree / Do Not Agree

STATION
PERMISSION
(PHARMACY)

1. ~~Chief Pharmacist~~ **Technician**

Name/Signature: GEORGE MACHERA

Agree / ~~Do Not Agree~~

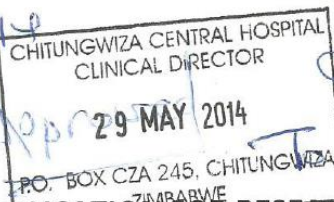
	16/02/2014).
I promise to forward conclusions of this study to the CLINICAL DIRECTOR Name: <u>MAICHTHWA G. T.</u> Signature: <u>[Signature]</u>	
STATION PERMISSION (ANAESTHESIA & CRITICAL CARE)	1. Consultant Name <u>DR H.N. CHITAMBA.</u> <u>[Signature]</u> Agree / Do Not Agree
	2. Ward Manager (Theatre matron) Name <u>M. Musochi</u> <u>[Signature]</u> Agree / Do Not Agree
STATION PERMISSION (PHARMACY)	1. Consultant (Chief Pharmacist) Name <u>D. N. VURAGO</u> <u>[Signature]</u> Agree / Do Not Agree
	2. Pharmacy Manager Name _____ Agree / Do Not Agree

PARIRENYATWA GROUP OF
HOSPITALS
MAIN THEATRE MATRON
11 APR 2014
P.O. BOX CY 198
CAUSEWAY, HARARE

PARIRENYATWA GROUP
OF HOSPITALS
CHIEF PHARMACIST
11 APR 2014
P.O. BOX CY 198, CAUSEWAY
ZIMBABWE

29/5/14

b. Appr



Chitungwiza Central Hospital
 base with Dr. Mubengeriwa

APPLICATION FOR RESEARCH AT YOUR HOSPITAL

Name of Applicant	Dr Gerald Tapiwa Nyakatawa
Address	Dept Anaesthesia & CCM, UZCHS Mazowe St, Belgravia, Harare. Zimbabwe.
Institution	University of Zimbabwe College of Health Sciences
Supervisor	Dr F.D. Madzimbamuto Dr S. Shumbairerwa and Dr H.N. Chifamba
Project Proposal Title	A Survey of Anaesthetic Drug Availability: Impact on Anaesthesia Practice and Patient Care in Harare
Objectives	1. To investigate how common anaesthetic drug shortages are in Harare's hospitals 2. To assess how anaesthetic drug shortages change the way anaesthetist deliver anaesthesia care 3. To assess how anaesthetic drug shortages affect patient care 4. To investigate the causes of anaesthetic drug shortages in Harare's hospitals
Methodology	Population: Anaesthesia care givers and hospital pharmacists in Harare's hospitals. Design: Cross-sectional study. 1. Two different study questionnaires have been designed, one for the anaesthetists and the other for the pharmacists. 2. Data on drug shortages will be collected from the theatres daily over a period of three months. The Zimbabwean essential drug list for anaesthesia will be considered 3. Anaesthetists' questionnaires will be placed in each theatre, on every anaesthetic machine for the anaesthetists to complete daily. They will be collected at the end of every theatre day, over a period of 3 months. 4. Private hospitals will be coded A,B,C.... Anaesthetist questionnaires will be administered in the theatres once a week in a blinded and randomized manner over the period of 3 months. Hospitals will remain anonymous throughout the time of the study. 5. Reminders about the study will be sent out to all anaesthetists at least once a month at the Department of Anaesthesia Wednesday meetings. 6. Pharmacists' questionnaire shall be administered at the end of the study period. 7. At least 60% response rate is the target in this study. 8. The researcher will be assisted by staff from the Department of Anaesthesia and the nurses working in the theatres. 9. Data on drug shortages collected from the anaesthetists will be reconciled with pharmacy data/stock levels regularly Data concerning drug shortages and stock levels will be collected from each hospital pharmacy records at the end of the study period