Utrecht University

Awareness of Medication Safety
An International study

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PREFACE

In front of you lies a bachelor thesis, which is the result of a study into awareness of medication safety in various countries around the world. This study was by order of The Global Initiative on Medication Safety Foundation (GIMS). With this thesis, I am finishing my bachelor degree in Pharmacy at Utrecht University.

Health and human wellbeing has always been something that has captivated me from a young age. My background as a Dutch citizen born in Afghanistan has contributed to enlarging my vision of the world. Sick relatives, that are located in less developed countries, who have little or no access to medical specialists and medicines, have made me realize the value of good health care. Their stories about corruption, counterfeit medicines and negligence of healthcare actors have very much shocked me. For a long time, I wondered how I could understand the system better in order for me to mean something to them. Therefore, this study, led by GIMS, fit me like a glove. I conducted the research with great enthusiasm and passion, and in retrospect I have obtained many answers to questions that I had before I started this study.

I would like to thank all those who have contributed to the realization of this thesis. First of all, I would like to thank Mr. Erik ten Hoff, who has guided me and provided detailed feedback and reflection. I would also like to thank my second supervisor, Richard Slobbe for his insights and sharing his experiences and knowledge. Also, a word of gratitude goes out to Mrs. Aukje Mantel, who despite her busy schedule and numerous activities always made the effort to help me and to lead my thesis in the right direction.
A special thanks goes to Ms. Fanoes Bayat for her accurate and detailed vision and help. Finally, I would like my dear mother, father, sisters, brothers, cousins, friends, and friends for their endless patience and support. I could not have done it without your encouragement. I hope to make you all proud with this thesis.

Introduction

Over the last decade, applied researchers have become increasingly interested in medication safety. In 1991 the Harvard Medical Practice Study published a study showing that the number of casualties due to medical error reaches up to tens of thousands. As a result, the quality of care was brought into question by the US Institute of Medicine. A thorough debate led to the publication of a detailed report in the late 1999s, "To err is human – Building a safer health system", which led to much commotion in the field. [1]

Healthcare errors are for the most part related to the use of medication, dose prescription, treatment administration, and failures related to medication (e.g. adverse effects of medication). These findings still pose a threat to the global health. It is not fully clear how different countries in the world think about this topic, and what they do about it.[2]

The Global Initiative on Medication Safety Foundation (GIMS) wants to initiate and create a higher level of (awareness of) medication safety in various countries. The term medication safety is a broad term, and is interpreted differently by various countries. GIMS drafted its own definition for the term medication safety: "Minimize health risks originated by the global use of medicine".

To minimize these health risks originated by the global use of medicine, GIMS aims at creating awareness and responsibility in the medical chain, health care governance and patients worldwide. GIMS focuses on supporting responsible parties in the medical chain and health care governance to improve the level of professionalism of the processes and structures of prescribing and dispensing of medicine and guidance of patients in how to use medicine. GIMS was founded in 2014 and is supported by the board of Foundation Farmacie Mondiaal.

The present study was conducted within the GIMS framework. The main goal of this bachelor thesis is to gain insight in the degree of awareness of professionals and concerned directors (in the medical chain in different countries) regarding the health risks through the use of medicines (medication safety).

The secondary goal is to gain insight in the policy and law, in the process of prescribing, dispensing and the guiding of patients with the use of medicines in the different countries. It will be studied how this process and the sub processes are structured, and how the data is processed, coupled and/or automated/digitized. We look which ICT systems are used in the medical chain. The conditions that determine the parameters are also important (economy, 3G/4G coverage, internet infrastructure, culture, religion,war, governments, education, availability and accesability of medicines).

LITERATURE STUDY AND PRE-DISCUSSION

This study attempted to identify factors that can influence medication safety. These factors are called the critical dynamics and could play a prominent role in medication safety. These critical dynamics have emerged from literature study and pre-discussion.

The influence of government on medication safety: Medication is provided, depending on power in a region or country. After all, those in power determine what medication enters the country and to whom it is made available. The policy makers define the rules and regulations regarding transmitting and acquiring medication.

The influence of Technology on medication safety: With a proper ICT infrastructure in the pharmacy certain tasks can be automated which will lead to fewer human errors and thus a higher medication safety. A capable ICT infrastructure willl also improve monitoring and treatment of patients.

The influence of accessibility and availability of medication on medication safety: Availability: In the case of low availability of medication. the focus of the pharmacist may be on obtaining medication, at the cost of the medication safety.
Accesibility: Especially in less developed countries, access to medicines is a big concern, as these countries do not carry a universal health care coverage. Medication is typically provided via the public or private sector. Many private sector healthcare systems fail to supply affordable and high-quality medicines to their poorer population. Therefore, governments that work together with organizations such as WHO aim to publicly supply and distribute essential medicines at low or no cost.

Communication between different care sectors: Communication between different actors can play a major role in medication safety. After all, the communication plays a key role in the proper prescription and dispensing of medicines, in which the GP and the pharmacist could surely complement each other.

The influence of culture and religion on medication safety: Culture and religion can have a big impact on medication use of patients. Certain beliefs of religion can lead to under-use of medications, causing people to avoid the doctor so do not use medication. For example, sometimes vaccinations are avoided by people of faith.

The influence of war on medication safety: War is a concept which has great influence in various fields, including pharmacy. In a region or country ravaged by war, especially responsible medication use is something that has little value and is not a primary requirement.

The influence of Knowledge and education on medication safety: Knowledge and education can play a major role in medication safety for both professionals and patients. For the professionals, delivering too little knowledge leads to lower medication safety. For the patient, too little knowledge leads to less confidence in the medication, allowing under-use of medication to occur.

The influence of the social economic state on medication safety: The socio-economic status of a country or region plays an important role obtaining medication. Not only the socio-economic status of a country or region, but also socio-economic condition of the patient plays a very prominent role in medication safety. Especially in less developed countries patients from a lower socioeconomic class have less access to insurance and to medicines (see Figure 1).

Among themselves, critical dynamics are very interdependent. For example, war affects the economic condition of a country, and the economic state then affects the technology in a certain country. Better developed countries have more money and therefore more access to, for example, complex and expensive IT systems. These IT systems provide then make for better communication between different care sectors, as patient-related information can be tracked accurately and shared with other health care providers (eg. medical records).
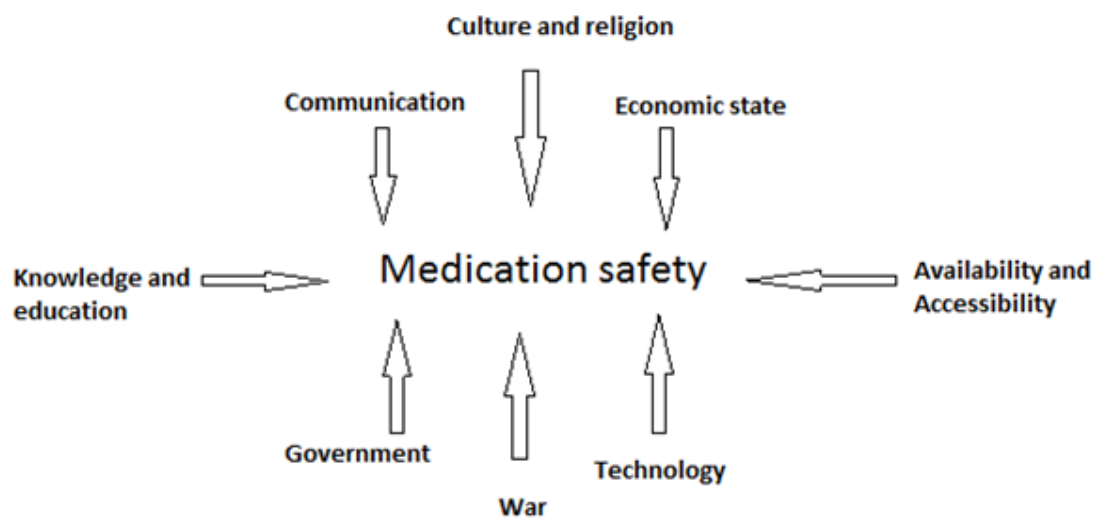
Figure 1: Factors that influence Medication Safety

METHODS

Regions and Countries

This study will focus on the following countries: The Netherlands, Germany, France, Sweden, Greece, Afghanistan, Laos, Japan, Egypt, Ghana, South Africa, Canada, and Suriname.In the African countries, it is important that in terms of medication the focus will be on HIV, malaria and tuberculosis. Since they are dominating diseases in those countries.

Literature study and interviews

Each country is studied through a literature study and by interviewing professionals in the countries. For each country a literature study is done on what is already known about the health risks of using medicines (medication safety) in that country. Therefore, this bachelor thesis has a scientific nature. The search for studies on the topic of medication safety was done at organisations, foundations, governments, universities and other sources.

Literature was collected through PubMed, Google Scholar and Scopus by searching for medication safety and pharmaceutical country profile. These searches were made using the keywords: pharmaceutical country profile, and pharmaceutical policy. Additionally, WHO reports and policy documents also served as a source of information. These WHO reports are found at the website of the World Health organization.

The interviews took place after the literature study was finished. The student tried to make contact with pharmacists, professional associations, insurance companies, governments and the WHO.

Interviews were conducted on the basis of a questionnaire with representatives of each country. This was performed in a dynamic approach in which the questionnaire was altered based on later insights. A preliminary questionnaire was developed and discussed by Chuck van de Cappelle and supervisors Richard van Slobbe and Erik ten Hoff (see appendix 2). The questions have emerged from the literature and discussion, in which the critical dynamics that can influence medication safety are appointed.

Data

Our data is collected in a few sections for each country. Mostly each section contains questions regarding the ciritical dynamics from the literature and fordiscussion. As mentioned before, the data is obtained with the help of literature searches and by conducting interviews. The data gathered starts with questions regarding policies and legislation in the studied countries. These questions are asked to find out what role the government plays in medication safety in the country. It explores, amongst others, the legislation regarding importing, fabricating and distributing of medicines (see appendix 1.1 for questions).Afterwards, questions will be answered regarding the diagnosing and prescription of medicines. These questions are asked in order to draw an image of the initial contact of the patient with the healthcare system (see appendix 1.2 for questions).

Subsequently, the questions regarding the proceedings that take place in pharmacies are answered. The processes that take place in the pharmacy play a big role in the responsible and safe use of medication by patients. Also, in this section questions are asked regarding the technology used in the different countries (see appendix 1.3 for questions).

Beside policy, legislation, prescription and dispensing of medicals, accessibility and availability of medicals have a great impact as well on the health care system within a country. In this sections questions awnsered regarding accessibility and availability (see appendix 1.4 for questions).

Moreover, the contact between professionals (pharmacist and GP) is reviewed (see appendix 1.5 for questions). These questions are asked to determine to what extent there is contact between the different actors in the healthcare process.

Additionally, there is a summary shown of notable quotes of the various interviews for the different countries, and data regarding the critical dynamics ` culture and religion, war and knowledge and education, and economic state` (see appendix 1.6 for questions).

Finally, questions will be asked about the level of awareness of healthcare professionals regarding the critical dynamics that influence medication safety (see Appendix 1.7 for questions).

Privacy – The respondents were contacted through E-mail, social media and Skype. Most of the interviews were conducted through Skype. Participation of the respondents was voluntary and confidential. The participants gave their consent through E-mail.

Neutral point of view – Culture, religion and governmental power are sensitive issues and can have an important impact on the national and local process of prescribing, dispensing and the rational use of medicine. A neutral stand was important while doing the interviews with professionals.

The analysis – The collected data for this study was analysed by using excel to produce conventionally arranged tables of the results.

RESULTS

The findings of this study are seperated in eight sections. The results are subdivided by critical dynamic.

Firstly, section 1 deals with policy and law regarding the critical dynamic goverment. The data shown in section 1 is mostly obtained from the literature. Secondly, section 2 contains findings about the process of diagnosis and prescribing. Thirdly, section 3 mentions findings regarding processes in pharmacy regarding the critical dynamic technology. Additionally, section 4 includes findings about the critical dynamic availability and accesability of medicines. Section 5 involves data about the level of contact among professionals regarding the critical dynamic communication. Section 6 includes findings regarding the critical dynamics culture and religion, war and knowledge and education, and economic state. Section 7 includes a few quotes from the interviews regarding some of the critical dynamics. Finally, section 8 includes findings about awareness of the critical dynamics.The information shown in the sections 2-8 are obtained from the interviews among professionals.

In total, several professionals from 13 different countries were contacted. These countries are named in the method. After intensive email contact there was no cooperation from 7 of the 13 countries. Eventually, six countries cooperated: Afghanistan, Armenia, Ghana, Laos, The Netherlands, South Africa. A total number of 11 interviews were conducted (see table 1). It should be noted that Armenia was initially not one of the countries to be studied. However, due to the limited response from the other countries the decision was made to add Armenia to the study, because there was cooperation from an Armenian pharmacist.

Table 1. Amount of interviews

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Amount of interviews	3	1	2	2	2	1

Tabel 1: Number of interviews conducted in each country.

Policy and law

This study shows that the six countries studied all carry a National Medicine Policy. However, the rules of the NMP are not always met. It appears that there are no laws in the countries to implementing the National Medicine Policy. What is also striking is that for all the countries there are Standard Treatment Guidelines, but it is important to point out that these guidelines are often out-dated and not kept up-to-date. For the six countries studied it also applies that there is a laboratory available to carry out quality control of medicines. Although all countries seem to have access to these quality controls, they are not always implemented. So it appears that the laboratory for quality control of medicines in Laos is not certified. This would cause medicines that qualify for such quality control to be transported to Thailand. This is a time-consuming, but also expensive process, which is often skipped.

The data also shows that there are laws requiring manufacturers to be licensed in all the countries studied except for Laos, for which there is no data available on this topic. It is also

remarkable that the presence of the pharmacist in a pharmacy is required by law. Despite this obligatory presence of the pharmacist by law, this is not always the case (see table 2).

Table 2. Section 1: Policy and Law

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. National medicine policy (NMP)	Exists : ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	Exists: ✓ [6]	Exists: ✓ [7]	Exists: ✓ [8]
B. NMP law implementation plan	Exists:X[3]	-	Exists:X[5]	Exists:X[6]	Exists:X[7]	-
C. Market authorization for all pharmaceutical products	Required: ✓ [3]	Required: ✓ [4]	Required: ✓ [5]	Required: ✓ [6]	Required: ✓ [7]	Required: ✓ [8]
D. Legal provisions to perform inspection	Exists: ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	-	Exists: ✓ [7]	Exists: ✓ [8]
E. Legal provision on import control	Exists: ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	Exists: ✓ [6]	Exists: ✓ [7]	Exists: ✓ [8]
F. Licensing manufacturers	Required: ✓ [3]	Required: ✓ [4]	Required: ✓ [5]	-	Required: ✓ [7]	Required: ✓ [8]
G. Market control and quality control	Exists: ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	-	Exists: ✓ [7]	Exists: ✓ [8]
H. Laboratory for quality control	Exists: ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	Exists: ✓ [i]	Exists: ✓ [7]	Exists: ✓ [8]
I. Laws about monitoring adverse drug reactions	Exists:X[3]	Exists: ✓ [4]	Exists:X[5]	-	Exists : ✓ [7]	Exists : ✓ [9]
J. National standard treatment guidelines (STG)	Exists:X[3]	Exists: ✓ [4]	Exists: ✓ [5]	Exists: ✓ [6]	Exists: ✓ [7]	Exists: ✓ [8]
K. Good manufacturing practices (GMP)	Exists: ✓ [3]	Exists: ✓ [4]	Exists: ✓ [5]	-	Exists: ✓ [7]	-
L. Good distributing practices (GDP)	Exists:X[3]	Exists:X[4]	Exists: ✓ [5]	-	Exists: ✓ [7]	-
M. Presence of the pharmacist required (by law) in the pharmacy	Required: ✓ [3]	Required: ✓ [4]	Required: ✓ [5]	Required: ✓ [6]	Required: ✓ [7]	Required: ✓ [ii]

✓ =exist   X=does not exist   - = data unavailable

Table 2: The existence of policy and law in the six studied countries. De results with the numbers 3,4,5,6,8,9,10 are obtained from the literature. The result with note i is obtained from the interview with a healthcare professional from Laos. The result with number ii is obtained from the interview with a healthcare professional from South Africa.

Diagnosis and Prescribing

In this section, a distinction can be made on the basis of the development of the country. Next to the general practitioner (GP) and pharmacist (PH), there are also traditional healers (TD) in less developed countries that patients turn to when they experience symptoms. These traditional healers do not work on the basis of scientific theories, but only on experience.

Furthermore, the data show that the GP is generally the official prescriber of medicines in the six countries studied. However, there are also other parties such as traditional healers and pharmacists who provide advice to use certain medicines without informing the GP. By doing this, they take over the tasks of the doctor, while they are neither qualified nor trained. On the other hand, the doctor takes over duties of the pharmacist by prescribing

and providing medicines on their own. A remarkable note is that doctors need a license to dispense medication in South Africa.

Besides the doctor, (pharmaceutical) shop assistants also dispense medicines without any knowledge of it. For example, in Laos, Afghanistan and Ghana applies that the so-called pharmaceutical shop assistants should deliver medicines. These shop assistants have not had training and are only regular employees (see table 3).

Table 3. Section 2: Diagnosis and prescribing

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Place to visit ill patient	GP:✓ PH:✓ Other:TD	GP:✓ PH:✓ Other:X	GP: ✓ PH:✓ Other:TD	GP: ✓ PH:✓ Other:TD	GP: ✓ PH:✓ Other:X	GP:✓ PH:✓ Other:TD
B. Diagnosis patient	GP:✓ PH:✓ Other:TD	GP:✓ PH:X Other:X	GP: ✓ PH:✓ Other:X	I GP: ✓ PH:✓ Other:X	GP: ✓ PH:x Other:X	GP: ✓ PH:X Other:X
C. Prescriber of medicines	GP: ✓ PH:X Other:X	GP: ✓ PH:X Other:X	GP: ✓ PH:X Other:X	GP: ✓ PH:X Other:X	GP: ✓ PH:X Other:X	GP: ✓ PH:X Other:X
D. Prescription	Digital:X Paper:✓	Digital:X Paper:✓	Digital:X Paper:✓	Digital:X Paper:✓	Digital: ✓ Paper:X	Digital:X Paper:✓
E. Dispensing medicines by	GP:✓ PH:✓ PH assistant:✓ Shop assistant:✓	GP:✓ Ph:✓ PH assistant:✓ Shop assistant:X	GP:✓ Ph:✓ PH assistant:✓ Shop assistant:✓	GP:✓ PH:✓ PH assistant:✓ Shop assistant: ✓	GP:✓ PH:✓ PH assistant:✓ Shop assistant:X	GP:✓ PH:✓ PH assistant:X Shop assistant:X

✓ =Yes   X=No

Table 3:Initial contact between the patient and healthcare professionals such as the Great practitioner (GP), pharmacist (PH) and contact between patients and a traditional healer (TD) for the six studied countries. All the results shown in this section are obtained from the interviews.

Processes in pharmacy

In all countries, except for the Netherlands and South Africa, medicines may be dispensed without a prescription (over the counter medicines excluded). For example, in Laos it is possible to purchase antibiotics at a local snack shop, without any explanation or instructions for use.

Moreover, for the six countries applies that there is great variation in medication checks carried out for a medicine prescription. For example, in the Netherlands, dosage is checked by arrival of a prescription at the pharmacy, as well as any interaction with drugs -which the patient already is using- , contraindications, double medication and finally it is also discussed how the patient's therapy is or should be. This is in contrast to countries such as Afghanistan, Laos where no form of control is carried out by arrival of a prescription at the pharmacy.

It is noticeable that the information provided to the patient by dispensing medicines, for all countries except Ghana and the Netherlands, is very basic and limited to the frequency of use and the times of use.

ICT systems are used for different purposes in the countries studied. For example, countries such as Armenia, Laos, Ghana, the Netherlands and South Africa use ICT systems for

managing the stock of medicines. It is especially notable that there is a big difference between the Netherlands and five other countries.

It also applies for most countries studied that only very basic ICT systems are available, and therefore keeping medical records is difficult. In countries such as Ghana, South Africa and Laos there are special programs for HIV, TB and Malaria, in special clinics or hospital pharmacy. In these programs medical records are kept and attention is paid to patient compliance. It is also monitored what medications patients already use to help identify a possible interaction. For these programs much money is donated by agencies and aid organizations (see table 4).

Table 4. Section 3: Processes in pharmacy

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Dispensing without prescription	Allowed:✓ Not allowed:X	Allowed:✓ Not allowed:X	Allowed:✓ Not allowed:X	Allowed:✓ Not allowed:X	Allowed:X Not allowed:✓	Allowed:X Not allowed:✓
B. Medication checks	Dosage control:X Drug interaction:X Contra-Indication:X Dubbel medication:X Patient compliance check:X No checks:✓	Dosage control:✓ Drug interaction:✓ Contra-Indication:X Dubbel medication:X Patient compliance check:X No checks:X	Dosage control:✓ Drug interaction:✓ Contra-Indication:X Dubbel medication:X Patient compliance check:X No checks:X	Dosage control:X Drug interaction:X Contra-Indication:X Dubbel medication:X Patient compliance check:X No checks:✓	Dosage control: ✓ Drug interaction:✓ Contra-Indication:✓ Dubbel medication:✓ Patient compliance check:✓ No checks:X	Dosage control: ✓ Drug interaction:✓ Contra-Indication:X Dubbel medication:✓ Patient compliance check:X No checks:X
C. Information by dispensing	Basic information: ✓ Adverse effects:X	Basic information:✓ Adverse effects:X	Basic information: ✓ Adverse effects:✓	Basic information: ✓ Adverse effects:X	Basic information:✓ Adverse effects:✓	Basic information:✓ Adverse effects:X
D. ICT-systems used for	Stock monitoring:X Elec. Ordering and paying:X Checks on prescription:X None:✓	Stock monitoring:✓ Elec. Ordering and paying:X Checks on prescription:X None:X	Stock monitoring:✓ Elec. Ordering and paying:X Checks on prescription:X None:X	Stock monitoring:X Elec. Ordering and paying:X Checks on prescription:X None:✓	Stock monitoring:✓ Elec. Ordering and paying:✓ Checks on prescription:✓ None:X	Stock monitoring:✓ Elec. Ordering and paying:X Checks on prescription:X None:X
E. Patient medical record	Paper:X Digital:X None:✓	Paper:X Digital:X None:✓	Paper:X Digital:X None:✓	Paper:X Digital:X None:✓	Paper:✓ Digital:X None:X	Paper:X Digital:X None:✓

✓ =Yes   X=No

Table 4: Processes after a prescription arrives at the pharmacy such as medication checks, information given to the patient by dispensing the medicines, using ICT-systems and keeping track of medical records for the six studied countries. All the results shown in this section are obtained from the interviews.

Availability and accessibility of medicines

Based on the interviews it can be concluded that the availability of medicines in all countries is good. During the interviews, interviewees were asked to assess the availability of medicines in the country, where 1 = bad, 2 = average. 3 = good, and 4 = excellent.

For countries such as Afghanistan, Laos, Ghana, and South Africa applies that there are many ways to buy medicines from for example: importers, wholesalers, foundations, aid organization (Aid org), and the ministry of public health. For these countries, the illegal sale of medicine plays an important role, especially in border areas. These drugs are not tested for quality and are not always recorded in the respective countries. Consequently, many counterfeit drugs enter these countries and are delivered to patients with all its consequences (see table 5).

Accessibility of medicines typically remains a very large problem in less developed countries. Especially the less wealthy section of the population without health insurance have little access to medicines and are therefore are usually tend towards alternative therapies.

Table 5. Section 4: Availability of medicines

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Availability of medicines in the country	Bad:X Average:X Good:✓ Excellent:X	Bad:X Average:X Good:✓ Excellent:X	Bad:X Average:X Good:✓ Excellent:X	Bad:X Average:X Good:✓ Excellent:X	Bad:X Average:X Good:✓ Excellent:X	Bad:X Average:X Good:✓ Excellent:X
B. Pharmacists buy medicines from	Importers:✓ Wholesaler:✓ Foundation:✓ Aid org:✓ Ministry:✓	Importers:✓ Wholesaler:✓ Foundation:X Aid org:X Ministry:X	Importers:✓ Wholesaler:✓ Foundation:✓ Aid org:✓ Ministry:✓	Importers:✓ Wholesaler:✓ Foundation:✓ Aid org:✓ Ministry:✓	Importers:X Wholesaler: ✓ Foundation:X Aid org:X Ministry:X	Importers: ✓ Wholesaler: ✓ Foundation:X Aid org:X Ministry:X

✓ =Yes   X=No

Table 5: The degree of availability of medicines in the country and the method of acquiring medication by the pharmacy within the six countries studied. All the results shown in this section are obtained from the interviews.

Contact among professional

For all countries except Laos, applies that a prescription from the GP may only be changed after an approval of the GP is provided. The interviews showed that, despite this rule, prescriptions are in some cases changed without the consent of the GP.The contact between the pharmacist and the physician is very different among the countries studied. In the Netherlands, there is relatively more communication between these medical professionals compared to the other countries studied. However, it should be mentioned that there are differences between contact of pharmacists and GP's within each country (see table 6).

Table 6. Section 5: Contact among professionals

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Legislation on prescription pharmacist	Allowed:X Allowed by approval:✓ Not allowed:X	Allowed:X Allowed by approval:✓ Not allowed:X	Allowed:X Allowed by approval:✓ Not allowed:X	Allowed: ✓ Allowed by approval:X Not allowed:X	Allowed:X Allowed by approval:✓ Not allowed:X	Allowed:X Allowed by approval:✓ Not allowed:X

B. Contact among pharmacist and Great practitionar	Yes:X No:✓	Yes✓ No:X	Yes✓ No:X	Yes:X No:✓	Yes✓ No:X	Yes:X No:✓
✓ =Yes X=No						

Table 6: Contact among professionals for the six studied countries. All the results shows in this section are obtained   from   the   interviews.

Culture & religion, war, knowledge & education, and social economic state

The interviews showed that critical dynamics such as culture and religion, war, knowledge and education, and economic state play a very important role in the (safe) use of drugs in the six countries studied (see Table 7).

In several studies in the six countries, the professionals saw many opportunities to improve and grow. A notable result is that the desire to improve was very large, but the cooperation from the authorities, especially in less developed country, was missing. Also, this study showed that in countries such as Ghana, Laos and Afghanistan factors such as faith and religion play a role in the safe use of medicines. For example, the lacks of effect of counterfeit medicines explained by voodoo (see table 8).

Table 7. Section 6: Culture and religion, war, knowledge and education, and social economic state

	1. Afghanistan	2. Armenia	3. Ghana	4. Lao	5. Netherlands	6. South Africa
A. Culture and religion	Effect:✓	Effect:X	Effect:✓	Effect:✓	Effect:X	Effect:X
B. War	Effect:✓	Effect:X	Effect:X	Effect:X	Effect:X	Effect:X
C: knowledge and education	Effect:✓	Effect:X	Effect:✓	Effect:✓	Effect:✓	Effect:✓
D. Economic state	Effect:✓	Effect:✓	Effect:✓	Effect:✓	Effect:✓	Effect:✓
✓ =Yes X=No						

Table 7: The effects of the critical dynamics "Culture and religion, war, knowledge and education and economic state" for the six countries. All the results shown in this section are obtained from the interviews.

Table 8. Section 7: Summary of key quotes regarding the critical dynamics

Definition of medication safety	*Ghana* – "This involves all those processes (medical/non-medical) put in place to improve benefits of medicines and reduce risks of such medicines in small of large populations."
Factors affecting medication safety	*Ghana* – "These include ignorance among patients and clients about the effects of medicines; weak but gradually improving regulatory systems; inadequate education on medicines from dispensers; and influx of counterfeiting medicines."
Will to improve the pharmaceutical system	*Afghanistan* – "Will for improvement is certainly there, but there are a lots of factors affecting the pharmaceutical system: education, economic status, the government. Sometimes we feel helpless. Our will for improvement is not enough to really make a change."
Impact of culture and religion on medication safety	*Laos* – "If a certain medication is not showing any effect, it is because of voodoo and not the cause of a counterfeit medicine." [translated, reworded]

Key role in medication safety	*The Netherlands* – "Unique identification of patients. Each patient is unique and needs special attention. If we are informed about their background, their name, address, date of birth, medical record, we can help them based on what they exactly need)."

Table 8: Key quotes regarding definition of medication safety, factors affecting medication safety, the will to improve the pharmaceutical system, impact of culture and religion on medication safety, and key role in medication safety for Ghana, Afghanistan, Laos, and the Netherlands. All the results shown in this section are obtained from the interviews.

Awareness of the critical dynamics

The awareness of pharmaceutical healthcare professionals regarding some critical dynamics are shown in Table 9. Nearly all interviews showed that awareness with regard to the critical dynamics `goverment, technology, availability and accesibility, commuication, culture and religion, war, knowledgde and education, economic and social state` was very high within the countries studied. Although the interviewees indicated they are aware of the critical dynamics, they found that in practice little effort was made to be actively engaged in these critical dynamics (see Table 9). Thus the passive awareness is high among the professionals and the active awareness is low among these professionals.

Table 9. Section 8: Awareness of critical dynamics

	1. Afghanistan	2. Armenia	3. Ghana	4.Laos	5. Netherlands	6. South Africa
A. Government	O	O	O	O	O	O
B. Technology	O	O	O	O	+	O
C. Availability and accesibility	+	O	O	O	O	O
D. Communication	O	O	O	O	O	O
E. Culture and religion	O	X	O	O	-	O
F. War	O	N/A	N/A	N/A	N/A	N/A
G. Knowledge and education	O	O	X	O	O	O
H. Socio-economic state	O	O	O	O	O	O

+= aware and actively engaged (active awareness) 0= aware but not practicing (passive awareness)	-= not aware X= no data N/A= not applicable

Table 9: Awareness of the critical dynamics `government, technology, availability and accessibility, communication, culture and religion, war, knowledge and education, and the social economic state in the six studied countries. All the results shown in this section are obtained from the interviews.

DISCUSSION AND CONCLUSION

The aim of this study was to create an overview of the level of medication safety in various countries and the influence of the critical dynamics on medication safety. Based on this research, there are large differences found in regulations and legislation, prescription and delivery, availability and access to medicines among the countries studied. The critical dynamics have a significant impact on both regulating and monitoring these rules. The level of passive awareness is high for nearly all the studied critical dynamics and the level of active awareness is low for almost all the studied countries. Below, the highlights of each country studied are described.

Afghanistan

This study shows that the Afghan government has been busy in recent years to draw up laws and regulations in the field of pharmaceutical care. Due to managerial instability the implementation of these rules is rather problematic. In addition, decades of war directed much damage in the country, which makes it difficult for pharmaceutical care to develop itself. The socio-economic condition of both the country and the patient is relatively bad, and there is little availability of medicines and little access for the lower socio-economic class. Access to medicines is the first step and, to many, a final step, because obtaining medicines by itself is very difficult. Awareness (active & passive) among patients about the safe use of medicines is also very low. Also, health care professionals are mainly engaged in the prescribing and dispensing of medicines rather than focusing on the safe use of medicines. The communication between healthcare professionals is also very limited. The doctor usually holds a monopoloy position where there is little to no value placed on the knowledge and expertise of the pharmacist. The passive awareness of the pharmaceutical world on this topic is very high. However, this is not the case for the other health care professionals (such as doctors). Furthermore, access to internet for students and pharmacists remains very limited. There is little access to published articles from Europe and America, which inhibits the scientific development of healthcare professionals (in the making).

Finally, culture and religion also make an important contribution to the (safe) use of medication by patients in Afghanistan. For example, certain patients just go to traditional healers because this is culturally and religiously permissible. Sometimes these patients are seriously ill and are in need of professional treatment. By visiting only the traditional healers they deny themselves of the right to be treated professionally. The interviews clearly showed that pharmacists in Afghanistan are passive aware of the risks attached to medicine use. It also revealed that there is much knowledge of the pharmacotherapeutic field, but this does not result in better pharmacotherapy of patients. One of the biggest reasons for this was believed to be corruption and failure of administrators to cooperate with these healthcare professionals.

Recommendation or question for further research
How should people in a country like Afghanistan, where many critical dynamics such as war, socioeconomic state, knowledge and education level have a negative influence on medication safety, seek to still try to use medication responsibly?

Armenia

The government of Armenia has drawn strong laws and regulations related to drug use. Implementation of these laws, however, is still a major problem in the country. Also, developments in technology and the existing ICT technologies are only used for inventory control. The availability of medicines is high in the country. Medicines are both manufactured domestically and brought in through imports. However, the accessibility of these medicines varies depending on the socioeconomic status of the individual. A notable result from the data was that especially many Armenians from the lower socioeconomic class are not able to afford a visit to the doctor. Therefore, in the case of illness, these people immediately go the pharmacy in order to save the cost of a doctor visit. Because of this, the division of roles between doctors and pharmacists in Armenia is disrupted. The communication between healthcare professionals is there, but at low scale.

The awareness of risks of medicine use among the population is relatively low. Antibiotics are bought over the counter without a prescription and the information provided to patients is very basic and limited to the frequency of use and time of use. The interviews revealed that passive awareness of the influences of the critical dynamics of medication safety was high among pharmaceutical healthcare professionals. However, they are not yet able to use this awareness to take action.

Recommendation or question for further research

How should people in Armenia change the dynamics between the GP and the pharmacist?

Ghana

This study clearly shows that the Ghanaian government has drafted many laws in pharmacotherapeutic care. Numerous laws relating to the manufacture and distribution and dispensing of medicines are set in the country. However, implementation of these laws remains an obstacle in Ghana. In addition, ICT technologies are very basic and still underdeveloped. The availability of medicines is high in the country, but availability of these drugs to different social groups within the population is not evenly distributed. For example, patients from a lower socioeconomic class have less access to (more expensive) drugs.

The socioeconomic status of patients determine in what pharmacy they end up and how much information they receive about the medicines they are using. Besides the socio-economic state of Ghana, culture and religion also play a prominent role in the medication safety of the country. For example, people with certain beliefs only visit traditional healers, or they will not vaccinate themselves out of religious beliefs.

These beliefs can indirectly exert much influence on pharmacotherapy and thus the quality of life of patients. Also, there is a very low level of exchange of information between healthcare professionals. The passive awareness of the impact of the various critical dynamics of medication safety is high among pharmaceutical healthcare professionals. However, the awareness of patients regarding the influence of these factors on medication is very low.

Recommendation or question for further research

How should people improve awareness of the factors that influence medication safety among the Ghanaian population?

Laos

In the past 20 years, the Democratic Republic of Laos has developed many laws in the field of health care. Yet, also to Laos applies that the implementation of the law remains a major challenge. Furthermore, this study showed that access to technology and ICT systems in Laos is very limited and thus also access to internet and scientific publications. Knowledge of the pharmaceutical care is believed to be low among healthcare profesionnals. It also showed that despite the control on imported medicines, there are still many illegal medicines imported, mainly in border areas. These counterfeit medicines are delivered to patients, with all its consequences. The ineffectiveness of these drugs is generally attributed to vodoo and cultural norms. These cultural conditions inhibit the application of knowledge and experience from medical science.

Moreover, the poor socio-economic condition of both the country and the patient make for limited access to medicines for the lower socio-economic class. The awareness of the risks associated with medicine use, especially among the local population, is very low. Antibiotics are sold at local snack shops and the information provided to patients on medication dispensing is almost non-existent. However, the passive awareness of pharmaceutical health care professionals with respect to the critical dynamics is high. Nevertheless, making changes remains very difficult for these healthcare professionals.

Recommendation or question for further research

If a country can not draft, implement and maintain their own laws, whose responsibility is it when the population is exposed to risks associated with incorrect medication (use)?

Netherlands

The Dutch government takes a great responsibility in pharmacotherapeutic care. For example, the government has many rules drawn up to ensure the quality of the process of medication delivery. However, it should be noted that generally the focus is more on the rules and proving that they work according to the rules rather than patient focused attention. This obviously varies between healthcare professionals, depending on their desire to practice their profession as pure as possible.

Besides the government, technology also plays an important role for medication safety in the Netherlands. The Dutch pharmacy system has advanced ICT technologies in which patients are uniquely identified and medical records are kept. Unique identification of patients contributes to individual attention and therapy orientation. A high level of communication between different actors in the healthcare also contributes to medication safety. Although there is much contact in the Netherlands between the GP and the pharmacist, the role of the pharmacist is not always taken seriously. There are many specialists who refuse to accept the advice of a pharmacist. Thus they are undermining the skills and knowledge of a pharmacist, which may be essential in the treatment of the respective patient. Awareness of the non-pharmaceutical health care professionals in this area is very low.

In addition to the above mentioned factors, there are also new challenges in the field of pharmacotherapy that play a role in the Netherlands. A good example is the multicultural society. This ensures that there are many individuals with different cultures and religions that live together in one country. In order to also provide accurate pharmacotherapy to these individuals, it is necessary to reflect on the habits, culture and religion of these

individuals. The awareness in this area appears to be too low. Finally, the economic condition of the patient also plays a role in medication safety in the Netherlands. Patients from higher socioeconomic class have greater access to medicines. A good example is the medicine that are not covered by health insurers, such as antacids (which are not used chronically). This leads to undermedication, which can ultimately reduce the quality of life of a patient. Actors in healthcare are well aware of this, but the rules remain unchanged until today.

Recommendation or question for further research

How should people in a country like the Netherlands, which has advanced ICT technologies, many medical specialties, many means of communication between different branches of care, provide better focus on patients?

South Africa

The study found that the government of South Africa has strong laws and regulations drawn up regarding use of medicine. Technological developments remain stagnant. Basic ICT technologies surely exist in the country, but these are mainly used for stock control, despite the fact that ICT technologies include some medication monitoring signals. One reason could be that patients have no fixed pharmacy which means no medical records are kept. As a result, the pharmacotherapy per patient can not be kept up to date, therefore, the tool of the ICT technologies to provide monitoring signals (e.g., such as drug-drug interaction), is not used. Although pharmaceutical healthcare professionals are aware of this, it is very difficult for them to change the situation. Unique identification of individuals is not applicable in South Africa which disrupts complete patient-oriented therapy.

The availability of medicines is high in the country. Medicines are both brought in through imports as a domestically manufactured. The accessibility of medicines on the other hand varies depending on the socioeconomic status of the individual. Furthermore, the interviews showed that communication between the GP and the pharmacist takes place at very low levels. Also, the knowledge of the pharmacist would not be sufficient in the pharmacotherapy area. Besides the above mentioned, culture and religion, also in South africa, play a role in medication safety. The traditional healers, especially in rural areas, play a major role in therapy of patients with all its consequences. Noticably, the interviews showed that there are already programs concerning awareness of medication safety. This could indicate that the level of awareness of medication safety is high in the country. Despite the professionals indicating that the awareness was high, taking action to change things remains very difficult. They explained this by placing medication in a contextual framework in which various factors and actors have roles in medication safety in a country or region. Thus the passive awareness is high, while the active awareness of the critical dynamics on medication safety is low.

Recommendation or question for further research

How would people in a country like South Africa, where awareness concerning medication seems to be high, provide more action to increase medication safety in the country?

Limitations

This study is, as previously defined, based on both literature and interviews. Great contradictions between the literature and interviews were not found. The information from the interviews was obtained from professionals in the pharmaceutical field. It should be

noted that the sample was small and that each country held few interviews. This allows no firm conclusions to be drawn, but this study certainly provides an indication of the pharmacotherapeutic situation in the countries studied. The question remains whether the results of the interviews can be extrapolated to the rest of the region or country. Furthermore, it is possible that the interviewee can give a different picture of reality because they felt compelled to give socially desirable answers.

Closure

Illegal imports of medicines, lack of quality control of medicines imported into the country or made, lack of guidelines that indicate how one should go to work systematically to address a specific disease, and lack of communication between the dispenser and the patient medical professional mutually have a negative influence on the medication in a country or region. Based on this research, there are large differences found in regulations and legislation, prescription and delivery, availability and access to medicines among the countries studied. Factors such as education, war, government, culture and religion and economic state of a country have a significant impact on both regulating and monitoring these rules. The level of passive awareness is high for nearly all the studied critical dynamics. However the level of active awareness of the critical dynamics on medication safety is very low for almost all the studied countries.

This study is not able to provide hard outcomes, but can certainly provide a basis for a follow-up study in the field of medication safety in the world, especially in increasing the active awareness of healthcare professionals.

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APPENDIX 1: QUESTIONS

Questions 1.1
A: Is there a national medicine policy in this country?
B: Is there a law of implementation of the national medicine policy?
C: Are there legal provisions on Market authorization for all pharmaceutical products?
D: Are there Legal provisions to perform inspection where pharmaceutical activities are performed?
E: Are there Legal provisions to control the imported medicine?
F: Are there legal provisions requiring licensing of manufacturers?
G: Are there legal provisions requiring market control and quality control for medicines?
H: Is there a laboratory for quality control in this country?
I: Are there Legal provisions monitoring adverse Drug?
J: Is there a National Standard Treatment Guidelines (STGs) available?
K: Are there Legal provisions requiring manufacturers to comply with GMP?
L: Are there legal provisions requiring importers, distributers and wholesalers to comply with GDP?
M: Are there legal provisions requiring the presence of the pharmacist in the pharmacy?

Questions 1.2
A: Where does a patient go when he doesn't feel well?
B: Who makes the diagnosis?
C: Who is allowed to prescribe medicines?
D: How are medicines prescribed? Digital or by paper?
E: Who are allowed to dispense medicines?

Questions 1.3
A: Is it allowed to dispense medication without a prescription?
B: What kind of checks are done on a prescription?
C: What kind of information is given to the patient by dispensing medication?
D: What are the ICT-systems used for?
E: Do patients have a medical record?

Questions 1.4
A: What is the state of the availability of medicines in your country?
B: Where can pharmacists buy medicines?

Questions 1.5
A: Is the pharmacist allowed to change a prescription by himself or does he need approval from a doctor?
B: Is there contact among pharmacist and the GP?

Questions 1.6
A: Does culture and religion affect medication safety?

B: Does war affect medication safety?
C: Does knowledge and education affect medication safety?
D: Does the economic state of a country or patient affect medication safety?

Questions 1.7
A: To what extent are people aware of the influence of the government on medication safety?
B: To what extent are people aware of the impact of technology on medication safety?
C: To what extent are people aware of the influence of availability and accesibility on medication safety?
D: To what extent are people aware of the influence of communication on medication safety?
E: To what extent are people aware of the influence of culture and religion on medication safety?
F: To what extent are people aware of the impact of war on medication safety?
G: To what extent are people aware of the influence of knowledgde and education on medication safety?
H: To what extent are people aware of the influence of social economic state on medication safety?

Appendix 2: Interviews

The professionals will be interviewed on the basis of a questionnaire. This is done by a dynamic approach, in which the questionnaire can be adjusted on the basis of later insights. It is important that the students take an open, neutral stand to the respondents. The students should not judge during the interview. The questionnaire is given below. The questions are written in general. In the African countries, it is important that in terms of medication the focus will be on HIV, malaria and tuberculosis.

Questionnaire
Diagnosis and prescribing

1. Where does a patient go when he doesn't feel well?
2. Who makes the diagnosis?
3. What happens after the patient has been diagnosed?
4. Who is allowed to prescribe medicine?
5. How are medicines prescribed?
   I. Digital or by paper?
6. What happens after a medicine is prescribed?
7. Who are allowed to sell medicine?

Prescription processing

8. What happens when a prescription enters the pharmacy? What is the process from a prescription that enters the pharmacy to medication dispensing by the responsible person?
   I. What kind of ICT-systems are used in this process?
   II. What are the ICT-systems used for?
9. Are there any checks done on a prescription?
   I. Who does those checks?
   II. What kind of checks are done? (Drug interactions, dosage control, double medication, contraindications)
10. Are there certain medicines that need extra vigilance?
11. Is the prescription included in a patient medical record?
    I. Is this done in a paper file or a digital file?
    II. What kind of ICT-system is used for this patient medical record?
12. Do patients always need to go to the same pharmacy? Or are they always going to different pharmacies?

Dispensing and guiding

13. What happens when a medicine is dispensed to a patient for the first time?
14. To what extent is an explanation given on how the medicine should be used?

15.   To what extent is the importance of patient compliance explained to the patient?
    I.   How is the compliance of the patient checked afterwards?

Availability of medicines

16.   What is the state of the availability of medicines?
17.   To what extent does the availability of medicines affect the medication safety?
18.   What do you do when a patient has a prescription for a medicine that is not available in your pharmacy?
19.   What is the procedure for a pharmacist to buy medicines?
20.   Where can pharmacists buy medicines? (Pharmaceutical companies; foundations; (aid) organizations; health insurance companies; or governments?)
21.   What is the state of accessibility of medication in your country?

Contact with other professionals

22.   To what extent do you have contact with other health care professionals?
    I.   What kind of contact is this?
23.   What happens when the pharmacist does not agree with the prescription?
    I.   Is the pharmacist allowed to change a prescription by himself or does he need approval from a doctor?
24.   Do pharmacists and general practitioners have a joint system?
    I.   What kind of system is this?
25.   To what extent are other pharmacists in your country allowed to look into a patients medication overview?
    I.   Is there a joint system between pharmacies?
    II.   What kind of system is this?

The pharmacy and pharmacist

26.   What education is required to become a pharmacist?
27.   Are there pharmacies that belong to a pharmacy chain?
28.   Who owns the pharmacies in your country in general? The pharmacist, a pharmacy chain, a company, the government or a combination of those?

Medication safety

29.   Can you explain what you think medication safety is?
30.   To what extent do you have the will to improve the medication safety?
31.   What do you think of the level of medication safety in your pharmacy?
32.   Do you see opportunities to improve the medication safety in your pharmacy?
33.   Do you know any studies that have been done on the topic of medication safety in your country?
34.   Are there certain factors such as culture or religion that influences medication safety in your country?

35. Do you think medication safety is a topic that needs more attention/awareness?

End of the interview

1. How have you experienced the interview?
2. Is it good if I have the possibility to contact you later with new insights?
3. Do you want to have your name in the final project report?
4. Do you want to keep informed about the developments of this project?

Appendix 3: Research proposal

Background

The health risk through the use of medicines is a problem that not everyone is familiar with. It is not fully clear how different countries in the world think about this topic, and what they do about it. The term medication safety is a broad term, and is interpreted differently by various countries.

The Global Initiative on Medication Safety Foundation (GIMS) drafted its own definition for the term medication safety: "Minimize health risks originated by the global use of medicine".

GIMS was founded in 2014 and is supported by the board of Foundation Farmacie Mondiaal. GIMS wants to initiate and create a higher level of (awareness of) medication safety. To minimize the health risks originated by the global use of medicine, GIMS aims at creating awareness and responsibility in the medical chain, health care governance and patients worldwide. GIMS focuses on supporting responsible parties in the medical chain and health care governance to improve the level of professionalism of the processes and structures of prescribing and dispensing of medicine and guidance of patients in how to use medicine.

Problem statement

The main goal of this bachelor thesis is to gain insight in the degree of awareness of professionals and concerned directors (in the medical chain in different countries) regarding the health risks through the use of medicines (medication safety).

The secondary goal is to gain insight in the process of prescribing, dispensing and the guiding of patients with the use of medicines in the different countries. It will be studied how this process and the sub processes are structured, and how the data is processed, coupled and/or automated/digitized. We look which ICT systems are used in the medical chain. The conditions that determine the parameters are also important (economy, 3G/4G coverage, internet infrastructure, culture, religion, governments, availability of medicines)

APPROACH

Regions and countries

Two students will each work on separate bachelor theses. These theses differ from each other in the target countries that are being studied. The countries are:

- o **Europe**: The Netherlands, Germany, United Kingdom, Belgium, France, Switzerland, Sweden, Poland, Portugal, Greece
- o **Asia**: Afghanistan, Iran, Israel, United Arab Emirates, Laos, Japan
- o **Africa**: Egypt, Ghana, Kenya, Rwanda, South Africa
- o **North America**: United States of America, Canada
- o **South America**: Suriname, Argentina

o **Australia**: Australia

Chuck van de Cappelle will study: United Kingdom, Belgium, Portugal, Poland, Switzerland, Iran, Israel, United Arab Emirates, Rwanda, Kenya, United States of America, Argentina, Australia

Negina Nangrahary will study: The Netherlands, Germany, France, Sweden, Greece, Afghanistan, Laos, Japan, Egypt, Ghana, South Africa, Canada, Suriname

In the African countries, it is important that in terms of medication the focus will be on HIV, malaria and tuberculosis. Since they are dominating diseases in those countries.

Literature study and interviews

Each country will be studied through a literature study and by interviewing professionals in the countries. For each country a literature study will be done on what is already known about the health risks of using medicines in that country. Therefore, this bachelor thesis has a scientific nature. The interviews take place after the literature study is finished. The student will try to make contact with pharmacists, professional associations, insurance companies, governments and the WHO.

The professionals will be interviewed on the basis of a questionnaire. The students will do this by a dynamic approach, in which the questionnaire can be adjusted on the basis of later insights.

For each country a literature study will be done on the awareness of the health risks when using medicines (medication safety) in that country.

The search for studies on the topic of medication safety will be done at organisations, foundations, governments, universities and other sources. Besides the search for studies, we will ask respondents in the interviews if they are aware of studies in the field of medication safety in their country.

The following questions will be studied for each country in the literature:

o	What is the general awareness on medication safety?
o	What studies have already been conducted in the field of medication safety? And what are the results of these studies?
o	How is the health care structured in the concerning country?
o	What laws and regulations does the government set in terms of medication safety?
o	Which guidelines do professional organisations have in terms of medication safety?

Neutral point of view

Culture, religion and governmental power are sensitive issues and can have a major impact on the national and/or local process of prescribing, dispensing and the use of medicines.

GIMS is a non-governmental, non-political and non-religious organization. GIMS will adopt a neutral position at all times. The students should also take a neutral stand during the whole bachelor thesis.

FINAL PRODUCT

The bachelor thesis will result in two final products: a project report and an overview of the main results of the studied countries. The project report will be a text document containing the approach, literature study, results, conclusions and advices. How the overview document will be is not clear yet.

The products will be written in English, and be published on the website of GIMS.