RISK ASSESSMENT OF PRESCRIBING ERRORS ON MEDICAL PRESCRIPTIONS IN MALTA AND GERMANY

A thesis submitted in partial fulfilment

of the requirements for the award of

Doctorate in Pharmacy

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2018

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Dedicated to those for whom this work is useful

on their path to produce good

Denen gewidmet für die diese Arbeit nützlich ist,

auf dem Weg Gutes zu bewirken

Acknowledgement

I would like to express my appreciation and gratitude to all those who were in any way involved in this research study. My aspirations and aims could not have been fulfilled without their assistance, guidance and cooperation.

Firstly, I would like to thank my supervisor Professor Anthony Serracino Inglott for introducing the thesis title and his constant advice throughout the research. Thank you for giving me the opportunity to grow in this field of research.

I am greatly indebted to my co-supervisor Dr. Maresca Attard Pizzuto, for her continuous support and valuable guidance through the whole study. Without her patience and her encouraging and calming character this study would have never been finished. Thank you very much.

I would like to thank my friend and fellow student Amar Abbas, who went with me through all the good and hard times during this research.

Special thanks to my friend Sarah Spiteri Staines who helped me a lot getting into contact with medical practitioners at Mater Dei Hospital in Malta. My close friend Dr. Markus Darius Stein who supported me a lot to understand prescribing errors from a German medical practitioner perspective. My friend Soyoung Baek who helped me as a Korean pharmacist to look at pharmacy practice from her point of view and has given me a lot of inspirations.

The honour goes to my parents, who have always been there for me and always will be there for me and my sister who led my way.

Last but not least, I want to thank all my friends, who are not mentioned, but had so much patience with me, while I was isolating myself from society for the last 3 years. Thank you.

Abstract

Errors on a medical practitioner's prescription may lead to erroneous dispensing by the pharmacist. A risk assessment of errors on medical prescriptions in Malta and Germany was undertaken. This study developed a comparative research method with the aim of (1) identifying and analysing the current status of processes that may lead to prescribing errors by prescribers and to pharmacist's reduced detection of erroneous prescriptions and (2) assessing the risk of prescribing errors from a medical practitioner's and pharmacist's perspective.

Interviews with medical practitioners were conducted in Malta and in Germany to identify root causes of prescribing errors. Interview results were used to develop two questionnaires, one for medical practitioners, entitled 'Prescribing Error Questionnaire' (PEQ_{med}) and one for community pharmacists (PEQ_{pharm}). PEQ_{med} and PEQ_{pharm} were validated by 16 experts using a two-round structured communication technique. The PEQ_{med} and the PEQ_{pharm} consisted of two main sections. Section one analysed the current status of root causes by asking practitioners to rate selected causes of prescribing errors and pharmacists to rate the causes of reduced detection of prescribing errors. Section two asked participants to rate potential prescribing errors on a scale from 1 (low score) to 4 (high score) by their probability of occurrence and severity of consequences to get an overall 'Risk Priority Number' (RPN) (1 - 4 low risk) (6 medium risk) (8 - 16 high risk). The results showed that two hundred and four medical practitioners (104 Malta, 100 Germany) and 189 pharmacists (86 Malta, 103 Germany) answered the PEQ_{med} and the PEQ_{pharm} respectively. Interruption rates while consulting with a patient as a root cause of prescribing errors showed a statistically significant

difference among medical practitioners (p<0.001) with 63 in Malta (66%) compared to 32 (32%) in Germany. The interruptions among community pharmacists also showed a statistically significant difference (p=0.02) with higher interruption rates in Malta (47%, n=40 Malta; 32%, n=33 Germany). Stress was indicated to be another root cause of prescribing errors within the medical practitioners' group (75%, n=78 Malta; 67%, n=67 Germany) (p>0.05), whereas the group of pharmacists showed a statistically significant difference (p=0.02) with higher perceived stress in Malta (73%, n=63) compared to Germany (61%, n=63). Prescribing errors due to illegible handwriting (average RPN of 6.81 for medical practitioners, 7.95 for pharmacists) and the use of abbreviations (average RPN 5.29 medical practitioners; 5.81 pharmacists) were rated as the two most common risks among medical practitioners and pharmacists leading to potential dispensing errors in Malta. German medical practitioners' and pharmacists' most common risks were the omission of duration of use from the prescription and longer duration of short-term use drugs (average RPN 6.42 and 6.21 medical practitioners; 6.08 and 7.6 pharmacists, respectively).

The awareness of medical practitioners and community pharmacists can be increased to avoid future errors. Specific risk minimisation strategies on the basis of identified prescribing error risk should be addressed to reduce risks in the specific country.

Keywords: Pharmacists - Prescribing Error - Risk Priority Number - Root Cause - Risk Minimisation

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List of Abbreviations

ADE	Adverse Drug Event
ACCP	American College of Clinical Pharmacy
ADR	Adverse Drug Reaction
AMK	German Pharmacists Committee
BMG	German Federal Ministry of Health
CIR	Critical Incident Reporting
CIRS	Critical Incident Reporting System
DRP	Drug-related Problem
EU	European Union
FMEA	Failure Mode and Effect Analysis
FIP	International Pharmaceutical Federation
HCP	Health Care Professional
IOM	Institute of Medicine
ISO	International Organisation for Standardisation
MCQ	Multiple Choice Question
ME	Medication Error
MMA	Malta Medicines Authority
MTM	Medication Therapy Management
MUR	Medicines Use Review
NSAID	Non-Steroidal Anti-Inflammatory Drug

PCNE	Pharmaceutical Care Network Europe
PEQ_{med}	Prescribing Errors Questionnaire Medical Practitioners
PEQ_{pharm}	Prescribing Errors Questionnaire Pharmacists
PMC	Poly Medication Check
PSS	Perceived Stress Scale
RCA	Root Cause Analysis
RPN	Risk Priority Number
SmPC	Summary of Product Characteristics
SPSS	Statistical Package for Social Sciences
STOP	Strategical, Technical, Organizational and Personal
UK	United Kingdom
US	United States of America
VAS	Visual Analogue Scale
WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION

1.1. Drug Therapy Safety

The publication of the report "*To Err is Human*" by the United States (US) Institute of Medicine (IOM) in 1999 led for the first time to a thematic discussion about errors in health care (Kohn et al, 2000). The IOM is part of “The National Academies” of the US and is an independent and non-profit organization working independently of the US government to provide objective and binding opinions. A major focus of the report was medication errors (MEs) and their impact on patients. In the US, every eighth death was attributable to MEs. Expressed in figures, between 44,000 and 98,000 people died of MEs every year, resulting in health care system costs between € 14 and € 23 billion (Kohn et, 2000). Surprised by this high prevalence, national and international awareness increased towards the complex and error-prone, high risk medication process. Patient safety and risk management became the focus of health care.

Drug therapy as well as the non-drug treatment are associated with a risk to the patient. According to the World Health Organisation (WHO) survey in 2009[1] 10% of global hospital admissions were caused by adverse drug events (ADE). Other studies found that about every 20th hospital admission was drug-related and that drug-related deaths are even the fourth leading cause of death in the US (Leape et al, 1991; Lazarou et al, 1998; Brennan et al, 2004). A study conducted between 2003 and 2007 in Germany, showed that 5% of hospital admissions were the result of ADEs (Stausberg and Hasford, 2011). Of these ADEs, approximately 25% were caused by a ME and considered preventable (Dormann et al, 2003).

[1] World Health Organization (WHO). Patient Safety Research [Internet] WHO 2009 [cited 2018 May 31]. Available from: http://apps.who.int/iris/bitstream/10665/70145/1/WHO_IER_PSP_2009.10_eng.pdf

The various findings from reports triggered many countries to conduct comparative studies based on the IOM report and to set up institutions aiming to increase patient safety. In 2002, the European Health Committee, a committee of the Council of Europe, decided to establish a commission of experts for "*Management of Safety and Quality in Healthcare*".[2] In addition to the terminology and frequency of drug-related problems (DRP), the commission has defined the following recommendations for prevention as best practices in drug therapy:

i. Electronic prescription software
ii. Control of the prescription by a pharmacist
iii. Individually packaging medicines for each patient (unit dose)
iv. Special attention in high risk medicines
v. Point of care verification

In 2007 the German Federal Ministry of Health (BMG) developed an action plan for drug therapy safety with the aim to sustainably increase the safety of drug therapy in Germany. The main focus of this plan was to protect the patient from preventable harm that is caused by drug therapy (patient safety).[3] The increase in drug therapy safety is directly related to the improvement of therapeutic outcomes.

[2] Expert Group on Safe Medication Practices (P_SP_PH/SAFE). Creation of a better medication safety culture in Europe: Building up safe medication practices [Internet]. Council of Europe 2006 [cited 2018 May 31]. Available from: https://www.edqm.eu/medias/fichiers/Report_2006.pdf

[3] Bundesministerium für Gesundheit. Aktionsplan 2008 / 2009 zur Verbesserung der Arzneimitteltherapiesicherheit (AMTS) in Deutschland [Internet] Drug Commission of the German Medical Association 2007 [cited 2018 May 31]. Available from: https://www.akdae.de/AMTS/Aktionsplan/Aktionsplan-2008-2009/index.html

The BMG action plan from 2007 and the following from 2009 contributed to the perception of the importance of drug therapy safety among German health care professionals (HCPs). These action plans initiated further incentives, such as the development of a standardised, patient-specific medication plan, which will be electronically accessible, as well as databases of scientific data on specific drug therapies on the internet. The third edition of the action plan from 2013[4] implies the current relevance of the drug therapy safety topic. In the current version various interventions to optimise the high-risk medication process are assigned to six main focuses:

i. Awareness of patients and HCPs (community pharmacists, medical practitioners and nurses) for drug therapy safety
ii. Improvement of information on medicinal products
iii. Improvement of interdisciplinary communication among HCPs within the drug therapy
iv. Usage of electronic devices and interdisciplinary accessible scientific databases
v. Drug therapy research
vi. Organisation of implementation and continuation of the drug therapy safety action plan

Drug therapy safety is any measure designed to protect patients from preventable harm associated with drug therapy (Jaehde et al, 2013; Müller et al, 2014).[5] At the same time

[4] Bundesministerium für Gesundheit. Aktionsplan 2013 - 2015 des Bundesministeriums für Gesundheit zur Verbesserung der Arzneimitteltherapiesicherheit in Deutschland [Internet] Drug Commission of the German Medical Association 2013 [cited 2018 May 31]. Available from: https://www.akdae.de/AMTS/Aktionsplan/Aktionsplan-2013-2015/index.html

[5] Aktionsbündnis Patientensicherheit e.V. Patientensicherheit. [Internet] Aktionsbündnis Patientensicherheit 2016 [cited 2018 May 31]. Available from: http://www.aps-ev.de/

drug therapy safety targets to minimise risks in a patient's drug therapy, such as preventable ADEs. Risks arise not only from individual misconduct, but also from non-optimal processes in the medication use process. The processes should be systematically analysed and improved. It is important that all HCPs (community pharmacists, medical practitioners and nurses) and patients involved in the medication use process work together to identify and minimise risks.

Besides drug therapy safety, drug safety (pharmacovigilance) have been established to ensure the safety of a drug with various measures such as collecting, monitoring, evaluating or reporting adverse drug reactions (ADRs).[6] It also includes evaluation of the risks and benefits of the drugs after their market launch. Frequent ADRs are recorded in clinical trials. Rare and post-marketing ADRs can be identified by community pharmacists and medical practitioners via reporting systems (Weidmann and Jüngst, 1991). According to the professional regulations, pharmacists are obliged to report ADRs in Malta to the Malta Medicines Authority (MMA) and in Germany to the German Pharmacists Committee (AMK) (Zagermann-Muncke et al, 2010; Borg et al, 2018). Not all community pharmacists and medical practitioners comply to their obligation to report ADRs and so further measures to minimise risks are necessary (Hazell and Shakir, 2006; Lopez-Gonzalez et al, 2009).

[6] World Health Organisation (WHO), The Importance of Pharmacovigilance - Safety Monitoring of Medicinal Products. [Internet] WHO 2002 [cited 2018 May 31]. Available from: http://apps.who.int/medicinedocs/en/d/Js4893e/

1.2 Definition of Drug-Related Problems

The term "*drug-related problems"* (DRPs) is an umbrella term for events or circumstances that actually or potentially prevent the achievement of desired therapeutic goals in the drug therapy of the patient (Hepler and Strand, 1990). The Pharmaceutical Care Network Europe (PCNE) foundation uses a very similar definition as a basis for DRPs "*A drug-related problem is actually or potentially intervening with desired health outcome."*[7]

DRPs can be divided into two categories. The first category describes ADRs that are defined by the WHO as "*a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function*".[8] ADRs are either medication side effects or allergic reactions that are predictable, such as peptic ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs) and mostly avoidable or reactions that are unpredictable such as idiosyncratic reactions. The second category is known as medication errors (MEs) that may cause or lead to inappropriate medication use, either by the HCP or the patient (van den Bemt et al, 2007). MEs are, in contrast to ADRs, preventable and do not necessarily harm the patient, as ADRs always harm the patient with different severity levels. Both MEs and ADRs could lead to increased patient

[7] PCNE classification for drug related problems V8.01. [Internet] Pharmaceutical Care Network Europe Foundation 2017 [cited 2018 March 31] Available from: http://www.pcne.org/upload/files/215_PCNE_classification_V8-01.pdf

[8] World Health Organisation (WHO), International drug monitoring: the role of national centres, in Technical Report Series No. 498 [Internet]. WHO 1972 [cited 2018 March 31]. Available from: http://whqlibdoc.who.int/trs/WHO_TRS_498.pdf

morbidity and mortality and hospitalisation which would incur added costs to healthcare (Classen et al, 1997; Wittich et al, 2014).

The PCNE and the Commission of Experts of the Council of Europe categorise DRPs differently than van den Bemt (2007). The PCNE divides DRPs into two categories, just like van den Bemt. The first category defines MEs as problems based on an error, a slip, or a lapse. The second category, unlike van der Bemt (2007), are defined as ADEs[7,9] by the PCNE and the Commission. An ADE is a harmful and unintended reaction associated with the use of a drug (Bates et al, 1999; van den Bemt et al, 2000). In contrast to the WHO definition of an ADR, which assumes proper use of the drug, the definition of an ADE also includes undesirable effects that occur as a result of MEs. ADEs and MEs overlap in the categorisation. The interface of MEs with ADEs are called preventable ADEs. All ADEs usually lead to harm to the patient. MEs outside the interface lead to no harm. In this research the DRP definition of the PCNE and the Commission was used, as a wrongly prescribed drug that can lead to a side effect. It is not the side effect as the cause that lead to the problem, but the wrong prescription of the medical practitioner. To consider problems from the point of view of wrong actions as MEs, is important for the continuation of this research. The relationship between MEs, ADEs, and ADRs is illustrated in Figure 1.1.

[7] PCNE classification for drug related problems V8.01. [Internet] Pharmaceutical Care Network Europe Foundation 2017 [cited 2018 May 31] Available from: http://www.pcne.org/upload/files/215_PCNE_classification_V8-01.pdf

[9] Expert Group on Safe Medication Practices (P_SP_PH/SAFE). Creation of a better medication safety culture in Europe: Building up safe medication practices [Internet]. Council of Europe 2006 [cited 2018 May 31]. Available from: https://www.edqm.eu/medias/fichiers/Report_2006.pdf

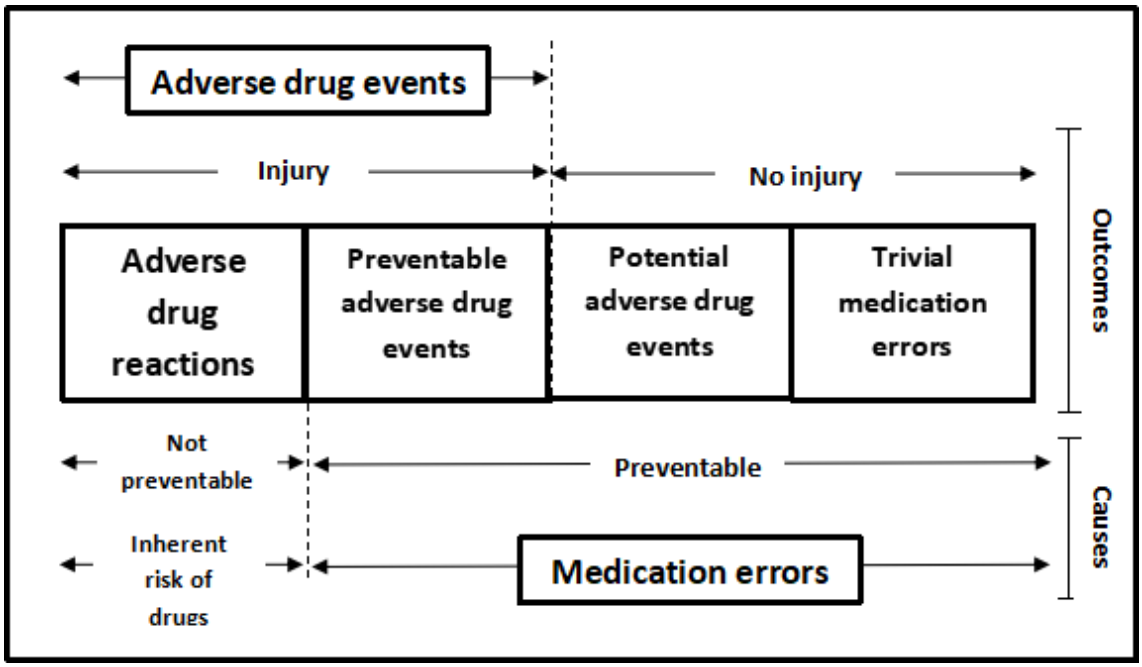

Figure 1.1: Relationship between Medication Error, Adverse Drug Event, Adverse Drug Reaction

Adopted from: Expert Group on Safe Medication Practices (P_SP_PH/SAFE). Creation of a better medication safety culture in Europe: Building up safe medication practices [Internet]. Council of Europe 2006 [cited 2018 May 31]. Available from: https://www.edqm.eu/medias/fichiers/Report_2006.pdf

The incidence of ADEs has been extensively studied in the US. The results showed that about 5.7% of inpatients were affected by ADEs and about 2.4% to 6.7% of hospital admissions were due to ADEs.[1] The main risk factors for ADEs were the dosage and the route of administration (Evans et al, 2005). Eichenberger (2009) found that the main risk factors for DRPs are potential drug-drug interactions. The analysis of data from regional pharmacovigilance centres in Germany showed a frequency of 3.25% for hospitalisation due to ADEs in outpatients (Rottenkolber et al, 2011).

1.3. Definition of Medication Errors

There is inconsistency and no common agreement of the ME definition (Ferner and Aronson, 2006). Some definitions limit MEs only to a particular part of the medication use process (Baker et al, 2002) or limit the clinical outcomes that could be caused by errors (Dean et al, 2000), while others are ambiguous and unclear (Kaushal et al, 2001).[10,11] Ferner and Aronson (2006) proposed a definition which is accepted and adopted by the Australian Council for Safety and Quality in Health Care as well as examined with a superior result to other ME definitions (Yu et al, 2005): "*A medication error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient.*" Ferner and Aronson (2006) understand the term "*treatment process*" also known as medication use process, collectively as diagnosis, prescribing, dispensing, patient adherence or application and follow up or monitoring of a drug. The most common agreement of all these definitions is that MEs are preventable and could be avoided to some extent (Dean et al, 2000; Barker et al, 2002; Ferner, 2012).

1.3.1. Categorisation of Medication Errors

Reason (2000) divides MEs into two approaches, the "*person approach*" which sees errors as a result of insecure actions from an individual's carelessness, low motivation,

[10] ASHP guidelines on preventing medication error reduction in hospitals. [Internet] ASHP 2018 [cited 2018 May 31]. Available from: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-hospitals.ashx?la=en&hash=CFDD375E109297517C3CB96BDADE7B0D59E2560A

[11] National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP). About Medication Errors What is a Medication Error? [Internet]. NCCMERP 2017 [cited 2018 May 31]. Available from: http://www.nccmerp.org/about-medication-errors

ignorance or inexperience and the "*system approach*", which is understood as errors resulting from problems that arise under the aspect of workplace deficits within the work organisation.

MEs have been classified into three stages: (1) a degree of harm caused stage, (2) a psychological approach stage and in (3) a therapy management stage.

The degree of harm caused, classifies MEs into; no harm caused, low harm caused, moderate harm caused, severe harm caused and death.[12]

A psychological approach of medication errors considers two types: mistakes and skill-based errors (Ferner and Aronson, 2006). Ferner and Aronson's (2006) types of ME categories can be further divided into four classifications (Figure 1.2).

Knowledge-based errors can be understood as, general, specific, or expert based errors. As an example, general knowledge is to know that penicillin can cause allergic reactions. To know that the patient has an allergy to penicillin would be specific knowledge. The knowledge that Co-amoxiclav would cause an allergic reaction, in case the patient has an allergy is expert knowledge. Not being aware of any of these facts would be a knowledge-based error. A rule-based error can be understood as an incorrect application of a good rule or as a failure to apply a good rule and applying a bad rule instead. An action-based error is defined as "*the performance of an action that was not*

[12] National Patient Safety Agency (NPSA). The fourth report from the Patient Safety Observatory, Safety in doses: medication safety incidents in the NHS [Internet]. NPSA 2007 [Cited 2018 May 31]. Available from: http://www.nrls.npsa.nhs.uk/EasySiteWeb/getresource.axd?AssetID=61392

what was intended" (Norman, 1981). A slip is when a medical practitioner intends to prescribe amlodipine but instead writes amitryptiline.

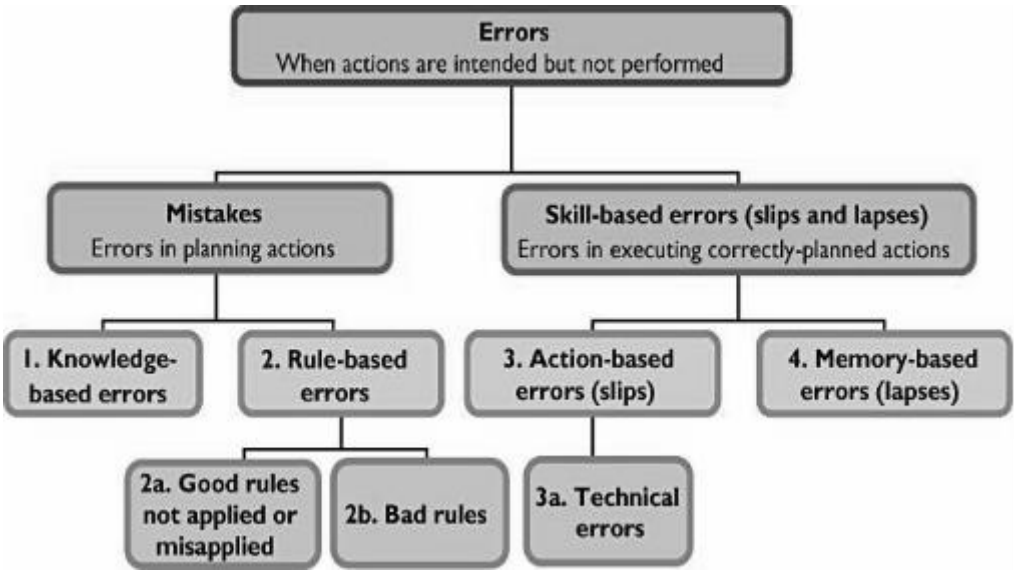

Figure 1.2: The Classification of Medication Errors based on a Psychological Approach
Adopted from: Ferner RE, Aronson JK. Clarification of terminology in medication errors. Drug Safety. 2006: 29(11): 1011-1022.

Technical errors are a part of action-based errors. Technical errors have been defined as occurring when "*an outcome fails to occur, or the wrong outcome is produced because the execution of an action was imperfect*" (Runciman et al, 1993). An example is the addition to an infusion bottle of the wrong amount of drug (Ferner et al, 2001). Memory-based errors occur when something is forgotten. An example for this would be when a medical practitioner prescribes penicillin to a patient, with the knowledge that the patient has an allergy, but forgot to remember.

The therapy management stage of MEs can be understood as MEs in the medication use process. Figure 1.3 shows an example of a medication use process or in this case a medication use cycle.[13] In each of the four main stages of this process, diagnosis, prescribing, dispensing, and patient adherence, MEs can occur that could cause harm to the patient, lead to inappropriate medication use or have the potential to do so (van den Bemt et al, 2007).

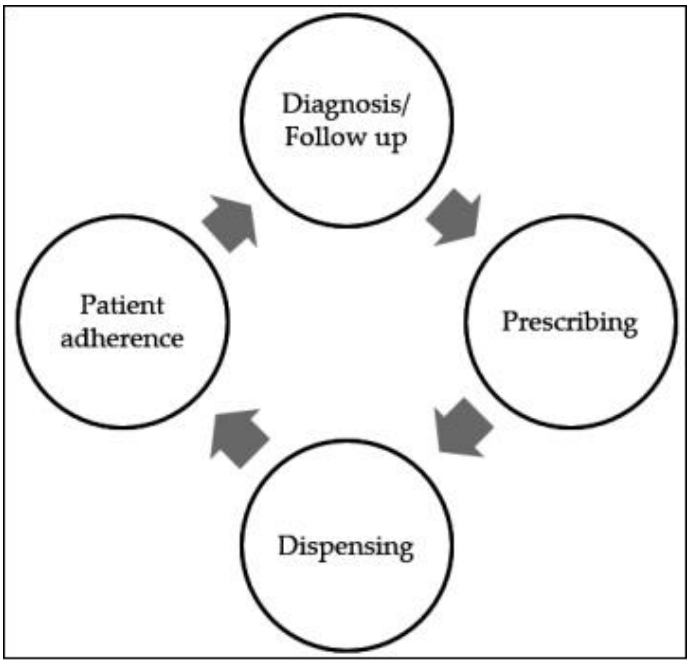

Figure 1.3: Cycle of the Medication Use Process
Adopted from: Management Sciences for Health. Managing for rational medicine use. MDS-3-Managing Access to Medicines and Health Technologies. [Internet] MSH 2012 [cited 2018 May 31]. Available from: https://www.msh.org/sites/msh.org/files/mds3-ch27-rationaluse-mar2012.pdf

A diagnosis involves the medical practitioner to identify the disease of the patient that needs a treatment. If the wrong problem is diagnosed, for example the wrong disease, the effect would be a subsequent use of the wrong treatment and a wrong drug would

[13] Management Sciences for Health. Managing for rational medicine use. MDS-3-Managing Access to Medicines and Health Technologies. [Internet] MSH 2012 [cited 2018 May 31]. Available from: https://www.msh.org/sites/msh.org/files/mds3-ch27-rationaluse-mar2012.pdf

be prescribed accordingly. Patients receive their prescribed drugs and are expected to take them according to their pharmacist guidance. Ways of inappropriate medication use according to the working papers of the former Finnish National Research and Development Centre for Welfare and Health Stakes and Rohto (2006)[14] are illustrated in Figure 1.4.

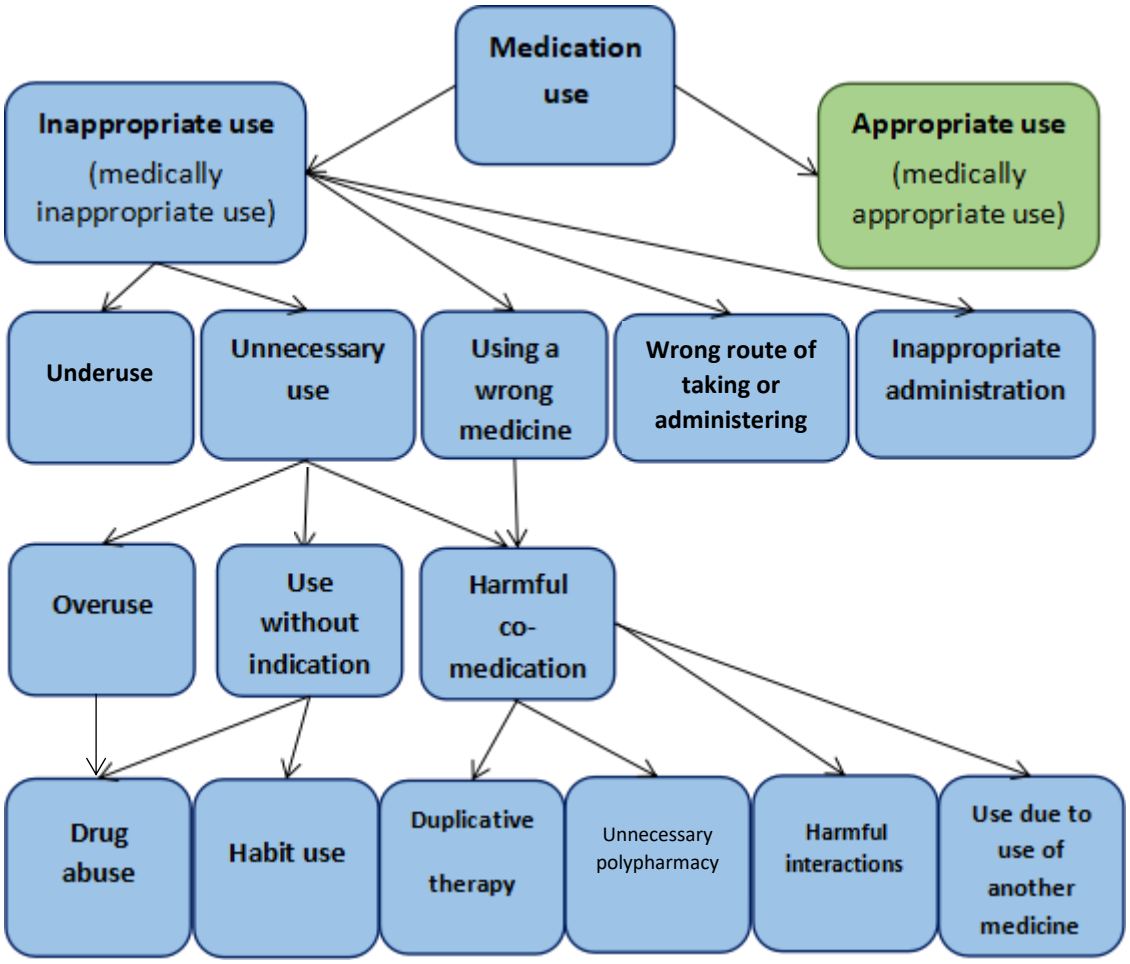

Figure 1.4: Drug-Related Problems can Occur for many Reasons during the Medication Use Process

Adopted from: Stakes & Rohto. Patient safety and safe pharmacotherapy glossary [Internet] National Research and Development Centre for Welfare and Health 28/2006 [cited 2018 May 31] Available from: http://www.stakes.fi/verkkojulkaisut/tyopaperit/T28-2006-VERKKO.pdf

[14] Stakes & Rohto. Patient safety and safe pharmacotherapy glossary [Internet] National Research and Development Centre for Welfare and Health 28/2006 [cited 2018 May 31]
Available from http://www.stakes.fi/verkkojulkaisut/tyopaperit/T28-2006-VERKKO.pdf

Leape and colleagues (1995) quantified MEs during the medication use process. The most frequent errors occurred with 39% in handwritten prescriptions, followed by application (38%), transmission (12%) and preparation of drugs (11%).

The risk to commit these kinds of errors are not completely avoidable but can be reduced by error detection and appropriate preventive measures (van den Bemt et al, 2000) which can also be understood as drug therapy safety measures. An example of a prevention measure is the systematic collection and analysis of critical and adverse events. Critical Incident Reporting Systems (CIRS) have been implemented in hospital settings, according to reporting systems in the aviation industry (Hoffman et al, 2008; Petschnig and Haslinger-Bauman, 2017).

1.4. Pharmaceutical Care

The term "*pharmaceutical care*" was defined by Hepler and Strand (1990) as "*The responsible provision of drug therapy for the purpose of achieving defined outcomes that improve a patient's quality of life*". Strand (1997) concreted this definition, by stating that pharmaceutical care is a "*working metho*d" in pharmacy practice. The pharmacist takes responsibility for DRPs, the needs of the patient and is jointly responsible for the development and implementation of medical / pharmaceutical solutions (Strand, 1997). The PCNE defined pharmaceutical care in 2013 as "*the pharmacist's contribution to the care of individuals in order to optimise medicines use and improve health outcomes*" (Alleman et al, 2014). Medical practitioners and pharmacists are equally responsible for the outcome of the drug therapy. The active role of the pharmacist is essential for achieving the desired therapeutic goals. The WHO defines the roles of a pharmacist in

their "*Good Pharmacy Practice*" guidelines.[15] Common roles for pharmacists concerning the guidelines are the preparation and dispensing of drugs, the improvement of the professional performance and the improvement of the effectiveness of the health care system. One additional role defined by the WHO guidelines is to provide effective medication therapy management (MTM) which reflects Strand's (1997) definition of pharmaceutical care, where pharmacists are co-responsible for the drug therapy. MTM activities are built upon the philosophy of pharmaceutical care. Core elements of a MTM are the assessment of the patient health status, the management of the patients' drug therapy, monitoring of the outcome and information providing concerning drugs and health-related issues. [16] The WHO guidelines are a recommendation to national pharmacy profession associations that are responsible to determine the role and the scope of the profession. The scope of practice of the pharmacists differs sometimes to a large extent among countries. In some constitutional states, pharmacists are able to participate only to certain areas of the medication use process (for example only dispensing), in others they have more access to a broader spectrum of activities, such as diagnosis or prescribing which could make activities of the MTM more convenient for pharmacists (Shah, 2009).

[15] World Health Organization(WHO). Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services [Internet] WHO 2011 [cited 2018 May 31]. Available from: http://www.who.int/medicines/areas/quality_safety/quality_assurance/FIPWHOGuidelinesGoodPharmacyPracticeTRS961Annex8.pdf

[16] American Pharmacists Association. National Association of Chain Drug Stores Foundation. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2.0) [Internet]. J Am Pharm Assoc 2003. [cited 2018 May 31]. Available from: https://www.pharmacist.com/sites/default/files/files/core_elements_of_an_mtm_practice.pdf

1.5. Drug-Related Problems Classification Systems

DRPs are a part of a patient's health-related problem that affect the effectiveness of their drug therapy. To identify, to solve and to prevent DRPs are a main focus in pharmaceutical care or MTM. To describe and evaluate pharmaceutical care activities to prevent DRPs, the documentation of the DRPs is an important process parameter (Kirwin et al, 2012).[17] The classification of DRPs is essential for the development of pharmaceutical care / MTM and the research in this area and has to be considered as an important part of the care process (Schaefer, 2002; van Mil et al, 2004). This led to the development of standardised DRP classification systems.

1.5.1. Hepler & Strand Classification

Strand et al (1990) published a landmark article on the first classifications of DRPs. The Hepler & Strand classification is a simple scheme containing eight types of DRPs and has been the foundation of pharmaceutical care and the newer DRP classifications. DRPs are classified as, untreated indications, improper drug selection, sub-therapeutic dosage, failure to receive drugs over dosage, adverse reactions, drug interactions and drug use without indication (Strand et al, 1990).

[17] American College of Clinical Pharmacy. Standards of Practice for Clinical Pharmacists [Internet] ACCP 2014 [cited 2018 May 31] Available from: https://www.accp.com/docs/positions/guidelines/standardsofpractice.pdf

1.5.2. Pharmaceutical Care Network Europe Classification

The PCNE classification has been developed for the study of DRPs, as well as a leading indicator of pharmaceutical care / MTM activities in experimental studies (van Mil et al, 2004). The classification includes six main categories for the assessment of the problem (for example dosage, interaction), six main categories for the cause (for example application, logistics), and five main categories for the level of intervention (for example medical practitioner, patient, drug). The PCNE classification also offers the possibility to code the result of the intervention. An investigation by Hohmann et al. (2004) has been shown that the PCNE classification for the detection of DRPs in hospitals is of limited use, as only a very small proportion of the problems could be detected with this classification system. Important categories of interventions and DRPs for inpatients, such as incompatibility, incorrect preparation, lack of preoperative break or lack of laboratory control cannot be clearly documented.

1.5.3. PI-Doc® Classification

The PI-Doc® system was developed for outpatients in Germany. It allows the documentation of DRPs and interventions. The categories for the classification of DRPs are designed exclusively for the private sector or community pharmacies and include incomplete prescriptions, double prescriptions and missing or wrong dosage, as an example. Important categories for the occurrence of DRPs for inpatients, such as transmission errors, incorrect preparation or mode of administration, are not integrated. Likewise, as a participating HCP group, nurses are missing. A modified PI-

Doc® system, which included new subcategories for hospital specific problems, was published in 2007 by Ganso et al (2007).

1.6. Contribution of Pharmaceutical Care in the Medication Use Process

The use of drugs is always associated with risks, so drug therapy is often referred to as a high-risk process (Grandt et al, 2005). In most cases, the benefit outweighs the risk. For this reason, it is important that the patient is informed about possible risks. Drug therapy safety can be improved by sensitising patients to the risks of drug therapy and their own responsibility for risk minimisation. Through education and counselling sessions on the importance of the correct drug use, patient compliance can be significantly supported and improved. In addition to medical practitioners and nurses, community pharmacists can also make an important contribution (Mowitz, 2010). Switzerland and the United Kingdom (UK) established models for community pharmacies to increase drug therapy safety by increasing information flow about drugs and by detection of problems related to drugs. In Switzerland a service to increase patient's adherence has been offered since 2010 to patients taking more than four drugs (Messerli and Hersberger, 2012).[18] This service is called Poly Medication Check (PMC) and its implementation in community pharmacy practice is remunerated by the government, which creates incentives for improved consultations and patient care by the community pharmacy.[18]

[18] Polymedikations-Check (PMC) [Internet]. Pharmasuisse 2018. [cited 2018 May 31]. Available from: http://www.pharmasuisse.org/de/1192/Polymedikations-Check.htm

In the UK the Medicines Use Review (MUR) service has been offered by community pharmacies as an additional service since 2005. This form of medication review is for patients who are taking high-risk medicines, such as anticoagulants, or who have recently been discharged from hospital with newly prescribed medicines. The patient's support and motivation to use the service of community pharmacies should increase the effectiveness of drug therapy and save healthcare costs.[19]

The examples in Switzerland and the UK shows that the community pharmacy has the potential to contribute to the increase of patients' drug therapy safety. In the high-risk process of drug therapy, the community pharmacy can act as a safety barrier (Scharpf et al, 2012). This is illustrated in the example of the Swiss-cheese model (Figure 1.5).

Every single slice of cheese stands for a possible safety barrier (for example medical practitioners, nurses, community pharmacists, electronic prescribing systems, patients). Every hole in the slices is a loophole in the safety barriers, such as a distraction of a medical practitioner in the writing process of a prescription that causes a prescribing error or a poor pharmaceutical intervention to detect and eradicate the error on the prescription which would cause a dispensing error. An erroneous prescription as a risk does not necessarily reach the patient in the form of an ADE, as it can be detected and corrected early by the medical practitioners, the pharmacists or the patients.

[19] Guidance on the Medicines Use Review service October 2013 [Internet] NHS Employers 2013 [cited 2018 May 31]. Available from: http://www.nhsemployers.org/~/media/Employers/Documents/Primary%20care%20contracts/Pharmacy/MUR%20Guidance.pdf

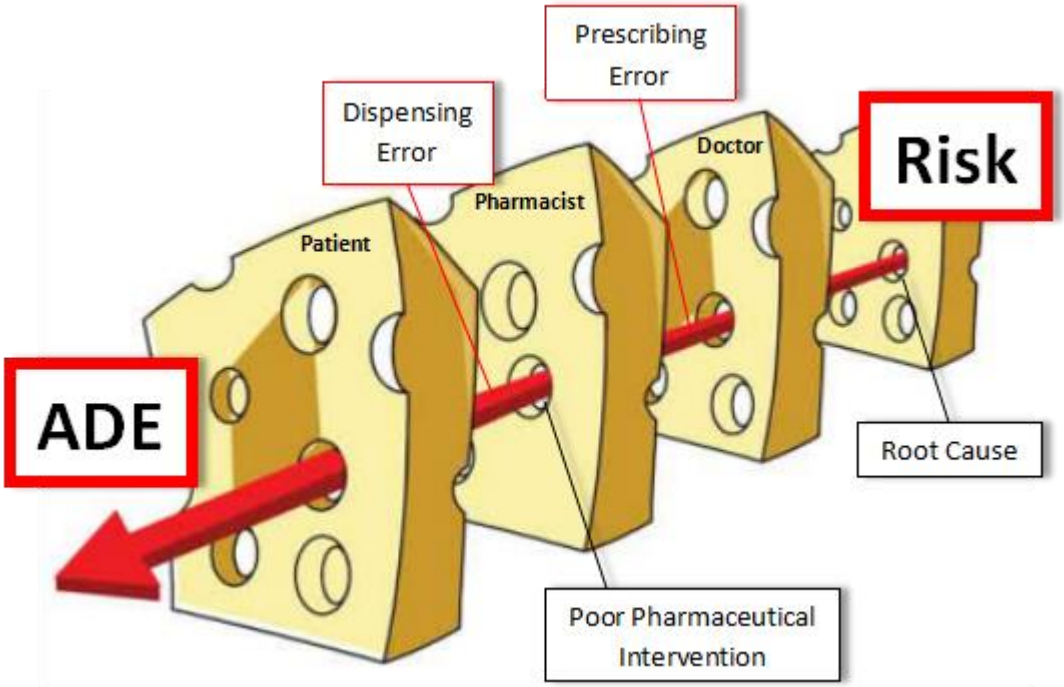

Figure 1.5: Swiss-Cheese Model
Adopted from: Reason J. Human errors: models and management. *BMJ* 2000; 320: 768-70.

The personal contact and intensive discussion with patients to eradicate potential errors are of particular importance. The community pharmacy setting gives the possibility to clarify ambiguities as well as problems with drug therapies during a patient consultation (van Mil et al, 2001). The fact that patient-oriented interventions in community pharmacies can increase drug therapy safety has already been demonstrated in studies on the detection and prevention of DRPs (Hämmerlein et al, 2007; Lewinski et al, 2010).

1.7. Development and Use of Risk Management in the Medication Process

Risk management was initially developed in industries with complex work processes or production processes that were very error-prone, such as in aviation or in the automotive industry. In aviation, risk management methods have evolved to reduce the risk of errors. Since complex processes are involved, the demand for maximum safety, the interaction of 'man and machine', teamwork and the constant high level of competence to work, are required. The basis of the methods is not to focus on personal failures or to sanction an individual person, but to analyse relevant processes and the interaction with each other in order to be able to identify and to eliminate organisational, technical or social vulnerabilities (Führing and Gausmann, 2004).

Risks are manifold and must be considered as such, but the human factor is still to be considered as the biggest risk. Examples include work overload, poor training and resulting lack of knowledge, as well as communication and documentation deficiencies. The guarantee to operate without errors is not possible. Table 1.1 shows an examples of human error rates according to Nolan (2000).

Table 1.1: Human Error Rates of Selected Activities
Adopted from: Nolan TW. System changes to improve patient safety. *BMJ*. 2000; 320(7237): 771–773

Activity (Unless otherwise indicated, assumes the activities are performed under no undue time pressures or stress)	**Probability of human error** (% of errors / % of opportunities for the error)
General error of commission - for example, misreading a label	0.3%
General error of omission in the absence of reminders	1.0%
Simple arithmetic errors with self-checking but without repeating the calculation on another sheet of paper	3.0%
Monitor or inspector fails to recognise an error	10.0%
Staff on different shifts fail to check hardware condition unless required by checklist or written directive	10.0%
General error rate given very high stress levels where dangerous activities are occurring rapidly	25.0%

The basis of risk management methods in aviation is the regular reporting of occurrences. In 1982, the US National Transportation Safety Board recorded and evaluated 46,000 incidents and accidents. These measures optimised the American flight safety standards (Helmreich, 2000).

The aviation industry shows similarities to the healthcare industry. The characteristics, such as complex work processes, the demand for maximum safety, the interaction of 'man and machine', teamwork and the level of competence are directly transferable to human health activities, such as they are found in the medication use process (Helmreich, 2000; Ricci, 2012; Neuhaus, 2016). Other high-risk industries, which are very technologically oriented with a focus on the production process differ concerning the

similarity to the healthcare industry. In both areas, aviation and healthcare the human is the service provider and errors may have fatal consequences. Not only material consequences are to be expected as a result of errors, but in many cases the consequence is the damage or the death of a person. These intangible consequences increase the need for safety in both areas and highlight why healthcare has been trying to implement the experiences from the aviation (Führing and Gausmann, 2004).

1.8. Risk Management Process

The term "*risk management*" can be understood as "*a comprehensive approach of systematically dealing with errors and threats that are faced by an organisation*" (Gausman, 2007). The approach is the monitoring and controlling of all risks that are threatening a system (Kromschröder and Lück, 1998; Burger and Buchhart, 2002). The International Organisation for Standardisation (ISO) defines risk management in a similar way, as a process that coordinates activities and efforts to direct and control an organisation or system with regard to risk.[20] In the risk management process, potential risks in a system should be identified, analysed and evaluated and eventually modified or eliminated. The measures that are chosen must be constantly reviewed to ensure whether the intended goals are met (Gausmann, 2007). Figure 1.6 shows the risk management process.

[20] International Organization for Standardization. ISO 31000:2009 Risk Management Standard - Principles and Guidelines [Internet]. ISO 2009 [cited 2018 May 31]. Available from: https://www.iso.org/iso-31000-risk-management.html

Figure 1.6: Risk Management Process
Adopted from: Gausmann P. Risikomanagement und geplante Behandlungspfade. In: von Eiff (ed.), Schriftenreihe Gesundheitswirtschaft, Band 2, Risikomanagement – Kosten- /Nutzen-basierte Entscheidungen im Krankenhaus, Wegscheid: WIKOM Verlag; 2007. p.200-213.

This process can be understood as continuous and must be carried out on a regular basis. Insights that are gained from monitoring the risk can be directly included in the identification and evaluation step. This leads to a closed control cycle of the risk management process and can optimise the risk situation of an organisation (Burger and Buchhart, 2002). The process begins with the identification of a risk which is followed by the evaluation of a risk. These two steps can be understood as 'plan' phase. The '*do*' phase is the management of the identified and evaluated risks, followed by the monitoring of the managing process to ensure the right outcomes which is considered as the 'check' phase. The cycle closes with the 'act' phase by identifying further actions that are needed and that were resulting from the monitoring step. The integrated plan-

do-check-act cycle (PDCA) (Deming, 1986) acts as an aid to understand which questions to ask or where to start in the process (Schmidt and Finnigan 1993; Joiner 1994).

1.8.1. Culture of Errors

The handling of errors in the system must be clarified to be able to operate a well-functioning risk management process. An error culture is part of every social system or evolves over time from an existing culture. This includes the way the members of the system deal with, view and evaluate errors. This procedure happens unconsciously. Members of social systems develop a certain way of behaving and observing, which is a characteristic of the prevailing error culture and at the same time shapes the entire system. Other social systems such as families for example have their own error culture. The culture of mistakes which exists in a system is determined by its members and the structure of the system (Heimerl et al, 2008). The “Culture of Blame” should be avoided. It can be described as a system behaviour that as soon as an error occurs, a guilty party is sought, named and punished, and the error itself stays not being assessed and measures to prevent the same error from occurring in the future are not being analysed (Schüttelkopf, 2018). It is crucial to deal with the people who make mistakes, blaming has an absolutely negative impact. It should rather start from the question “how to prevent this error from occurring?” The most important and effective mean is the communication among participants in the system (Schüttelkopf, 2018). In the course of risk management, the culture of error should be analysed, an awareness of error should be created, mistakes avoided and communicated in a respectful manner, instead of blaming members of the system.

1.8.2. Definition of the Context

The first step of the risk management process is the definition of the context. On an organisational level, the framework of the process, the resources, roles and responsibilities need to be determined. External influences must be considered and stakeholder's expectations and legal regulations also similarly shape the aims of the risk management process. In order to measure the performance of the processes, quantitative approaches using key indices (for example accident rates) can be used. To reach a high level of effectiveness, clear responsibilities and system limits are a crucial part of the process, independently if it is a single activity or a larger project. Inconsistencies in responsibilities can lead to undetected risks. In order to compare the different risks to each other, the criteria to evaluate them must be determined including the dimension of these criteria. Severity for example, might not be measured in the same dimension for a pharmaceutical supplier as for an aviation enterprise. Once the measure of comparison is defined, limits of acceptability are set before the risk assessment takes place, in order to have an objective tool for decisions, the limits of acceptability are necessary for the defined system.

1.8.3. Risk Identification

The first step of the risk assessment process begins with the identification of possible risks. Most systematic risk assessment techniques differ in their method on how to identify risks. The methods can be classified as: regressive, progressive, quantitative and qualitative approaches (Middendorf, 2007). Table 1.2 lists risk identification methods.

Table 1.2: Classification of Risk Identification Methods
Adopted from: Middendorf C. Aufgaben, Inhalte und Ansatzpunkte des Risikomanagements. In: von Eiff (ed.) *Risikomanagement: Kosten-/Nutzenbasierte Entscheidungen im Krankenhaus.* Wegscheid: WIKOM GmbH; 2007. p.58-81.

Method	Regressive method	Analytical method (progressive)
Quantitative	measurements	predictions
Qualitative	reports	prospects

Regressive methods examine risks that already occurred in the past. The methods are called regressive because they refer to already completed events. These methods allow obtaining more detailed information on the course and circumstances of an event, so that similar situations can be avoided in the future. Analytical methods try to detect risks in the stage in which they did not yet occur and can still be modified. A quantitative risk identification approach attempts to derive risks based on existing data by analysing literature. This approach can be considered as deductive. A qualitative approach aims to identify risk situations using subjective, experience-based assessments, such as through interviews or expert surveys (Middendorf, 2007).

All mentioned systematic methods rely on information. According to Middendorf (2007), the following five information sources are relevant for a comprehensive overview of a risk situation:

i. Analysis of internal documents and information systems
ii. Survey of individuals in the field
iii. Process analysis
iv. Analysis of incidents and near misses
v. External data and experts

A complete identification of all possible risks in a system is not realistic, independently of which method is applied. Reasons for this are random effects (aleatoric uncertainty), lack of knowledge (epistemic uncertainty), or influences from outside the studied system (Aven, 2011). Unidentified risks decrease the significance of a risk assessment and should be eliminated as much as possible (Holzer, 2005).

1.8.4. Risk Analysis

The aim of the risk analysis step is to understand the risk and to estimate its magnitude. This includes the rating of each risk according to predefined criteria, which could be for example severity, probability or detectability. These criteria involve a certain amount of uncertainty. The rating of severity for example can be determined in various ways, depending on the assumed consequences. It has to be clearly defined, if the worst-case scenarios or the most probable consequence is assumed for this rating. These considerations must be followed for all risks, otherwise their comparison is biased.

Additionally, the already applied corrective measures for a risk must be known in order to analyse the risk correctly. Once the hazards are described with the predefined criteria, the risk estimation takes place. To compare the risks, a common risk scale needs to be established for this step. This can be achieved using quantitative approaches (for example probability values as risk dimension), semi-quantitative approaches such as risk values on a predefined scale or qualitative approaches.

1.8.4.1. Methods and Tools for Risk Analysis

The next sections will introduce some methods that can be used to identify and analyse risks. These different methods are based on different high-risk industries such as the aviation industry (von Eiff, 2007).

1.8.4.2. Critical Incident Reporting

Critical Incident Reporting (CIR) is understood as a system-related collection of critical incidents with the aim of systematic processing and future avoidance of errors, sources of error and risks (von Heusinger and Schenkel-Häger, 2007). Near misses are important early warning indicators that help to reduce or avoid serious incidents in advance (Edmonson, 2004; Ahluwalia and Marriott, 2005; Hennke, 2009). Participants should collect near misses or adverse events through a central reporting system in order to establish a risk report to consequently reduce individual risks with training (Colvin, 2011). Incidents are often under-reported or vary in the quality of information obtained

(Noble and Pronovost, 2010), so that data from the CIRS alone may not be sufficient in identifying all risks.

1.8.4.3. Root Cause Analysis

The Root Cause Analysis (RCA) is a retrospective research process, developed to identify causes and contributing factors of an adverse event. As the CIR gathers the potential risks, the RCA complements it, trying to identify causes of the problem. The aim of the RCA is to obtain an understanding of the cause that leads to an adverse event and additionally prevent its recurrence (Jensen, 2004). The RCA is able to reveal the causality of adverse events, but the nature of the study is very labour intensive (Shojania et al., 2001). Moreover, due to its retrospective focus on results, it is limited because the problem under investigation has already occurred. Retrospect is the tendency for people to falsely believe that the measures that should have been taken to avoid an incident are obvious once all the facts are clear (National Patient Safety Agency, 2008). Outcome bias is the tendency to judge a past decision or action by its success or failure, rather than relying on the quality of the decisions made at that time (National Patient Safety Agency, 2008). Review and distortion of results may lead to misinterpretation of the findings in a retrospective study. Since RCA essentially involves case studies of very unpredictable events, it is difficult to know whether the root cause identified by the analysis is indeed the cause of the incident (Shojania et al, 2001).

1.8.4.4. Failure Mode and Effect Analysis

The failure mode and effect analysis (FMEA) is a systematic bottom-up process for identifying potential process failures before they occur. It is a tool, based on principles of reliability engineering, that is used to identify and assess potential failure modes in products, processes and systems (Habraken et al, 2009). Failure mode is defined as the different ways that a particular process or sub process step can fail to accomplish its intended purpose. For example, if the sub-process step is confirming known drug allergies with patient, then failure modes would include: (1) not recording drug allergies and (2) incompletely capturing drug allergies (DeRosier and Stalhandske, 2002). FMEA intends to (Crane, 2006):

i. Recognise and evaluate the potential failures of a process and the effects of those failures
ii. Identify actions that could eliminate or reduce the chance of the potential failures occurring
iii. Document the process flow

The components of an FMEA include the identification of potential failure modes, to identify the possible effects for each failure mode, conducting a root-cause analysis for the most critical effects, testing and implementing risk reduction strategies and monitoring the effect of actions taken to reduce the risk of failures. When analysing the possible effects for each identified failure mode, scores from one to ten, from low to high-risk, are assigned to each of the two variables (severity and probability). Severity refers to the seriousness of the patient outcome as a result of the failure modes.

Probability refers to how likely it is that the failure would occur. The product (severity X probability) of the two variables would yield a 'Risk Priority Number' (RPN) (Figure 1.7) for a particular failure mode, which can help to identify and prioritise potential failures that are most critical or that may need attention immediately by sorting from failure modes with the highest RPN to the lowest RPN.

Severity					
	Catastrophic (4)	**16**	**12**	**8**	**4**
	Major (3)	**12**	**9**	**6**	**3**
	Moderate (2)	**8**	**6**	**4**	**2**
	Minor (1)	**4**	**3**	**2**	**1**
		Frequent (4)	**Occasional (3)**	**Uncommon (2)**	**Remote (1)**
		Probability			

Figure 1.7: Calculation of the Risk Priority Number
The 'Risk Priority Number' (RPN) is calculated by multiplying the risk probability of occurrence and severity of consequences

1.8.6. Risk Evaluation

Risk evaluation is the last step of the risk assessment process. In this step, decisions are made about how to deal with the specific risks. A basic question needs to be answered for every single risk: "*Is it necessary to treat this risk?*" A risk does not necessarily need to be treated, accepting it might be an option as well. Whether it is treated or not, cannot be answered by the analyst alone, the board of an institution needs to be involved as well. Usually, acceptability levels are set independently from a single analysis when defining the context of the risk management process (Middendorf, 2007).

1.8.7. Risk Treatment

As a result of the risk assessment procedure, priorities are set in which order the different risks need to be treated. As a next step of the risk management process, possible corrective measures are identified and the resources for risk treatment are allocated. When the decision is made to treat a risk, possible corrective measures must be determined and evaluated. How numerous the alternatives of measures are, depends very much on the moment at which the risk assessment is carried out. If the assessment is done at an early stage, different alternatives exist compared to a late assessment. Usually, prevention of an accident is more favourable than the protection from possible consequences. Corrective measures try to influence one factor contributing to the risk, for example decreasing the probability or reducing the severity of an unwanted event. A systematic determination of the factors can be achieved by the Strategical, Technical, Organizational and Personal (STOP) approach. Once the alternatives for all risks are found, the allocation of the resources is done. A common

approach to do so is to decide based on the risk scores and reduce the most important risks present (Middendorf, 2007). A risk reduction only based on risk scores does not lead to ideal results. Financial concerns need to be considered as well to have an optimal resource allocation (Aven, 2011). Additionally, the risk reduction potential of every corrective measure can be considered to reach a better allocation of measures (Cox, 2012). Other approaches are using optimization algorithms to achieve an optimal resource allocation (Reniers and Sörensen, 2013).

1.8.8. Risk Control

In order to ensure that the corrective measures are effective and efficient, they must be controlled regularly. This includes obtaining further information about the hazard, the risk, and the control itself. This information can improve further risk assessments and show if the measure works as intended. Accident data and especially near misses are of high importance to do so. The results must be periodically analysed, and the insights recorded in a systematic way (Middendorf, 2007).

1.8.9. Risk Documentation

Risk documentation is a central element in the iterative risk management process. On one side, the documentation is necessary for giving information to all roles involved in the process. This includes all the details of the evaluation and the action plan to implement corrective measures. On the other side, an effective documentation helps to

re-use information for future analyses, training, and helps keeping track of costs and efforts (Middendorf, 2007).

1.8.10. Risk Communication

Risk communication is of high importance for every risk management approach and has a superior function. By communicating evaluation results to all the involved roles, it helps them to understand the decisions made and to include the expertise of all stakeholders. The communication is not only limited to the distribution of information, but also allows external knowledge to influence the context of a risk management approach (Middendorf, 2007).

1.9. Rationale of this Study

Approaches to continuous risk management have been established in industries such as the aviation industry for several years. The central element is a continuous cycle that includes the identification and characterisation of risks, the implementation of risk minimisation measures and monitoring measures.[21] The established pharmacovigilance systems in several European Union (EU) countries include all these elements, but so far, the focus has been on identifying ADRs in terms of regulatory decisions. A systematic

[21] EU: Volume 9 A of the rules governing medicinal products in the European Union – Guidelines on pharmacovigilance for medicinal products for human use [Internet] EC 2008 [cited 2018 May 31]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-9/pdf/vol9a_09-2008_en.pdf

implementation of the risk management cycle to the medication use process, from the medical diagnosis to the dispensing of the drugs in the community pharmacy, to identify and minimise ADEs is desirable and could not only lead to improved morbidity and mortality rates, but also to lower expenditures in the health sector.

1.10. Aims and Objectives

The first aim of this research study was to identify and analyse the current status of root causes that have the potential to lead to erroneous medical prescriptions and to suboptimal community pharmacists' intervention. The second aim was to analyse the risk potential that can arise from errors on medical prescriptions. The study was undertaken in Malta and Germany. The scenario selected for this research focused on the perception of medical practitioners and community pharmacists towards prescribing errors in Malta and Germany. The objectives were to:

i. Interview medical practitioners to identify root causes and prescribing errors
ii. Develop and validate two questionnaires, one for medical practitioners and one for pharmacists to assess the current status of root causes, their perception on the risk of prescribing errors and the role of the community pharmacists to intervene in prescribing error situations
iii. Calculate the magnitude of the prescribing error risk, ranked by medical practitioners and community pharmacist

CHAPTER TWO

METHODOLOGY

2.1. Study Design

The research study was divided into four phases (Figure 2.1). Phase one of the study consisted of the qualitative aspect to identify root causes and prescribing errors, interviews with medical practitioners and extensive literature review. The interviews were conducted, especially for the identification of root causes in the medication use process that have the potential to lead to prescribing errors in Malta and in Germany. Phase two included the development of a questionnaire. Findings from the interviews together with the literature review helped to establish questions for the questionnaire intended for medical practitioners and community pharmacists. The questionnaire consisted of three sections; analysis of the status quo of prescribing error root causes and reduced pharmacist error detection root causes, a risk analysis of prescribing errors with the help of probability and severity scores and a capability analysis of pharmacist to intervene in case of an erogenous medical prescription. In phase three the questionnaire was validated and disseminated in Malta and Germany in phase four.

2.2. Identification of Root Causes, Potential Prescribing Errors and Pharmacist Interventions

A primary and secondary literature search was undertaken to understand and identify root causes in the prescribing process that could lead to prescribing errors, potential MEs in the medication use process and community pharmacist intervention strategies to reduce or prevent errors and root causes for a suboptimal intervention. Search terms that reflected

the topic of MEs, ADEs or DRPs were chosen by the researcher to conduct feasible search results. Sources for the review were electronic databases such as Hydi, PubMed and Google Scholar.

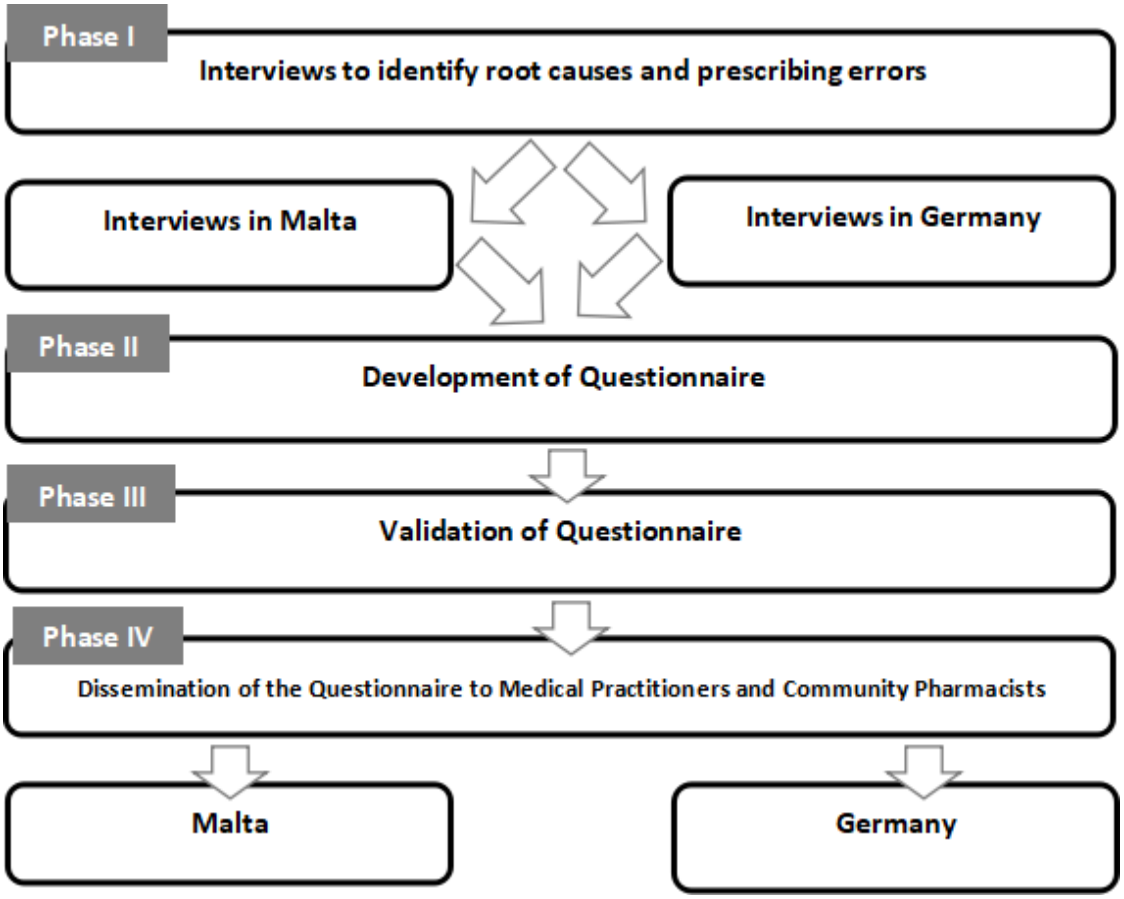

Figure 2.1: Study Design

2.3. Medical Practitioner Interviews for the Identification of Root Causes and Potential Prescribing Errors

Interviews with medical practitioners were conducted to identify and discuss root causes in the prescribing process and resulting prescribing errors. Interviews were chosen as part of

the method design to explore and to get a better understanding of error causes in the prescribing process that may lead to erroneous prescriptions, in private clinics and hospitals in Malta and in Germany.

A semi-structured interview type was chosen which, on the one hand, has a framework of interview themes to be explored, but on the other hand leaves the interviewer extensive freedom in the execution of the interview (Kühn and Witzel, 2000). This type of interviews encourages the interviewee to speak more openly and enables important topics that might not been mentioned or thought of by the interviewer to be addressed. The open questions guided the conversation to stay on track with the main aim and not to deviate from the topic. The possibility of a certain comparability among the same interviews is given with a semi-structured interview type (Harrell and Bradley, 2009).

After working on the theoretical foundations of qualitative research as well as interview techniques (Mayring, 2002; Flick et al, 2005; Kvale, 2007), themes were developed (Table 2.1) based on the study by Avery et al (2012).

2.3.1. Interview Sessions

A srandom sampling approach was chosen for medical practitioners in Malta and in Germany, to secure participation of practitioners from private clinics and hospitals. Medical practitioners were randomly chosen, personally visited and invited to participate in the interview. The inclusion criteria were that the participants must have a group of patients

that get their written prescription filled in a community pharmacy. A written information letter and consent form (Appendix 1) was prepared prior to the interview session. The interviews were audio-taped upon seeking participants permission.

Table 2.1 Main Themes Discussed in the Medical Practitioner Interviews

Main aim of the interview
Definitions of Drug Related Problems, Adverse Drug Events and Medication Errors
Background of interviewee
Process of prescribing in practitioner's office
Risk Management System for prescribing process
Knowledge of the patients
Knowledge of patient characteristics and medical background
Own therapeutic knowledge and prescribing skills
Usage of information sources and technologies
Working environment
Team factors that cause error
Individual factors that cause errors

Each interview lasted about 45 to 60 minutes and was conducted either in English or in German language. The researcher carried out the interviews in a closed room at the practitioner's premises during office hours between February and November 2017.

2.4. Health Care Professional Questionnaire to Analyse Root Causes, Prescribing Errors and Pharmacist Interventions

The scenario studied in this questionnaire was the rating of root causes that had the potential to lead to prescribing errors and root causes that reduce the pharmacist detection of prescribing errors. The prescribing error root causes were found in the conducted interviews with medical practitioners and the literature review. Root causes for reduced pharmacist's detection were found through literature review. Medical practitioners and community pharmacists were asked in this scenario to what extent they are exposed to the root causes mentioned in the questionnaires. The second scenario studied was the risk analysis of prescribing errors, caused by medical practitioners. The question asked for this scenario was '*How do medical practitioners and community pharmacists rank the probability and severity of potential prescribing errors?*' Pharmacists were asked to rate the prescribing errors from their own experience and medical practitioners were asked to rate the errors concerning general occurrences as they think the errors occur. The third scenario asked medical practitioners and pharmacists about the role and capability of community pharmacists, whether they are supportive and capable of preventing selected prescribing

errors on medical prescriptions. The three scenarios focused on medical practitioners' and the community pharmacists' perspective.

Two self-administered questionnaires were developed, one for medical practitioners and one for community pharmacists, both in English for Maltese participants and in German for their German counterparts. The questionnaires were entitled 'Prescribing Errors Questionnaire Medical Practitioners' (PEQ_{med}) and 'Prescribing Errors Questionnaire Pharmacists' (PEQ_{pharm}).

Besides the root causes found in the medical practitioner interviews, the following studies were compared with the interview findings and implemented in the later root cause rating part of the questionnaires (Landrigan et al, 2004; Li et al, 2004; Giampaolo and Pietro, 2009; Slight et al, 2013; Ryan et al, 2014; See et al, 2014). The main literature source for the prescribing errors were the work from Dean et al (2000) which provided the examples of prescribing errors that were used for the risk analysis process in this research. Interview findings from this study were implemented into the prescribing errors of Dean et al (2000).

2.5. Validation of the Prescribing Errors Questionnaire

A two-stage structured communication technique was used for the validation of both of the questionnaires to obtain the opinion of a panel of experts. Consensus methods such as the Delphi are used in clinical guideline development (Murphy et al, 1998) and are well accepted

methods to elicit feedback from experts in a specific field of interest (Hsu and Sandford, 2007).

2.5.1. Characteristics of the Validation Method

The applied validation method in this research has been strongly oriented to the Delphi technique. The Delphi technique is an iterative process (Mehr and Neumann, 1970) that attempts to build consensus and consistency of opinion from a group of experts regarding an area of interest or inquiry (Hsu and Sandford, 2007; Geist, 2010). It is based on the logic that "n heads are better than one" (Dalkey, 1969). This technique is particularly useful where opinions and judgements of experts are needed and when it is not possible to gather experts in one meeting (Hsu and Sandford, 2007). According to Linestone and Turoff (1975), structured communication techniques are methods that guarantee anonymity of the participants. The promise of anonymity enables participants to be open and truthful about their opinions on certain issues, which provides the researcher with insightful data (Keeney et al, 2010). Anonymity can reduce the likelihood of participants to be influenced by peer pressure or other extrinsic factors (Goodman, 1987), since anonymity is a means to reduce the influence of socially dominant individuals (Dalkey, 1969).

Panels for structured communication methods usually consists of 10 to 30 participants, but studies with groups of up to 100 participants have been conducted. Delbecq et al. (1975) mentions that if the group of participants is homogeneous, with similar characteristics, a group of 10 to 15 subjects would be sufficient.

2.5.2. Panel Selection for the Validation-Process

For the validation process of this questionnaire through a structured communication method, two main groups of HCPs (medical practitioners and pharmacists) were invited to participate. A statistician was involved with respect to the feasibility of the statistical analysis and a German translator was included to review the German translation as the questionnaire was originally developed in English and translated into German. Contact was made through personal invitation of the researcher by direct contact or via telephone. All experts agreed to participate.

A total of 16 heterogeneous experts participated: 4 Maltese medical practitioners (3 practitioners working in the hospital, 1 general practitioner working in a private clinic), 3 Maltese community pharmacists, 3 German medical practitioners (2 hospital practitioners, 1 private clinic practitioner), 4 German community pharmacists and 1 statistician and 1 translator of the German language.

2.5.3. Validation Method for the Questionnaire

The Validation method used in this research, contained two rounds before a consensus was reached. The first round was based on a five-point Likert scale questionnaire in which participants rated their level of agreement on the relevance of the particular question in context with the research topic. On a second five-point Likert scale the experts were asked to rate the structure, accuracy and clarity. Additional columns as an option for further comments or suggestions were given. The same participants were invited to take part in the

second round and one Maltese hospital medical practitioner refused to participate. Amendments were made for the second validation round, if the same comments were mentioned by at least three experts from round one and the same number for round two. The low number of three experts was chosen on the assumption that some participants could not consequently focus on the questionnaire because of their stressful working conditions which might mean that they would not observe important mistakes in the questionnaire. Any statement from a participant that was repeated by at least two others was therefore considered important.

2.6. Structure of the Questionnaires

The questionnaire was divided into four sections. Section I Demographics contained participants demographic details. Section II Root Cause Ranking quantified the identified root causes from the interviews and the literature. Section III Prescribing Errors Risk Analysis listed identified prescription errors which were part of the risk assessment and which were rated according to their probability of occurrence and severity of consequences. Section IV Role of the Community Pharmacist focused on the role of the community pharmacist in the medical use process and their error intervention abilities.

The questionnaires contained a combination of close-ended questions of the yes-no type, the multiple-choice type and the five-point Likert scale type where respondents could indicate their answers at the most appropriate point from a range from 0 (low score) to 4 (high score). Remarks could be made in a comment box below each question.

Section I: Demographics

This section included four multiple choice questions (MCQs) for the PEQ_{med}. The PEQ_{pharm} consisted of two MCQ and one yes-no question. Medical practitioners and community pharmacists were asked about their years of experience and their average working hours. Medical practitioners were asked about their speciality and their working institution. The PEQ_{pharm} consisted of a question, asking Pharmacists whether they accomplished some postgraduate education training in pharmacy practice.

Section II: Root Cause Ranking

The PEQ_{med} differed in two questions from the PEQ_{pharm} and additionally had one more question than the questionnaire for pharmacists. The section of the root causes ranking in the PEQ_{med} had twelve questions, ten were five-point Likert scale questions, two questions had to be answered with yes or no, with an additional close-ended part. The PEQ_{pharm} contained eleven questions, nine were identical to the PEQ_{med}. All of the questions were of the five-point Likert scale type. Question 5 to 8 in the PEQ_{med} were identical to question 4 to 7 in the PEQ_{pharm} and were related to the work environment. The participants were asked about the time period with their patients, interruption level during the consultation process and about their self-perception of stress and the work atmosphere. The following five questions in this section were prescriber-related and referred to the knowledge of the HCPs

about their patients, the information about the prescribed or dispensed drugs and what information they use in case of uncertainty. Three of these questions were subdivided into an additional cluster of questions. The clusters of PEQ_{med} and PEQ_{pharm} differed from each other with respect to the patient information and sources of information questions. The PEQ_{med} included an additional question that asked medical practitioners for their satisfaction of their medical knowledge. In the PEQ_{med}, two questions dealt with prescription control systems to get an overview of whether the participants have a system that co-reviews the medical prescriptions and whether the participants have an electronic data system for their patients that stores all necessary information.

Section III: Prescribing Errors Risk Analysis

This section asked HCPs to rate fourteen defined prescribing errors as they appear on the medical prescription or after consulting with the patient on a scale of 1 (low score) to 4 (high score) for severity of consequences to get an overall 'Risk Priority Number' (RPN) (1 - 4 low risk) (6 medium risk) (8 - 16 high risk). Probability was rated using a five-point Likert scale for medical practitioners on a scale from 1 (low score) to 4 (high score) to request an individual evaluation of a specific error as they think it generally appears. The same rating was used for pharmacists with the exception that they should rate the probability by their own experience. The severity was also assessed with a five-point Likert scale. Medical practitioners and pharmacists should rate the general severity based on their own assumptions. The questionnaire used mainly the validated prescribing errors by Dean et al

(2000) to serve as a basis for this assessment. The scores were later used to calculate the risk priority number (RPN) according to section 1.8.5.4.

Dean et al. (2000) developed 42 prescribing errors with the help of a two stage Delphi method, in which he asks a panel group of HCPs to indicate the extent to which general scenarios represented a prescribing error. The specific scenarios used were on the other hand developed following a review of previous prescribing error studies.

Since not all prescribing errors by Dean et al were applicable to a community pharmacy setting, a total of 28 clinical setting errors were excluded for the questionnaire in this study. The remaining 14 errors used are listed in table 2.2.

Section IV: Role of the Community Pharmacist

This section contained two questions of the five-point Likert scale type. Both questions were identical in the PEQ_{med} and PEQ_{pharm}. The first one asked the participants, whether the community pharmacists play a main role in recognising and correcting prescribing errors. The second question focused on the abilities and possibilities of community pharmacists to recognise and correct certain prescribing errors. This question was divided into nine sub-sections that listed selected abilities / possibilities and were rated by participants with the Likert scale.

Table 2.2: Prescribing Error Scenarios

Adopted from: Dean et al What is a prescribing error? *Qual Health Care* 2000; 9:232-237.

Scenarios
Omission of the prescriber's contact details
Illegible handwriting
Omission of dose
Omission of frequency
Omission of duration of use
Omission of the route of administration, when drug can be given by different routes
Omission of patient indication
Using abbreviation
Misspelling a drug name
Prescribing by brand name rather than active ingredient
Longer duration of short term use medication
Prescribing a drug without informing the patient of its use
Prescribing contrary to treatment guidelines
Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified released formulations)

Prescribing errors that were used from the study of Dean et al (2000) to assess the potential risk from a medical practitioner's and community pharmacist's perspective.

2.7. Dissemination of the PEQ

An online and a hardcopy version of the PEQ_{med} and PEQ_{pharm} (Appendix 2 and 3) were prepared in English and German. The online version was developed using Google Docs. In Malta, invitations to participate were sent to medical practitioners via email (921 medical practitioners' invitations). The email addresses were requested by the Medical Association of Malta and internet research.

The email invitations briefly explained the purpose of this study and the requirements for participation. Maltese pharmacists were invited using social network portal groups (338 pharmacist invitations). Both HCPs were personally visited and invited to participate in the questionnaire (52 medical practitioners, 22 pharmacists).

In Germany, invitations were sent via email or through phone calls. The contact details were taken from a German medical practitioner register (1749 medical practitioner invitations). Pharmacists in Germany were contacted via emails from a pharmacy register (188 pharmacy invitations) and personal visits (31 pharmacists).

2.8. Data Analysis

The data from the questionnaire was coded and analysed using the Statistical Package for Social Science (SPSS) version 24 (IBM Corporation, New York, USA). The Likert scale, being a rational scale, was chosen in eleven of twenty questions in the PEQ_{med} and in eleven of the nineteen questions in the PEQ_{pharm}, because of the ease with which data can be

analysed, the ease to run the questionnaire and the freedom of respondents to give a neutral answer rather than an obligatory yes or no opinion. In contrast to choice-based scales, rating scales express the intensity of an ordinal preference evaluation. The percentage of medical practitioners and community pharmacists who gave the highest rating, anchored by 4 on the Likert scale was used to evaluate root causes of prescribing errors and the perception of prescribing errors. The Chi square test was used to assess the association between two categorical variables. The null hypothesis specifies that there is no association between the two variables whilst the alternative hypothesis specifies that there is a significant association between the two variables. The null hypothesis was accepted if the p value exceeded the 0.05 level of significance and was rejected if the p value was less than the 0.05 criterion.

2.9. Ethical approval

Ethics approval was not sought since this study involved the voluntary participation of medical practitioners and community pharmacists after having been given a clear explanation of the study.

2.10. Publications

Two abstracts (Appendix 4 and 5) related to the research were accepted for the forthcoming International Pharmaceutical Federation (FIP) World Congress 2018 held between

September 2nd and 6th 2018 in Glasgow, UK and the American College of Clinical Pharmacy (ACCP) Global Conference 2018 on October 20th to 23rd 2018 in Washington, USA.

CHAPTER THREE

RESULTS

This chapter is divided into three sections. The first section presents the results of medical practitioners' interviews that were used for the development of the two questionnaires PEQ_{med} for medical practitioners and PEQ_{pharm} for community pharmacists. The second section shows the results of the validation process of the questionnaires. The last section consists of the results of the two questionnaires PEQ_{med} and PEQ_{pharm}. The PEQs aimed to analyse the current status of processes that may lead to prescribing errors and suboptimal pharmacists' prescribing error intervention. A risk assessment of prescribing errors and the ability of community pharmacists to intervene is put forward.

3.1. Medical Practitioner Interviews

Eleven medical practitioners (5 Malta, 6 Germany) were interviewed to identify root causes that have the potential to lead to prescribing errors and to describe their prescribing practice. Table 3.1 presents the characteristics of the interviewed participants.

Table 3.1: Characteristics of Medical Practitioners in the Interview to Identify Root Causes

Institution	**Malta**	**Germany**
Hospital	2	3
Private Clinic	2	3
Health Centre *(only Malta)*	1	-
Years of experience	**Malta**	**Germany**
2 - 5 years	3	2
6 - 10 years	1	3
11 - 30 years	1	1

3.1.1. Medical Practitioner Interviews for the Identification of Root Causes in the Medication Use Process

Two main categories, work environment factors and prescriber-related factors emerged from the data analysis of the literature review and medical practitioners' interviews. Table 3.2 outlines the categories, their associated groups and the number of responses of participants from the interview.

Table 3.2: Identified Root Causes in the Medication Use Process

Root Causes		Malta (n=5)	Germany (n=6)
Work environment factors	Work atmosphere	5	5
	Interruptions while treating patients	**5**	**6**
	Sufficient time to allocate with patient	3	3
	Stress level	**5**	**6**
	Working hours	3	4
	Technical equipment	4	6
Prescriber-related factors	Patient information	4	6
	Medication information	3	5
	Medical knowledge	3	5
	Medical affairs knowledge	4	3
	Source of information	2	4

Categorisation of root causes found in medical practitioners' interviews and literature review. Medical practitioners mentioned stress (N=11) and interruptions (N=11) as most common cause of prescribing errors.

The following section summarises the root causes of prescribing error mentioned by the majority of medical practitioners in the interview (n≥4 Malta, n≥5 Germany).

Work atmosphere

The conditions of the work atmosphere were mentioned by the majority of interview participants (n=10) as a contributing factor for errors. For example, whether the working place was organised, structured and clearly arranged or more chaotic. Nine medical practitioners mentioned the pressure to perform and the time pressure as main factors that contribute to an unorganised working place.

Interruptions while treating patients

Interruptions while treating a patient were mentioned by all interviewed medical practitioners (N=11) as a source for errors. Interruptions could be made either by colleagues for medical urgencies or minor social natures, by phone calls or by patients themselves. All interviewees mentioned the time loss due to reorganisation and to reincorporate into the previous case again. The risk of forgetting important activities or facts while reorganising could cause medication errors.

Stress level

All participants (N=11) of the interviewees agreed that stress at their work place was one of the key factors that could contribute to errors in the prescribing process. It was mentioned by 8 medical practitioners that too many activities and thoughts at the same time are factors contributing to stress and it could be challenging to focus on the main activity under such circumstances. Two practitioners mentioned that stress even affects their personal life and has an impact on their work-life balance which could result in poor physical and mental health consequences.

Technical equipment

All medical practitioners in Germany (n=6) mentioned that the usage of computer systems for prescribing drugs and electronic patient record charts for keeping up-to-date with their patients are beneficial in preventing prescribing errors. All of the practitioners interviewed in Germany (n=6) mentioned the problems with the computer systems that can also cause prescribing errors.

Patient information

Ten medical practitioners agreed that knowing the patient for a long time and knowing his or her medical conditions, reduces on the one hand the risk of prescribing errors, but on

the other hand increases the likelihood of overlooking important facts. All practitioners (N=11) mentioned that this long-term relationship between the medical practitioner and the patient, allowed them to recognise patients that are more overacting and those who needed more attention.

Difficulties arise when medical practitioners prescribe for new or walk-in patients. Resorting to previous illnesses, medications and other important information was quoted as very difficult, because of poor communication skills of patients or often the patients' medical history notes were not precise or incomplete and just relying on self-reporting made the prescriber uncomfortable. Eight of the ten medical practitioners felt it was safer not to prescribe in certain situations.

Medication information

Most of the interviewed medical practitioners (n=6) recognise poor information of drugs as an error contribution factor and tended to develop a collection of familiar medications that they were comfortable with to prescribe. They mentioned that such a behaviour was very common among their colleagues and that it "*helped to estimate the risk*" as they became familiar with the ADEs of this specific medication.

Medical Knowledge

Medical practitioners in Malta (n=3) with less than 5 years experience and medical practitioners in Germany (n=5) mentioned that their medical training at university needed a bit more improvement. It was mentioned that medical practice had been taught very poor in undergraduate level and which may have the effect of an uncomfortable and insecure feeling towards medical knowledge in their career. All medical practitioners (n=8) who mentioned that medical knowledge could contribute to prescribing errors, agreed that most of their obtained knowledge was learning on the job, by talking to other colleagues or seeking help from other HCPs.

3.2. Validation of the Prescribing Error Questionnaires: Round I

The validation panel included sixteen individuals with different expertise and who participated in a two round structured communication method to validate the PEQ. One expert did not continue to participate in the second validation round.

The PEQ_{med} and the PEQ_{pharm} contained seventeen identical questions. PEQ_{med} had three additional questions and two modified questions as compared to PEQ_{pharm}. PEQ_{med} and PEQ_{pharm} were validated by all sixteen participants. The questions that differed in the PEQ_{med} were validated by medical practitioners, a translator and a statistician (n=9). Pharmacists validated the PEQ_{pharm} instead of practitioners (n=9). Twelve experts gave positive feedback for PEQ_{med} and PEQ_{pharm}. Nine experts mentioned that the main topic, the rating of

prescribing errors which were relevant to the research were a drawback, because of the length to rate fourteen prescribing errors by their probability and severity. The rating of the risk could not be shortened, due to its importance to this study. Modifications of this questionnaire were made after the first validation round.

3.2.1. Amendments to Section I: Demographics

The first question in the PEQs asked individuals about the year of experience: "*less than 2 years*", "*2 – 5 years*", "*6 – 10 years*" and "*more than 10 years*". The selected year groups changed after validation round I to: "*0 - 5 years*", "6 – *10 years*", "*11 – 30 years*" and "*more than 30 years*", as 2 experts in Malta and 1 in Germany argued that experienced medical practitioners and community pharmacists could be distinguished, as there are strong distinctions in the year segments of practitioners and pharmacists.

The fourth question in the PEQ_{med} and the second question in PEQ_{pharm}, asking respondents about their district of practice, was completely removed from the PEQs, as experts claimed that medical practitioners and pharmacists in Malta are trained at the same medical or pharmacy school. All participants in Malta argued that a breakdown concerning districts would be irrelevant. There were no further changes to this section in the PEQs.

3.2.2. Amendments to Section II: Root Cause Ranking

The ninth question in the PEQ_{med} which was the eight questions in the PEQ_{pharm}, asking participants about the average time of consulting with a patient. The time brackets in the PEQ_{med} and PEQ_{pharm} differ in the time period. The medical practitioners' time brackets were longer than the ones for the pharmacists.

The time brackets of the question were amended in the PEQ_{med} from: "*less than 5 minutes*", "*5 – 10 minutes*", "*11 – 20 minutes*" and "*more than 20 minutes*" to "*less than 10 minutes, 10 - 20 minutes, 21 - 30 minutes, more than 30 minutes*". Six medical practitioners claimed that "*less than 5 minutes*" of consultation time would be too little.

Question number thirteen in the PEQ_{med} and question number eleven in the PEQ_{pharm} asking individuals about the amount of their regular patients, was re-worded to, "*How many of your patients are regular?*" The majority of participants (n=10) argued that the former question was too ambiguous and unclear.

The fourteenth and fifteenth question in the PEQ_{med} and the twelfth and thirteenth question in the PEQ_{pharm} were modified. One asking participants about their medical knowledge (PEQ_{med}) or their pharmaceutical knowledge (PEQ_{pharm}) and the other question asked participants about their medical affairs' knowledge. The majority of validation members (n=15) argued that the first version of the questions was misguiding the whole intention and were not accurate. Three participants gave examples of how the questions could be re-worded to fit the aim. The examples were summarised and adopted to the

questionnaire. "*Do you feel your medical knowledge is of high standard?*" and "*Do you feel satisfied with your current medical affairs knowledge?*"

The seventeenth question in the PEQ_{med} and the fifteenth question in the PEQ_{pharm} asking individuals about the medical / pharmaceutical information used on a regular basis, were removed from the questionnaires, as 5 medical practitioners and 2 pharmacists claimed that it would be difficult to categorise the information on a regular basis, as every case is different and different information would be used.

3.2.3. Amendments to Section III: Prescribing Errors Analysis

In this section all validating experts (N=16) criticised that the structure to rate the prescribing errors by severity and probability was not well understood. Six of the medical practitioner experts claimed that they did not understand whether the rating should be done out of own experience or from a general perspective.

The structure of the rating was modified and a sentence for medical practitioners and community pharmacists was added in the PEQs. Medical practitioners were asked: "*please rate the following prescribing errors by their probability and severity as you think they appear in general*" (PEQ_{med}). Pharmacists were asked: "*please rate the following prescribing errors by their probability as they appear in your practice and by their severity*" (PEQ_{pharm}).

One prescribing error was dismissed form the questionnaire "*prescribing a drug for which there is no evidence of efficacy*". The majority of experts (n=9) commented that medical

practitioners are well aware of evidence-based medicine and do not prescribe drugs that they are not familiar with.

3.2.4. Amendments to Section IV: Role of the Community Pharmacist

In this section the validating experts were asked to rank the capabilities of community pharmacists. The two listed capabilities, "*incomplete medication order*" and "*wrong rate*" were re-worded to "incomplete medical treatment" and "wrong frequency", as all medical practitioners in Malta (n=4) and 1 pharmacist in Malta claimed that it was not well understood.

3.2.5. Relevance of Questions after the Validation Round I

The expert panel was asked to rate the questions regarding their relevance with respect to the main aim of the questionnaire. The five-point Likert scale was used anchored by 1 (not relevant) to 5 (highly relevant). For the identical questions in the PEQs, 15 out of 17 questions were rated as 'relevant' or 'highly relevant' (Figure 3.1).

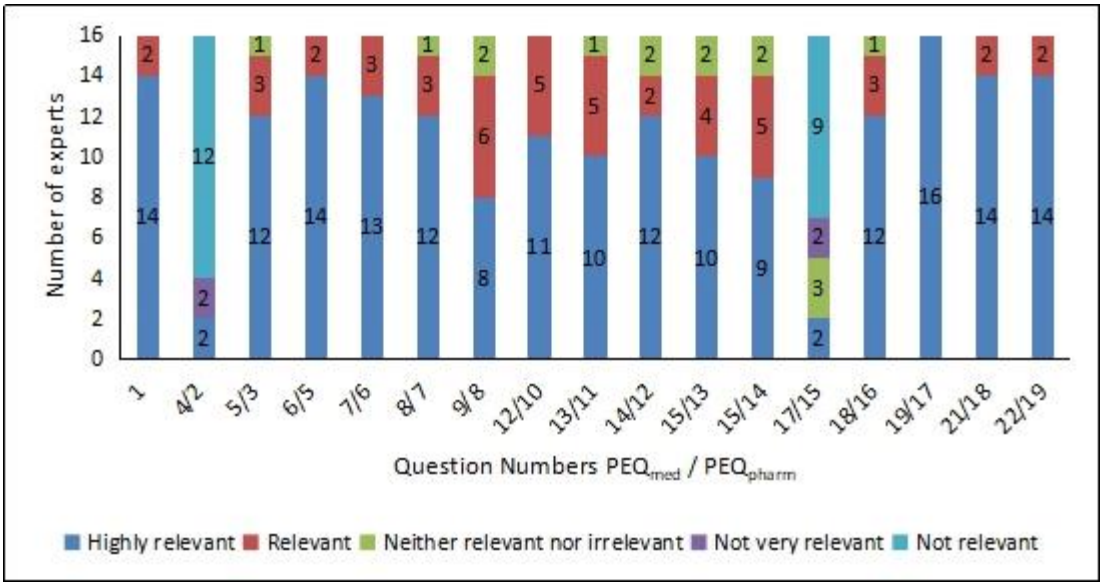

Figure 3.1: Expert Responses on Identical Questions, Relevance during Validation Round I (N=16)

The PEQs were divided into four sections. Question 1 – 5 (PEQ_{med}) / 1 – 4 (PEQ_{pharm}) were related to demographic data, questions 6 – 18 (PEQ_{med}) / 5 – 16 (PEQ_{pharm}) focused on the root cause ranking, question 19/17 analysed the risk of prescribing errors and questions 21/18 – 22/19 assessed the role of community pharmacists.

The five questions in the PEQ_{med} that differed from the PEQ_{pharm} were all rated as 'relevant' or 'highly relevant' at least from one person. Both of the two questions in the PEQ_{pharm} that differed from the PEQ_{med} were also rated as 'relevant' or 'highly relevant' from at least one person (Figure 3.2 and 3.3).

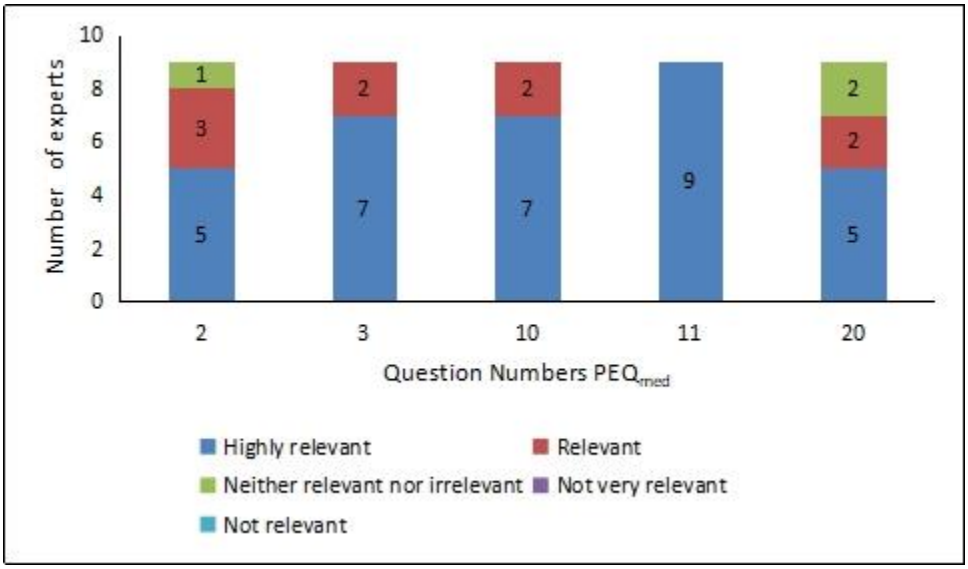

Figure 3.2: Expert Responses on Questions only in the PEQ_{med}, Relevance during Validation Round I (n=9)

Question 2, 3, 10, 11 and 20 were only included in the Prescribing Error Questionnaire Medical Practitioners (PEQ_{med}) as the five questions focused specifically on medical practitioners' matters.

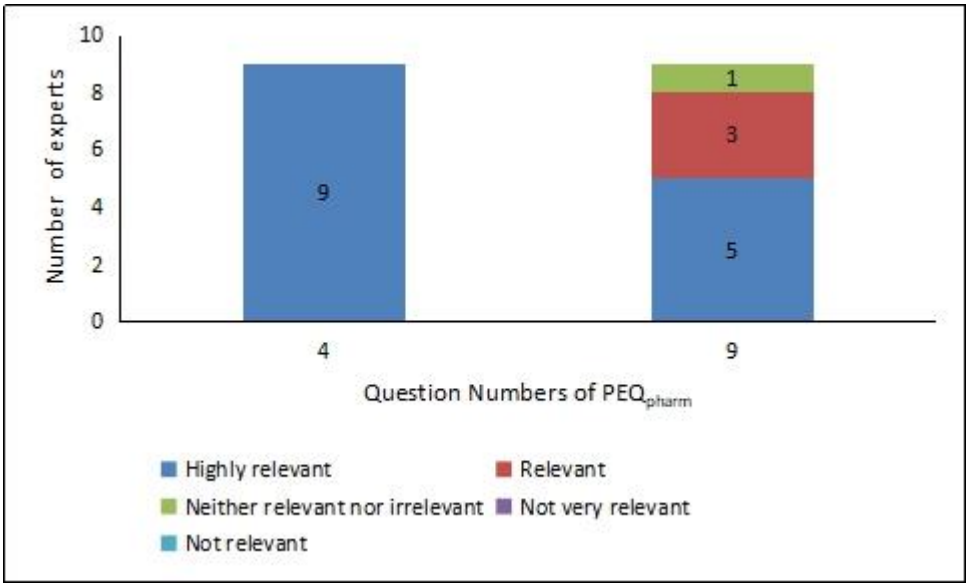

Figure 3.3: Expert Responses on Questions only in the PEQ_{pharm}, Relevance during Validation Round I (n=9)

Question 4 and 9 were only included in the Prescribing Error Questionnaire for Pharmacists (PEQ_{harm}) as the questions focused specifically on pharmacists' matters.

3.3. Validation, Amendments and Relevance of the Validation Method: Round II

Fifteen out of sixteen experts from the first validation round, participated in the second round.

With the second validation round a consensus was met with all participants (N=15). One prescribing error in section III was re-worded, as 6 experts claimed that the wording can cause ambiguity. "*Continuing a prescription for a longer duration than necessary*" to "*Longer duration of short term use medication (e.g. Clopidogrel)*". All questions in both questionnaires were rated as 'highly relevant' or 'relevant' (Figure 3.4).

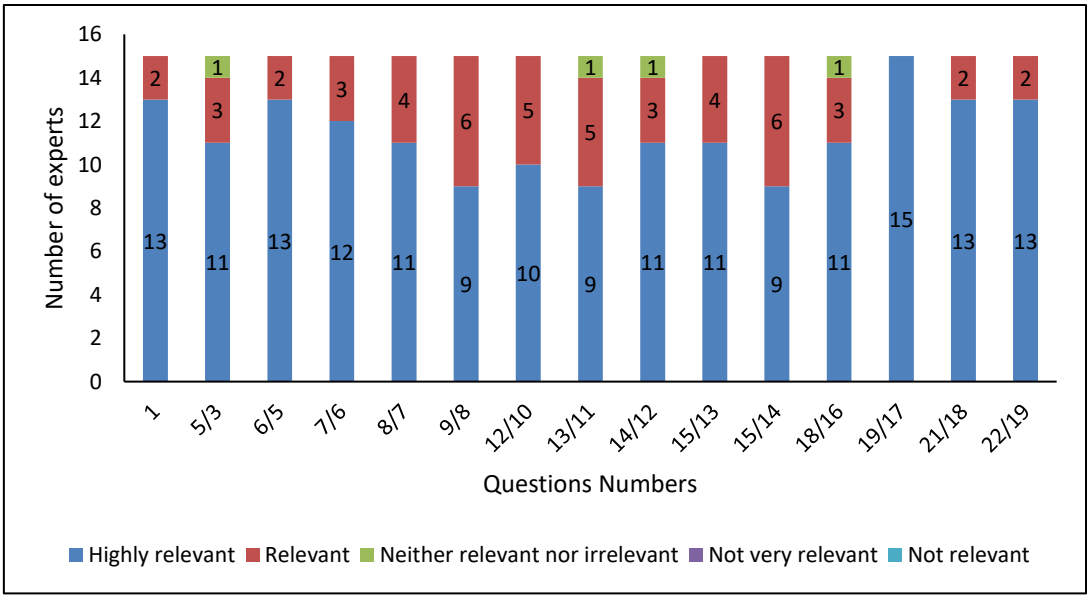

Figure 3.4: Expert Responses on Identical Questions Relevance in the Validation Round II (N=15)

The PEQs were divided into four sections. Question 1 – 5 (PEQ_{med}) / 1 – 4 (PEQ_{pharm}) were related to demographic data, questions 6 – 18 (PEQ_{med}) / 5 – 16 (PEQ_{pharm}) focused on the root cause ranking, question 19/17 analysed the risk of prescribing errors and questions 21/18 – 22/19 assessed the role of community pharmacists.

3.4. Prescribing Error Questionnaire for Medical Practitioners

Two hundred and thirty medical practitioners (130 Malta, 100 Germany) answered the PEQ_{med} respectively. Twenty-six responses of medical practitioners in Malta were invalid, as the respondents completed less than fifty percent of the questionnaire. The total number of valid responses was 104 medical practitioners in Malta and 100 in Germany.

The questionnaire was either sent via email or personal invitation to 973 medical practitioners in Malta and 1749 in Germany. The response rate was 10.69% for practitioners in Malta and 5.72% in Germany.

3.4.1. Demographics of Participants of the Prescribing Error Questionnaires Medical Practitioners

Medical practitioners were categorised by work characteristics. The experience of practitioners in Malta ranged from 0-5 years, 6-10 years and more than 30 years (34% n=35, 22% n=28 and 12% n=12 respectively). Most of the medical practitioners in Malta were family doctors (30%, n=31), followed by specialists / consultants (28%, n=29), specialist trainees (24%, n=25) and foundation doctors (18%, n=19). Sixty-one percent (n=63) spend 40 - 60 hours in practice, while 24 % (n=25) had a week of less than 40 hours, 15% (n=16) worked more than 61 hours. Forty-eight (47%) responding practitioners in Malta worked full time in a hospital, 39 (38%) had a private clinic and 17 (16%) indicated to work in a health centre.

In Germany the experience of medical practitioners ranged from less than 5 years (41%, n=41), 6 - 10 years (23%, n=23), 11 - 30 years (19%, n=19) up to more than 30 years (17%, n=17). The majority of medical practitioners in Germany were family doctors (54%, n=54). Second were specialist trainees (n35%, =35) and specialist /consultants (11%, n=11). The two-year Foundation Programme in the UK and in Malta to train postgraduates does not exist in Germany but can be compared with the German first year of the Specialist Training (Miani et al, 2015).[22,23] Eighty-nine (89%) responding practitioners worked in a private clinic and 11 (11%) in a hospital. With respect to the working hours, 67% (n=67) worked 40 - 60 hours per week, while 33% (n=33) spend more than 60 hours at work. Medical specialities (p=0.01), the type of institutions (p<0.001) and the working hours per week (p=0.03) of medical practitioners in Malta and Germany was found to be statistically significant. Table 3.3 shows the comparison of the characteristics of the participants in both countries.

3.4.2. Root Causes Ranking of the Work Environment (Medical Practitioners)

Medical practitioners were asked to rank the level of interruptions, the stress rate and the organisation of their work atmosphere as identified root causes at their work place on a five-point Likert scale from a range of 0 (low score) to 4 (high score).

[22] The Foundation Programme Curriculum 2016 [Internet] The UK Foundation Programme Curriculum 2016 [cited 2018 May 31] Available from: http://fpmalta.com/uploads/2016/fp_curriculum_2016.pdf

[23] Bundesärztekammer, Weitebildungsordnung 2003 [Internet]; Arbeitsgemeinschaft der deutschen Ärztekammern 2013 [cited 2018 May 31] Available from: http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/20130628-MWBO_V6.pdf

Table 3.3: Characteristics of Medical Practitioners in PEQ_{med} (Question 1 to 4)

Years of experience	Malta (N=104)	Germany (N=100)	*P* value
0 - 5 years	35	41	0.420
6 - 10 years	28	23	
11 - 30 years	29	19	
> 30 years	12	17	
Medical speciality			
Foundation Doctor *(Malta)* / 1. yr Specialist Trainee *(Germany)*	**19**	**0**	**0.010**
Specialist Trainee	**25**	**35**	
Family doctor	**31**	**54**	
Specialist / Consultant	**29**	**11**	
Working hours / week			
< 40 hours	25	0	**0.030**
40 - 60 hours	63	67	
61 - 80 hours	16	33	
Type of institute			
Hospital	**48**	**11**	**<0.001**
Private Clinic	**39**	**89**	
Health Centre *(only MT)*	**17**	**-**	

More medical practitioners working in a hospital in Malta participated in the 'Prescribing Error Questionnaire' PEQ_{med} than practitioners from Germany, whose majority practiced in private clinics.

Statistically significant differences (p<0.001) were found for the interruptions while treating patients, with 66.4% (n=63) of medical practitioners in Malta indicating that they are often/ very often interrupted during treatments, while 32% (n=32) of medical practitioners in Germany indicating an often / very often rate score when it comes to interruptions.

The organisation of the work place and the ensuing emotional perception, defined in this research as work atmosphere, showed that medical practitioners in Malta (64.4%, n=67) tend to observe their work environment more unorganised than German practitioners (46%, n=46) with a statistically significant difference (p=0.01). Medical practitioners in both countries experienced a high stress amount with a rate of 75% (n=78) in Malta and 67% (n=67) in Germany. The root causes rankings are summarised in Table 3.4.

Asking medical practitioners about the time spent with their patients from a scale of <10 minutes, 10 – 20 minutes, 21 – 30 minutes and >30 minutes, the majority of practitioners (56%, n=58 Malta; 56%, n=65 Germany) in both countries claimed to spend 10 to 20 minutes with their patients. More practitioners in Malta (26%, n=27) indicated to spend less than 10 minutes with the patient, compared to Germany (7%, n=7). The comparison of medical practitioners in Malta and Germany of the time spent with patients showed a statistically significant difference (p=0.003) and is shown in Figure 3.5.

Table 3.4: Root Causes Ranking of Interruptions, Stress and Work Atmosphere in the PEQ_{med} (Question 5 -7)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Interruption while treating patients	Malta	11 (10.6%)	30 (28.8%)	63 (66.4%)	104	**24.92**	**<0.001**
	Germany	28 (28.0%)	40 (40.0%)	32 (32.0%)	100		
Stress rate	Malta	11 (10.6%)	15 (14.4%)	78 (75.0%)	104	1.43	0.840
	Germany	13 (13.0%)	20 (20.0%)	67 (67.0%)	100		
Work atmosphere	Malta	8 (7.7%)	29 (27.9%)	67 (64.4%)	104	**13.32**	**0.010**
	Germany	22 (22.0%)	23 (23.0%)	46 (46.0%)	100		

Medical practitioners in Germany perceive less interruptions and a more organised work atmosphere than their Maltese counterparts.

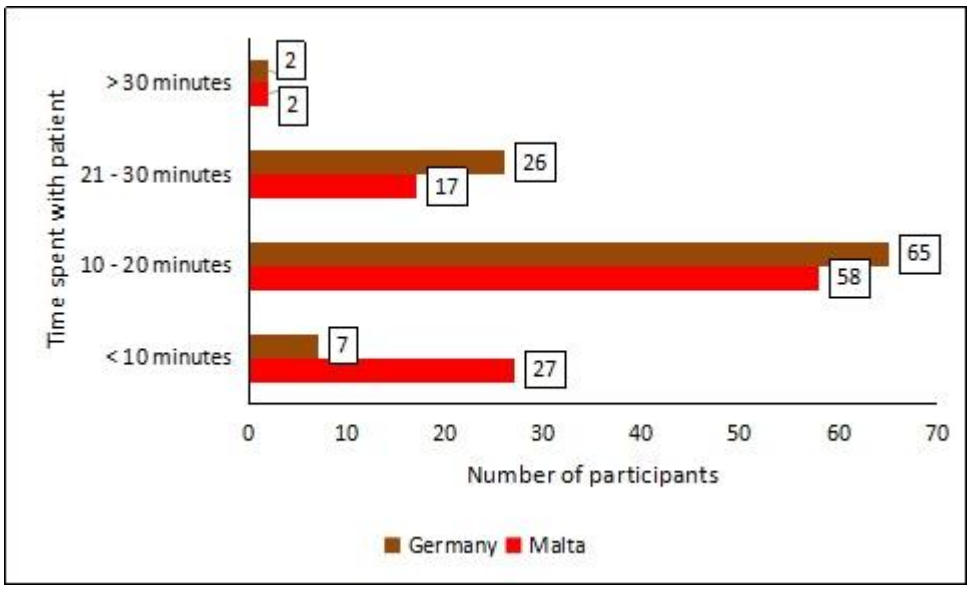

Figure 3.5: Time Spent with Patients (Medical Practitioners) (Question 8)

When medical practitioners were asked about the use of any kind of prescribing control system at their primary work, such as a computerised prescribing software or a self-developed method to double check prescriptions, 75% (n=77) of participants in Malta indicated in question 9 that a control system was not used at their primary work, while 88% (n=88) medical practitioners in Germany declared that a control system was in place at their working place (p<0.001).

Sixty-four percent (n=66) of the participating medical practitioners in Malta mentioned that they do not have an electronic record chart of their patients, while 83% (n=83) of German participants used electronic patient record charts at work (p<0.001) (Figures 3.6 and 3.7).

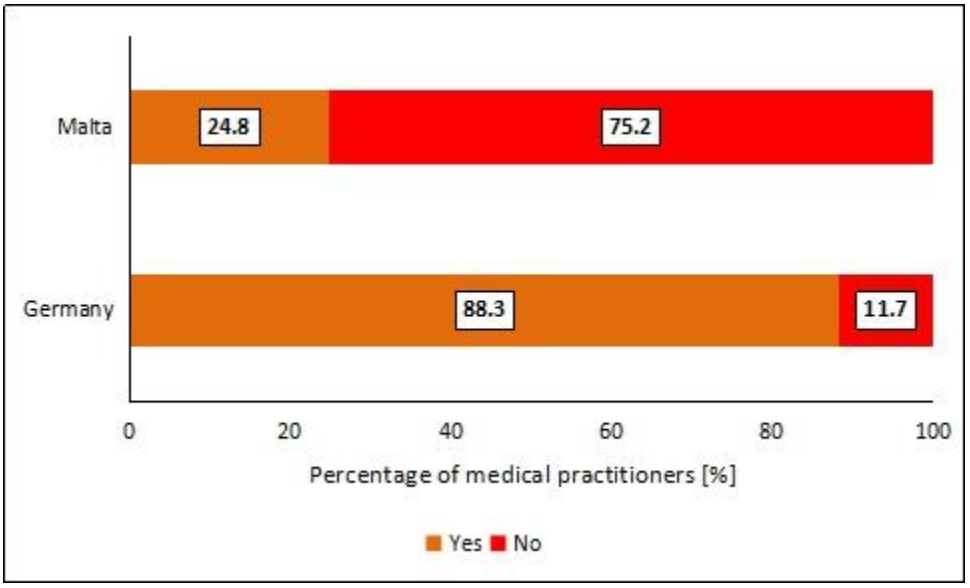

Figure 3.6: Medical Practitioner Usage of Prescribing Control Systems (Question 9)
There was a statistically significant difference (p<0.001) between the usage of prescribing control systems in Malta and Germany (χ^2 = 84.086)

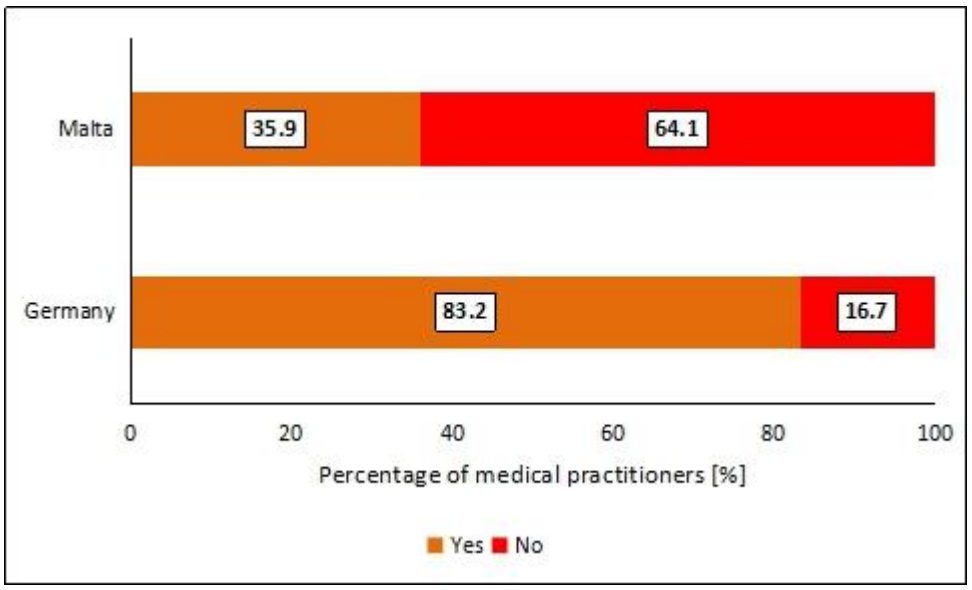

Figure 3.7: Medical Practitioner Usage of Electronic Patient Record Charts (Question 10)
There was a statistically significant difference (p<0.001) between the usage of electronic patient record charts in Malta and Germany ($\chi^2 = 47.169$)

3.4.3. Root Causes Ranking: Prescriber-Related (Medical Practitioners)

Medical practitioners were asked in question 11 to rank the information they have of their patients on a five-point Likert scale from a range 0 (not at all informed) to 4 (always informed). The patient information root causes were subdivided in the factors shown in table 3.5.

With regards to the medical history of patients, a difference in the rating were found with statistical significance between medical practitioners in Malta and Germany, 90.0% (n=90) of medical practitioners in Germany indicated that they were well or very well informed of their patients' medical history compared to practitioners in Malta, where 69% (n=72) of the medical practitioners stated a well or well patient history information basis.

Table 3.5: Root Causes Ranking of Patient Information in the PEQ_{med} (Question 11)

		Low Score	Fair Score	High Score	N	χ^2	p value
Medical History	Malta	2 (1.9%)	30 (28.8%)	72 (69.2%)	104	**16.82**	**<0.001**
	Germany	2 (2.0%)	8 (8.0%)	90 (90.0%)	100		
Changed Medication	Malta	35 (33.6%)	31 (29.8%)	38 (36.5%)	104	**11.75**	**0.019**
	Germany	16 (16.0%)	30 (30.0%)	54 (54.0%)	100		
Allergies	Malta	3 (2.9%)	16 (15.4%)	85 (81.7%)	104	1.29	0.730
	Germany	2 (2.0%)	14 (14.0%)	84 (84.0%)	100		
Vital signs	Malta	10 (9.6%)	22 (21.2%)	72 (69.2%)	104	4.19	0.240
	Germany	5 (5.0%)	14 (14.0%)	81 (81.0%)	100		
Personal statistics	Malta	25 (24.0%)	34 (32.7%)	45 (13.3%)	104	2.82	0.590
	Germany	17 (17.0%)	40 (40.0%)	43 (43.0%)	100		
Immunization	Malta	67 (64.5%)	27 (26.0%)	10 (9.7%)	104	0.77	0.940
	Germany	68 (68.0%)	22 (22.0%)	10 (10.0%)	100		
Lab tests	Malta	2 (1.9%)	20 (19.2%)	82 (78.9%)	104	1.74	0.690
	Germany	3 (3.0%)	15 (15.0%)	82 (82.0%)	100		

The majority of medical practitioners in Malta (n=58) and Germany (n=63) indicated in the listed patient factors to be well to very well informed about their patients.

The patient information of changed or recent withdrawn medication showed also a statistical significance (p=0.019) among both countries. Thirty-eight (37%) medical practitioners in Malta mentioned that they were well informed about the medication plan of their patients, compared to 54 (54%) practitioners in Germany indicating their awareness. Other factors such as patient allergies, vital signs, personal statistics or immunisation status of the patients did not show any statistically significant differences ($p>0.05$).

Medical practitioners were asked about the approximate number of regular patients they treat (Figure 3.8). Practitioners were asked to rank their answers on a scale from less than 20%, 20% – 50%, 51% – 80% to more than 80%. Comments on question 12 showed that most of the practitioners in Malta (38%, n=40) stated an amount of less than 20%. Most of the medical practitioners in Germany (37%, n=37) could indicate that more than 80% of their patients very regular and were known to a certain extent by the practitioners.

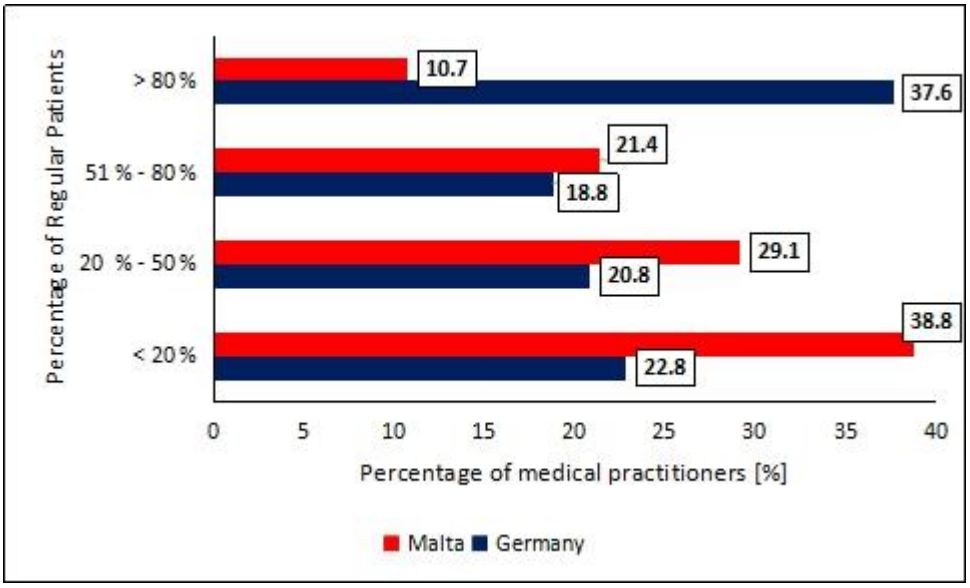

Figure 3.8: Medical Practitioner Amount of Regular Patients (Question 12)

Participants were asked to rate their medical knowledge and their current medical affairs knowledge on a five-point Likert scale from 0 (low score) to 4 (high score). Comments on question 13 and 14 found no statistically significant difference among the practitioners in both countries when asking about the medical knowledge and medical affairs knowledge. Medical practitioners from both countries (n=92 Malta and n=81 Germany) indicated to have a good or very good medical knowledge and a good knowledge about current medical affairs (Table 3.6).

Table 3.6: Root Cause Ranking of Medical Practitioner's Medical Knowledge and Medical Affairs Knowledge in the PEQ_{med} (Question 13 and 14)

		Low Score	Fair Score	High Score	N	χ^2	p value
Medical Knowledge	Malta	1 (1.0%)	11 (10.6%)	92 (88.5%)	104	4.63	0.201
	Germany	2 (2.0%)	17 (17.0%)	81 (81.0%)	100		
Medical Affairs Knowledge	Malta	1 (1.0%)	43 (41.3%)	60 (57.7%)	104	4.702	0.240
	Germany	2 (2.0%)	33 (33.0%)	65 (65.0%)	100		

Medical practitioners in Malta and Germany show similar perceptions about their medical knowledge and their current medical affairs.

Medical practitioners were asked about their sources of information while prescribing. Practitioners rated in question 15 selected examples of information sources on a five-point Likert scale from a range 0 (low score) to 4 (high score).

Consultation with colleagues while prescribing shows a difference in the rating with a statistical significance (p=0.029) between medical practitioners in Malta and Germany. Forty percent of medical practitioners in Germany (40%, n=40) indicated that in case of a medical enquiry, they often or always discuss issues with a colleague, while 23% (n=24) of practitioners in Malta stated that they often consult with a colleague in case a problem occurs.

A statistically significant difference is seen with the source of company information (p<0.001). Medical practitioners working in Malta are more likely to get information from the company summary of product characteristics (SmPC) than their German counterparts. Thirty-six percent (n=38) of practitioners in Malta used the SmPC often as help, compared to 8.0% (n=8) by German counterparts.

The consultation with a pharmacist did not show a statistically significant difference (p=0.38) in Malta and in Germany, but to seek advice from the pharmacist when uncertainty in the prescribing process occur, did not find much support among the medical practitioners in both countries. Fifty-two percent (n=55) of the practitioners in Malta stated never or rarely to consult a pharmacist, compared to sixty percent (n=60) in Germany who indicated that they never or rarely call in a pharmacist.

Other factors concerning sources of information such as reputable internet web pages, international guidelines, peer review journals or medical literatures did not show any statistical significances (p>0.05). The selected examples of information sources are listed in Table 3.7.

Table 3.7: Root Causes Ranking of Information Sources in the PEQ_{med} (Question 15)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Consultation with colleagues	Malta	25 (24.1%)	55 (52.9%)	24 (23.1%)	104	**10.82**	**0.029**
	Germany	13 (13.0%)	47 (47.0%)	40 (40.0%)	100		
Consultation with pharmacists	Malta	55 (52.8%)	33 (31.7%)	16 (15.4%)	104	4.18	0.380
	Germany	60 (60.0%)	23 (23.0%)	12 (12.0%)	100		
Reputable internet web pages	Malta	2 (1.9%)	11 (10.6%)	91 (87.5%)	104	8.61	0.070
	Germany	5 (5.0%)	22 (22.0%)	73 (73.0%)	100		
Drug company information	Malta	41 (39.5%)	25 (24.0%)	38 (36.5%)	104	**26.59**	**<0.001**
	Germany	50 (50.0%)	42 (42.0%)	8 (8.0%)	100		
International guidelines	Malta	11 (10.6%)	35 (33.7%)	58 (55.8%)	104	0.48	0.980
	Germany	10 (10.0%)	33 (33.0%)	57 (57.0%)	100		
Peer review journals	Malta	54 (51.9%)	33 (31.7%)	17 (16.3%)	104	7.96	0.090
	Germany	44 (44.0%)	32 (32.0%)	24 (24.0%)	100		
Medical literatures	Malta	39 (37.5%)	30 (28.8%)	35 (33.7%)	104	3.12	0.540
	Germany	44 (44.0%)	29 (29.0%)	27 (27.0%)	100		

The majority of medical practitioners in Malta and Germany seek internet webpages as help, when uncertainties in the prescribing process occur.

Question 16 investigated the medical practitioners' knowledge on prescribing selected drugs. Questions such as the knowledge about the interactions or the dose for certain indications were asked. Participants should rank their responses using a five-point Likert scale, from 0 as the lowest value to 4 as the largest.

In all eight categories except for contraindications and side effects, the majority of medical practitioners (>60%) in Malta and in Germany indicated a good or a very good knowledge about the prescribed drugs. No statistically significant differences were shown in the rating of drug information. The ranking is listed in table 3.8.

3.5. Ranking of Potential Prescribing Errors (Medical Practitioners)

Medical practitioners were asked to rate a list of prescribing errors by their probability of occurrence and severity of consequences as they thought relevant. Participants assessed in question 17 on a five-point Likert scale from the range of 1 (low probability) to 4 (high probability) the probability of prescribing errors. The severity scale ranged from 1 (no impact on patient) to 4 (will cause temporary harm patient).

Table 3.8: Root Causes Ranking of Information of Prescribed Drugs in the PEQ_{med} (Question 16)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Registered indication	Malta	5 (4.8%)	21 (20.2%)	78 (75.0%)	104	7.39	0.116
	Germany	3 (3.0%)	11 (11.0%)	86 (86.0%)	100		
Dose	Malta	2 (1.9%)	3 (2.9%)	99 (95.2%)	104	2.85	0.583
	Germany	3 (3.0%)	4 (4.0%)	93 (93.0%)	100		
Frequency	Malta	2 (1.9%)	3 (2.9%)	99 (95.2%)	104	8.74	0.070
	Germany	5 (5.0%)	7 (7.0%)	88 (88.0%)	100		
Duration of use	Malta	3 (2.9%)	10 (9.6%)	91 (87.5%)	104	2.36	0.670
	Germany	1 (1.0%)	8 (8.0%)	91 (91.0%)	100		
Active ingredient	Malta	6 (5.8%)	22 (21.2%)	76 (73.1%)	104	7.06	0.130
	Germany	3 (3.0%)	12 (12.0%)	85 (85.0%)	100		
Contraindication	Malta	5 (4.9%)	26 (25.5%)	71 (69.6%)	102	3.77	0.440
	Germany	7 (7.0%)	26 (26.0%)	67 (67.0%)	100		
Interaction	Malta	14 (13.5%)	50 (48.1%)	40 (38.5%)	104	3.25	0.520
	Germany	18 (18.0%)	37 (37.0%)	45 (45.0%)	100		
Side effect	Malta	6 (5.9%)	35 (34.3%)	61 (59.8%)	102	3.9	0.420
	Germany	8 (8.1%)	44 (44.4%)	46 (46.5%)	99		

Table 3.9 lists the calculated RPN from the average rated severity and probability by medical practitioners in Malta and Germany.

With regards to the omission of the prescriber's contact details, a statistically significant difference in the RPN was found (p<0.001) between medical practitioners in Malta and Germany. The calculation of the RPN of medical practitioners in Germany showed a lower score (average RPN=0.08) than medical practitioners in Malta (average RPN=4.82). Prescribing errors due to illegible handwriting on medical prescriptions showed a statistical significance (p<0.001) among both countries. The average RPN was 6.81 in Malta and 1.15 in Germany. That means that Malta has a higher risk of prescribing errors from occurring due to illegibility on medical prescriptions than in Germany. The omission of the duration of drug treatment, showed a statistically significant different in Malta and Germany. While in Germany the risk of the omission of the duration is higher, with an average RPN of 6.42, medical practitioners in Malta rated the risk lower with an average RPN of 4.38. Statistically significant differences were found in prescribing errors of omission of the patient indication and of a longer duration of short term use medication, such as Clopidogrel or oral glucocorticoids. The p value in both prescribing errors were 0.01. The statistically difference resulted from the average severity and average probability score. As the average RPN in the omission of patient indication is similar (5.19 Malta, 5.76 Germany), the risk and in both countries is similar. The prescribing error, prescribing contrary to treatment guidelines showed a statistically significant difference (<0.001), but the average RPN of 3.77 in Germany and of 3.44 in Malta did not show a high number and actions to reduce the risk are not recommended.

Table 3.9: Potential Prescribing Errors Rating in the PEQ_{med} (Question 17)

Prescribing Errors	Average Risk Priority Number		χ^2	*P* value
	Malta (n=104)	Germany (n=100)		
Omission of the prescriber's contact details	**4.82**	**1.08**	**180.36**	**<0.001**
Illegible handwriting	**6.81**	**1.15**	**154.55**	**<0.001**
Omission of dose	4.04	3.83	8.79	0.360
Omission of frequency	3.83	3.74	5.73	0.680
Omission of duration of use	**4.38**	**6.42**	**29.52**	**<0.001**
Omission of the route of administration, when drug can be given by different routes	3.84	2.56	1.75	0.990
Omission of patient indication	**5.19**	**5.76**	**21.31**	**0.010**
Using abbreviation	5.29	4.94	2.05	0.990
Misspelling a drug name	3.89	3.34	7.54	0.270
Prescribing by brand name rather than active ingredient	3.89	2.32	0.75	0.990
Longer duration of short term use medication (e.g. Clopidogrel)	**4.87**	**6.21**	**17.56**	**0.010**
Prescribing a drug without informing the patient of its use	4.31	4.56	1.43	0.920
Prescribing contrary to treatment guidelines	**3.44**	**3.77**	**20.88**	**<0.001**
Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified released formulations)	3.52	3.27	0.96	0.990

The average risk priority number is the result of the average rated severity multiplied with the average rated probability. The risk priority number shows the risk and magnitude of a certain prescribing error. The highest rated risks of prescribing errors were, illegible handwriting in Malta and a longer duration of short term use medication (e.g. Clopidogrel) in Germany.

Question 18 consisted of two parts. In part one medical practitioners were asked about whether they remember having made a prescribing error in the past. Seventy-two percent (n=73) of medical practitioners in Malta admitted having done an error in the past, seventeen percent (n=19) marked not to have done a prescribing error and eleven percent (n=12) mentioned that they were not aware about it. In Germany eighty-nine percent (n=89) were aware of having done a prescribing error (Figure 3.9).

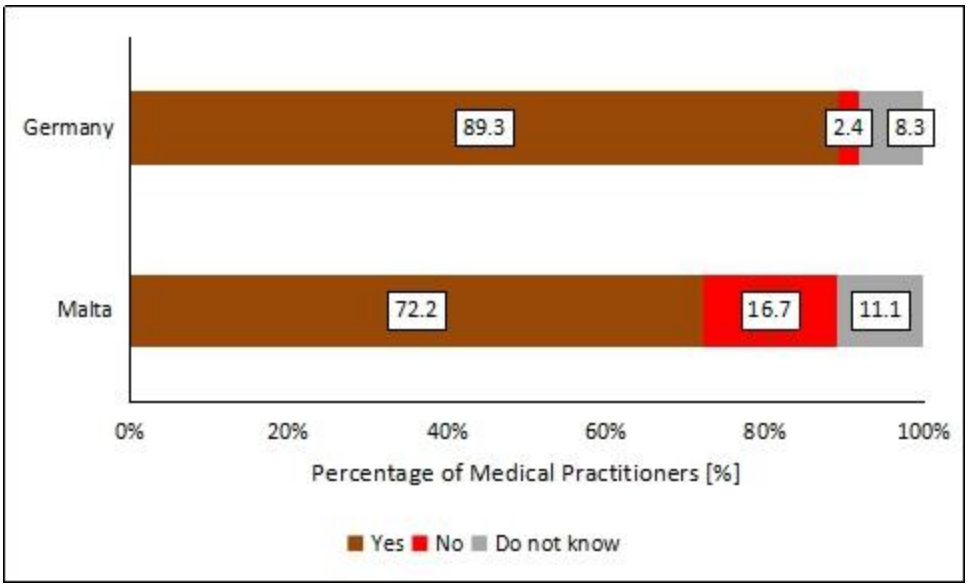

Figure 3.9: Medical Practitioner Awareness of Prescribing an Erroneous Medical Prescription (Question 18)

The majority of medical practitioners in Germany (n=89) agreed to having done a prescribing error compared to 72.2% of practitioners in Malta agreeing to having done an error.

In the second part of question 18, medical practitioners who agreed to being aware of committing a prescribing error in the past were asked to mark the type of prescribing errors committed, on a provided list. Fifty-one percent (n=46) of medical practitioners in Malta being aware of committing an error in the past, indicated having omitted their own

prescribers contact details or prescribed by drug brand name, rather than by the active ingredient. Most of the practitioners in Germany mentioned with 64% (n=58) the omission of patient indication and 45% (n=40) the omission of the drugs duration as their prescribing errors (Figure 3.10).

3.6. Perception of Medical Practitioners on Community Pharmacists

Medical practitioners in Malta and Germany were asked to indicate their perception whether community pharmacists are able to identify and intervene in erroneous medical prescriptions (Table 3.10). The practitioners rated their answer on a five-point Likert scale from 0 (not at all) to 4 (all the time). The vast majority of practitioners in Malta (88%, n=98) mentioned that they see the ability of the community pharmacist to identify and intervene, if it is necessary in prescribing errors on medical prescriptions. The counterparts in Germany saw the community pharmacists to indicate and intervene in prescribing errors less capable with thirty-two (32%) participants indicating a high score in the questionnaire (p<0.001).

Table 3.10: Medical Practitioner Perception of Community Pharmacists for Prescribing Error Identification and Intervention (Question 19)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Perception of Community Pharmacists for interventions	Malta	0 (0.0%)	6 (10.6%)	98 (88.5%)	104	**99.45**	**<0.001**
	Germany	8 (8.0%)	60 (60.0%)	32 (32.0%)	100		

A statistically significant difference is shown (p<0.001) in the trust of medical practitioners in Malta and Germany towards the community pharmacists' abilities for prescribing error identification.

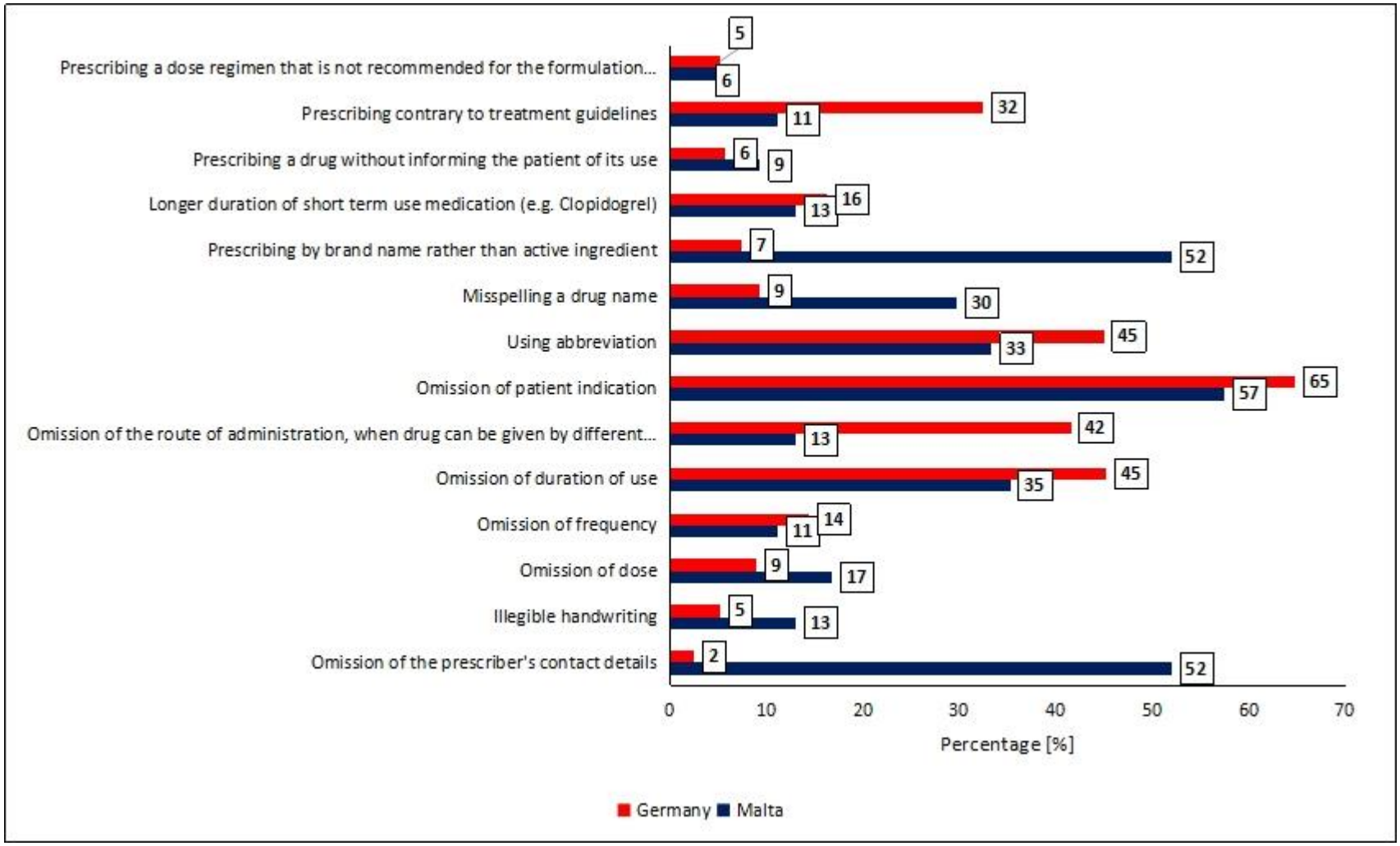

Figure 3.10: Comparison of the Type of Prescribing Errors Committed by Medical Practitioners in Malta and Germany

A list of selected prescribing errors was shown to medical practitioners. Practitioners were asked in question 20 to rate the capability of community pharmacists to recognise the listed prescribing errors. A five-point Likert from the range of 0 (very unlikely) to 4 (highly likely) was utilised to assess the pharmacists' capabilities. The results are listed in Table 3.11.

The capability to identify allergies to medications showed a difference in the rating of medical practitioners with a statistical significance (p=0.03). Forty-five percent (n=45) of medical practitioners in Germany indicated that allergies to prescribed drugs cannot be identified by pharmacists or they neither have a positive nor a negative relation about the issue, while 16.9% (n=28) of practitioners in Malta stated that allergies cannot be detected by pharmacists or have a neutral relationship towards it.

A statistically significant difference was observed with the capability to identify a duplication therapy (p<0.001) and to identify the wrong written dose on the prescription (p<0.001). Medical practitioners working in Malta are more likely to trust community pharmacists in identifying a duplicated prescribed drug (98%, n=102) and to correct a wrong prescribed dose of a drug (94%, n=98) than their German counterparts with a lower trust in pharmacists recognising duplications and wrong drug doses (62%, n=62; 38%, n=38, respectively). Sixty-two practitioners in Germany mentioned a highly likely or likely capability of pharmacists to correct drug duplications and 38 mentioned a high trust rate on the identification of the wrong dose of a drug.

The perception of medical practitioners on the capability of community pharmacists to intervene in a prescribing error of a wrong drug duration and a wrong drug frequency

showed a statistically significant difference (p<0.001) in Malta and in Germany. In both countries, the majority of medical practitioners (89%, n=92 Malta; 66%, n=66) trusted community pharmacists in being capable to identify and to intervene in a wrong prescribed drug duration or a wrong drug frequency, less practitioners in Malta (3%, n=3 wrong duration; 4% n=4 wrong frequency) mistrusted in the capabilities of the pharmacists than their German counterparts (17%, n=17 wrong durations; 18%, n=18 wrong frequency).

Other factors concerning sources the identification of drug-drug interactions, incompatibilities, wrong dosage forms or incomplete medical treatments did not show any statistical significances (*p*>0.05).

Table 3.11: Medical Practitioner Rating on Community Pharmacist's Capabilities to Identify and Intervene in Prescribing Errors. (Question 20)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Allergies to medications	Malta	10 (9.6%)	18 (17.3%)	76 (73.1%)	104	**10.99**	**0.030**
	Germany	14 (14.0%)	31 (31.0%)	76 (76.0%)	100		
Interactions	Malta	1 (1.0%)	14 (13.5%)	89 (85.6%)	104	1.09	0.780
	Germany	1 (1.0%)	9 (9.0%)	90 (90.0%)	100		
Duplications	Malta	1 (1.0%)	1 (1.0%)	102 (98.0%)	104	**45.95**	**<0.001**
	Germany	20 (20.0%)	18 (18.0%)	62 (62.0%)	100		

Table 3.11(Cont): Medical Practitioner Rating on Community Pharmacist's Capabilities to Identify and Intervene in Prescribing Errors. (Question 20)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Incompatibilities							
	Malta	4 (2.8%)	18 (17.4%)	82 (78.8%)	104	2.39	0.660
	Germany	6 (6.0%)	16 (16.0%)	78 (78.0%)	100		
Wrong dose							
	Malta	2 (1.9%)	4 (3.8%)	98 (94.2%)	104	**76.12**	**<0.001**
	Germany	31 (31.0%)	31 (31.0%)	38 (38.0%)	100		
Wrong duration							
	Malta	3 (2.8%)	9 (8.7%)	92 (88.5%)	104	**16.57**	**<0.001**
	Germany	17 (17.0%)	17 (17.0%)	66 (66.0%)	100		
Wrong frequency							
	Malta	4 (3.8%)	5 (4.8%)	95 (38.5%)	104	**28.87**	**<0.001**
	Germany	18 (18.0%)	20 (20.0%)	62 (62.0%)	100		
Wrong dosage form							
	Malta	1 (3.8%)	5 (4.8%)	98 (94.2%)	104	28.87	0.960
	Germany	1 (1.0%)	4 (4.0%)	95 (95.0%)	100		
Incomplete medical treatment							
	Malta	9 (8.7%)	33 (31.7%)	61 (62.0%)	104	7.01	0.070
	Germany	21 (21.0%)	28 (28.0%)	51 (51.0%)	100		

Medical practitioners in Malta trust mainly in the capability of community pharmacists to identify and correct duplication therapies. In Germany the main rated capability is the wrong dosage form.

3.7. Prescribing Error Questionnaire for Community Pharmacists (PEQ_{pharm})

One hundred and eighty-nine community pharmacists (86 Malta, 103 Germany) answered the PEQ_{pharm} respectively.

The questionnaire was either sent via email or personal invitation. Three hundred and sixty pharmacists in Malta and 188 pharmacies in Germany received an invitation. The PEQ_{pharm} in Malta had a response rate of 23.89%. As the PEQ_{pharm} in Germany were directly sent to community pharmacies without knowing the exact amount of pharmacists working in the premises, a response rate could not have been calculated.

3.7.1. Demographics of Participants of the Prescribing Error Questionnaires Community Pharmacists

No statistically significant differences were shown in the pharmacists' characteristics among Malta and Germany.

In Malta community pharmacists' experience ranges 0-5 years (38%, n=33), 6-10 years (52%, n=45) and more than 10 years (10%, n=8). Only 1% (n=1) of pharmacists spend working more than 40 hours in the community pharmacy, while 58% (n=50) had an average week of 21 - 40 hours, 42% (n=36) worked less than 20 hours. Fifteen percent (n=13) of community pharmacists in Malta held an additional postgraduate degree or additional training in terms of advanced pharmacy practice or clinical pharmacy.

In Germany the experience of community pharmacists ranged from less than 5 years (46%, n=47), 6 - 10 years (39%, n=40) up to more than 10 years (15%, n=16). Nine percent (n=5) of the participating pharmacists worked more than 40 hours per week, while the majority of 59% (n=61) had an average working week between 21 and 40 hours. Thirty-six percent (n=37) worked part time or worked as a locum pharmacist with less than 20 hours per week. In Germany 21 (20%) pharmacists held an additional degree or additional training in pharmacy practice. Table 3.12 shows the comparison of the characteristics of the participants in both countries

Table 3.12: Characteristics of Pharmacists in PEQ_{pharm} (Question 1 – 3)

Years of experience	**Malta (N=86)**	**Germany (N=103)**	***P* value**
0 - 5 years	33	47	0.06
6 - 10 years	45	40	
11 – 30 years	8	15	
> 30 years	0	1	
Working hours			
< 10 hours	7	5	0.09
10 - 20 hours	29	32	
21 - 40 hours	49	61	
> 40 hours	1	5	
Additional post graduate training in pharmacy practice	13	21	0.12

3.7.2. Root Causes Ranking of the Work Environment (Community Pharmacists)

Community Pharmacists were asked to rank the level of interruptions, the stress rate and the organisation of their work atmosphere as identified root causes at their work on a five-point Likert scale from a range 0 (low score) to 4 (high score).

Statistically significant differences (p=0.02) were observed for interruptions while consulting with patients, with 47% (n=40) of community pharmacists in Malta indicating that they are often / very often interrupted during patient consultations, while 32% (n=33) of community pharmacists in Germany indicating an often / very often rate score when it comes to interruptions.

Community pharmacists in Germany experienced a less stress rate than pharmacists in Malta with a rate of 4.7% (n=4) in Malta and 25.2% (n=26) in Germany (p=0.02). Community pharmacists in Malta indicate a more unorganised work atmosphere (69%, n=59) as their German counterparts (53%, n=55) (p=0.05). The root causes ratings are summarised in Table 3.13.

Table 3.13: Root Causes Ranking of Interruptions, Stress and Work Atmosphere in the PEQ_{pharm} (Question 4 – 6)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Interruption while consulting with patients	Malta	4 (4.7%)	42 (48.8%)	40 (46.5%)	86	**17.14**	**0.02**
	Germany	26 (25.2%)	44 (42.7%)	33 (32.1%)	103		
Stress rate	Malta	5 (5.8%)	18 (20.9%)	63 (73.3%)	86	**11.32**	**0.02**
	Germany	23 (22.3%)	17 (16.5%)	63 (61.2%)	103		
Work atmosphere	Malta	11 (12.8%)	16 (18.6%)	59 (68.6%)	86	**9.11**	**0.05**
	Germany	23 (24.3%)	23 (22.3%)	55 (53.4%)	103		

Community pharmacists in Germany perceive less interruptions and a less amount of stress at work than their Maltese counterparts.

Asking community pharmacists about the time consulting with their patients from a scale of <1 minute, 1 – 2 minutes, 3 – 5 minutes and >5 minutes, the majority of pharmacists (84%, n=72 Malta, 77%, n=79 Germany) in both countries claimed to spend 1 to 2 minutes with their patients. More pharmacists in Germany (20%, n=21) indicated to spend more than 5 minutes with the patient, compared to Malta (12%, n=10). The comparison of community pharmacists in Malta and Germany of the time spent consulting with a patient showed no statistically significant difference (p=0.127) (Figure 3.11)

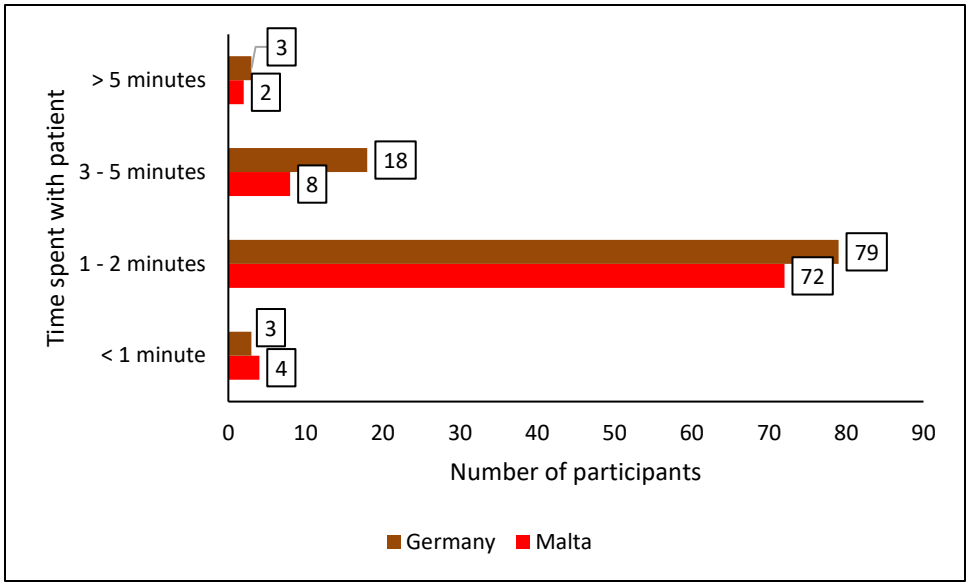

Figure 3.11: Time Spent with Patients (Community Pharmacists) (Question 7)

When community pharmacists were asked about the use of any kind of electronic dispensing help software at their work in a community pharmacy in question 8, 77.6% (n=67) of participants in Malta indicated that a dispensing software was not used at their work at a community pharmacy, while 98.7% (n=101) medical practitioners in Germany declared that a control system was in place at their working place (p<0.001) (Figure 3.12).

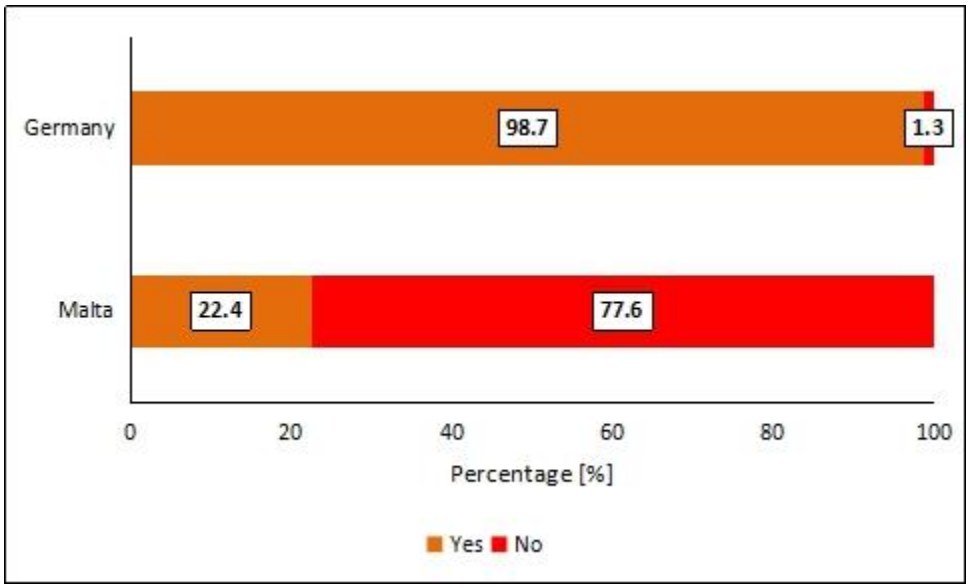

Figure 3.12: Community Pharmacist Usage of Dispensing help software (Question 8)
There was a statistically significant difference ($p<0.001$) between the usage of dispensing help software in Malta and Germany ($\chi^2 = 84.086$)

3.7.3. Root Causes Ranking: Prescriber-related (Community Pharmacists)

In question 9, community pharmacists were asked to rank the information they have of the patients coming to the pharmacy they work in on a five-point Likert scale from a range 0 (low score) to 4 (high score).

The root causes of insufficient patient information were subdivided in the following factors that are shown in table 3.14.

With respect to the patients' details, a difference in the ranking was found with a statistical significance of (p<0.001) between community pharmacists in Malta and Germany, 74.8% (n=77) of community pharmacists in Germany indicated that they were well or very well informed of their patients' medical history compared to practitioners in Malta, were 35.7% (n=30) of the community pharmacists stated a well or well patient history information basis.

The patient information of medical history of patients showed also a statistical significance (p<0.001) among both countries. No community pharmacist in Malta mentioned that they were well informed about the medical history of the patients, compared to 31 (30%) pharmacists in Germany indicating their awareness.

Statistically significant differences were found for the patient information of personal statistics (p=0.02), with none of the community pharmacists in Malta indicating that they are well or very well informed about patient statistics, while 5 (5%) community pharmacists in Germany indicated a well or very well information base regarding personal statistics.

Community pharmacists in Germany (3%, n=3) know less about their patients' laboratory tests than their Maltese counterparts. Community pharmacists in Malta with a rate of 25.6% (n=22) claim to be aware of their patients' laboratory tests.

The factors of changed medications did not show any statistically significant differences between Malta and Germany.

Table 3.14: Root Causes Ranking of Patient Information in the PEQ_{pharm} (Question 9)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Patient details	Malta	16 (19.1%)	38 (45.2%)	30 (35.7%)	84	**57.3**	**<0.001**
	Germany	13 (12.6%)	13 (12.6%)	77 (74.8%)	103		
Medical History	Malta	58 (69%)	26 (31.0%)	0 (0%)	84	**51.96**	**<0.001**
	Germany	23 (22.4%)	49 (47.6%)	31 (30.1%)	103		
Changed Medication	Malta	30 (34.9%)	34 (39.5%)	22 (25.6%)	86	8.526	0.070
	Germany	28 (27.2%)	40 (38.8%)	35 (34.0%)	103		
Personal statistics	Malta	56 (66.7%)	28 (33.3%)	0 (0.0%)	84	**9.48**	**0.020**
	Germany	48 (48.5%)	46 (46.5%)	5 (5.0%)	99		
Lab tests	Malta	62 (72.1%)	2 (2.3%)	22 (25.6%)	86	**36.03**	**<0.001**
	Germany	76 (76.7%)	20 (20.3%)	3 (3.0%)	99		
Details of the prescribing doctor	Malta	12 (13.9%)	36 (41.9%)	38 (44.2%)	86	**41.62**	**<0.001**
	Germany	5 (4.9%)	21 (20.4%)	77 (74.7%)	103		

The majority of participating community pharmacists in Malta (n=38) and Germany (n=77) claim to have the mostly patient information about the prescribing medical practitioner.

Community pharmacists were asked about the approximate number of regular patients they consult. The pharmacists ranked their answers on a scale from less than 20%, 20% – 50%, 51% – 80% to more than 80%. Most of the pharmacists in Malta (32%, n=28) stated an amount of 51 -80%. Most of the community pharmacists in Germany (37%, n=38) could indicate that more than 20 – 50% of their patients very regular and were known to a certain extent by the pharmacists. A statistically significant difference was observed with $p<0.001$ (Figure 3.13).

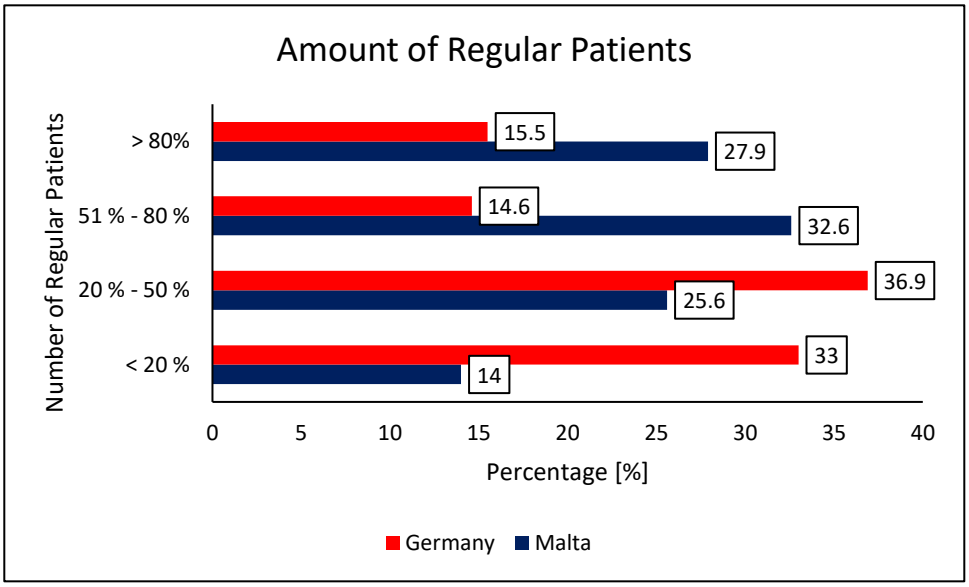

Figure 3.13: Community Pharmacist Amount of Regular Patients (Question 10)

Question 11 and 12 asked the participants to rate their pharmaceutical knowledge and their current medical affairs knowledge on a five-point Likert scale from 0 (low score) to 4 (high score). No statistically significant difference was found among the pharmacists in both countries when asking about the pharmaceutical knowledge and medical affairs knowledge. Community pharmacists from both countries (n=92 Malta and n=81 Germany) indicated to have a good or very good pharmaceutical knowledge and a good knowledge about current medical affairs (Table 3.15).

Table 3.15: Root Cause Ranking of Community Pharmacist's Pharmaceutical Knowledge and Medical Affairs Knowledge in the PEQ_{pharm} (Question 11 and 12)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Pharmaceutical Knowledge	Malta	1 (1.0%)	11 (10.6%)	92 (88.5%)	104	4.63	0.201
	Germany	2 (2.0%)	17 (17.0%)	81 (81.0%)	100		
Medical Affairs Knowledge	Malta	1 (1.0%)	43 (41.3%)	60 (57.7%)	104	4.702	0.24
	Germany	2 (2.0%)	33 (33.0%)	65 (65.0%)	100		

Participated community pharmacists in Malta and Germany showed similar perceptions about their pharmaceutical knowledge and their current medical affairs.

In Question 13, community pharmacists were asked about their sources of information while dispensing. Pharmacists ranked selected examples of information sources on a five-point Likert scale from a range 0 (low score) to 4 (high score). Examples of information sources are listed in Table 3.16.

Consultation with the prescribing practitioner while dispensing showed a difference in the rating with a statistical significance (p=0.01) between community pharmacists in Malta and Germany. Forty-eight percent (n=49) of community pharmacists in Germany indicated that in case of a medical enquiry, they often or always consult the medical prescriber, while 45.3% (n=39) of pharmacists in Malta stated that they often consult with the prescriber in case problems occur.

A statistically significant difference was observed with reputable internet websites or specific pharmacy dispensing software (p<0.001). Pharmacists working in Germany were more likely to get information from the internet. Seventy-two percent (n=75) of participated pharmacists in Germany used the internet often, compared to 53.3% (n=46) often usage by pharmacists working in Malta.

Table 3.16: Root Causes Ranking of Information Sources in the PEQ_{pharm} (Question 13)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Consultation with colleagues	Malta	23 (26.7%)	45 (52.3%)	18 (20.9%)	86	8 .94	0.060
	Germany	28 (17.8%)	59 (58.4%)	24 (23.8%)	101		
Consultation with prescribing practitioner	Malta	13 (15.1%)	34 (39.5%)	39 (45.3%)	86	**12.52**	**0.010**
	Germany	10 (9.8%)	43 (42.2%)	49 (48.1%)	102		
Reputable internet web pages, software or e-apps	Malta	15 (17.4%)	25 (29.1%)	46 (53.5%)	86	**19.74**	**<0.001**
	Germany	6 (5.8%)	22 (21.4%)	75 (72.8%)	103		
Drug company information	Malta	24 (27.9%)	31 (36.0%)	31 (36.1%)	86	8.23	0.080
	Germany	44 (43.6%)	37 (36.6%)	20 (19.8%)	101		
International guidelines	Malta	9 (10.5%)	32 (37.2%)	45 (52.3%)	86	**31.27**	**<0.001**
	Germany	47 (45.6%)	31 (30.1%)	15 (24.3%)	103		
Peer review journals	Malta	46 (53.5%)	32 (37.2%)	8 (9.3%)	86	6.25	0.180
	Germany	53 (53.5%)	27 (27.3%)	19 (19.2%)	99		
Medical literatures	Malta	39 (45.4%)	28 (32.6%)	19 (22.1%)	86	4.45	0.350
	Germany	49 (49.0%)	28 (28.0%)	23 (23.0%)	100		

The majority of participated community pharmacists in Malta and Germany seek internet webpages as help, when uncertainties in the dispensing process occur.

Question 14 investigated the community pharmacists' knowledge on dispensing prescribed drugs. Questions such as the knowledge about the interactions or the dose for certain indications were asked. Participants ranked their responses using a five-point Likert scale, from 0 as not at all informed to 4 as very well informed.

The information of drug frequency showed a difference in the rating of community pharmacists with a statistical significance (p=0.02) in Malta and Germany. Seventy-seven (90%) community pharmacists in Malta indicated that they were well to very well informed about the drugs frequency prescribed, while 92 (90%) pharmacists in Malta stated that they were well or very well informed.

In the other seven categories asking pharmacists about the knowledge of the prescribed drugs, community pharmacists in Malta (n=86) and Germany (n=103) indicated a good or a very good knowledge about the prescribed drugs. No statistically significant differences were shown in the other rating of drug information (p>0.05). The ranking is listed in table 3.17.

Table 3.17: Root Causes Rating of Information of Prescribed Drugs in the PEQ_{pharm} (Question 14)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Registered indication	Malta	2 (2.4%)	20 (23.3%)	64 (74.3%)	86	5.75	0.22
	Germany	0 (0.0%)	16 (15.5%)	90 (84.5%)	103		
Dose	Malta	1 (1.2%)	8 (9.3%)	77 (89.5%)	86	11.75	0.98
	Germany	1 (1.0%)	11 (10.7%)	91 (88.3%)	103		
Frequency	Malta	1 (1.2%)	8 (9.3%)	77 (89.5%)	86	**11.6**	**0.02**
	Germany	5 (4.9%)	6 (5.8%)	92 (89.3%)	103		
Duration of use	Malta	8 (9.3%)	7 (8.1%)	71 (82.6%)	86	**11.24**	**0.02**
	Germany	5 (4.8%)	18 (17.5%)	80 (77.7%)	103		
Active ingredient	Malta	1 (1.2%)	15 (17.4%)	70 (81.4%)	86	1.46	0.69
	Germany	0 (0.0%)	21 (20.4%)	82 (79.6%)	103		
Concentration	Malta	2 (2.4%)	25 (29.1%)	59 (68.6%)	86	4.70	0.32
	Germany	8 (7.8%)	35 (34.0%)	60 (58.2%)	103		
Interaction	Malta	9 (10.5%)	43 (50.0%)	34 (39.5%)	86	0.12	0.99
	Germany	11 (10.7%)	53 (51.5%)	39 (37.8%)	103		
Side effect	Malta	2 (2.3%)	27 (31.4%)	57 (66.3%)	86	3.96	0.27
	Germany	4 (3.9%)	41 (39.8%)	58 (56.3%)	103		

3.8. Rating of Potential Prescribing Errors (Community Pharmacists)

Community pharmacists were asked in question 15 to rate a list of prescribing errors by their probability of occurrences and severity of consequences as they experienced at their work place. A five-point Likert from the range of 1 (low probability) to 4 (high probability) was used to assess the probability of prescribing errors. The severity scale ranged from 1 (no impact on patient) to 4 (will cause temporary harm patient).

With respect to the omission of the prescriber's contact details, a difference in the RPN was found to be statistically significant ($p<0.001$). The calculation of the RPN of community pharmacists in Germany showed a lower score (average RPN=1.09) than pharmacists in Malta (average RPN=6.51).

Prescribing errors due to illegible handwriting on medical prescriptions showed a statistical significance ($p<0.001$) between the two countries. The average RPN was 7.95 in Malta and 1.17 in Germany. Malta has a higher risk of illegibility on medical prescriptions than Germany.

The omission of the dose of prescribed drugs, showed a statistically significant different ($p<0.001$) in Malta and Germany. Germany the risk of the omission of the dose is lower with an average RPN of 2.92, community pharmacists in Malta rated the risk higher with an average RPN of 5.30. The risk in Malta with an average RPN <6 should not need to be considered as dangerous.

Statistically significant differences were found in the prescribing errors of omission of patient indication and for prescribing a dose regimen that is not recommended for the formulation prescribed, such as a modified released formulation. The *p* value in both prescribing errors was 0.03. The statistically difference resulted from the average severity and average probability score. As the average RPN in prescribing a not recommended dose regimen is similar (5.16 Malta, 5.74 Germany), the risk in both countries is similar. The RPN in Germany with 5.74 is close to a RPN of 6 which would indicate a consideration of actions to minimise the risk. The average RPN of the prescribing error, omission of the patient indication is not similar. Malta with an RPN of 6.14 should consider actions to minimise the risk.

The average RPN in Germany of 7.6 and in Malta of 6.93 of the prescribing error, a longer duration of a short-term use medication, such as Clopidogrel, PPIs or oral glucocorticoids does not show a significant difference among both countries.

Table 3.18 lists the calculated RPN from the average rated severity and probability by community pharmacists in Malta and Germany.

Table 3.18: Potential Prescribing Errors Rating in the PEQ_{pharm} (Question 15)

Prescribing Errors	Average Risk Priority Number		χ^2	P
	Malta (n=86)	Germany (n=103)		
Omission of the prescriber's contact details	**6.51**	1.09	**133.51**	**<0.001**
Illegible handwriting	**7.95**	1.17	**117.19**	**<0.001**
Omission of dose	5.30	2.92	**44.34**	**<0.001**
Omission of frequency	4.77	**5.02**	5.57	0.590
Omission of duration of use	**6.30**	**6.08**	2.74	0.950
Omission of the route of administration, when drug can be given by different routes	5.12	3.64	16.37	0.060
Omission of patient indication	**6.14**	4.58	**17.30**	**0.030**
Using abbreviation	**5.81**	5.32	3.34	0.910
Misspelling a drug name	5.00	0.09	**142.52**	**<0.001**
Prescribing by brand name rather than active ingredient	4.74	2.46	**31.48**	**<0.001**
Longer duration of short term use medication (e.g. Clopidogrel)	**6.93**	**7.6**	**12.75**	**0.050**
Prescribing a drug without informing the patient of its use	**6.28**	**6.47**	6.56	0.580
Prescribing contrary to treatment guidelines	4.72	4.33	2.59	0.980
Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified released formulations)	5.16	**5.74**	**15.15**	**0.030**

The average risk priority number is the result of the average rated severity multiplied with the average rated probability. The risk priority number shows the risk and magnitude of a certain prescribing error. The highest rated risks of prescribing errors were, illegible handwriting in Malta and a longer duration of short term use medication (e.g. Clopidogrel) in Germany.

3.9. Perception of Community Pharmacists on Themselves

Community pharmacists in Malta and Germany were asked to indicate their perception whether they think their profession makes them capable of indicating and intervening in erroneous medical prescriptions. Pharmacists participating in this study ranked their answer on a five-point Likert scale from 0 (not at all) to 4 (all the time). The majority of pharmacists in Malta (63%, n=54) indicated a high capability to identify and intervene, if it is necessary in prescribing errors on medical prescriptions. The counterparts in Germany saw their whole professional capability to identify and intervene in prescribing errors less able to intervene, with 25 participants indicating a high score in the questionnaire (p<0.001) (Table 3.19).

Table 3.19: Community Pharmacist Perception of Themselves for Prescribing Error Identification and Intervention (Question 16)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Perception of Community Pharmacists for interventions	Malta	7 (8.1%)	25 (29.1%)	54 (62.8%)	86	**30.27**	**<0.001**
	Germany	19 (18.5%)	59 (57.3%)	25 (24.2%)	103		

A statistically significant difference is shown (p<0.001) in the trust of community pharmacists in Malta and Germany towards their capabilities to identify prescribing errors.

In question 17, a list of selected prescribing errors was shown to community pharmacists. The pharmacists were asked to rate the capability of their profession to recognise the listed prescribing errors. A five-point Likert from the range of 0 (very unlikely) to 4 (highly likely) was used to assess the pharmacists' capabilities. The results are listed in Table 3.20.

The capability to identify allergies to medications shows a difference in the rating of the medical practitioners with a statistical significance (p=0.03) in Malta and Germany. Forty-five percent of medical practitioners in Germany (n=45) indicated that allergies to prescribed drugs cannot be identified by pharmacists or have neither a positive nor a negative relation about the issue, while 16.9% (n=28) of practitioners in Malta stated that allergies cannot be detected by pharmacists or have a neutral relationship towards it.

A statistically significant difference was observed with the capability to identify a duplication therapy (p<0.001) and to identify the wrong written dose on a prescription (p<0.001). Medical practitioners working in Malta are more likely to trust community pharmacists in identifying a duplicated prescribed drug (n=102) and to correct a wrong prescribed dose of a drug (n=98) than their German counterparts. Sixty-two practitioners in Germany mentioned a highly likely or likely capability of pharmacists to correct drug duplications and 38 mentioned a high trust rate on the identification of the wrong dose of a drug.

The pharmacists' capability to intervene in a wrong prescribed duration and a wrong frequency showed for both pharmacists in Malta and Germany a statistically significant difference of p<0.001. In both countries, the majority of pharmacists trust their profession

in being capable to identify and to intervene in a wrong prescribed drug dose or a wrong drug frequency, less pharmacists in Malta (n=3 wrong duration, n=4 wrong frequency) distrust in the capabilities of the pharmacists than their German counterparts (n=17 wrong durations, n=18 wrong frequency).

Other factors concerning sources the identification of drug-drug interactions, incompatibilities, wrong dosage forms or incomplete medical treatments did not show any statistical significances (p>0.05).

Table 3.20: Community Pharmacist Rating on their Capabilities to Identify and Intervene in Prescribing Errors. (Question 17)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Allergies	Malta	15 (17.4%)	31 (36.1%)	40 (46.5%)	86	2.7	0.610
	Germany	22 (21.4%)	32 (31.1%)	49 (47.5%)	103		
Interactions	Malta	2 (2.4%)	20 (23.3%)	64 (74.3%)	86	5.75	0.200
	Germany	0 (0.0%)	14 (13.5%)	92 (86.5%)	103		
Duplications	Malta	0 (0.0%)	5 (5.8%)	81 (94.2%)	86	**53.01**	**<0.001**
	Germany	21 (20.4%)	29 (28.2%)	53 (51.5%)	103		

Table 3.20 (Cont): Community Pharmacist Rating on their Capabilities to Identify and Intervene in Prescribing Errors. (Question 17)

		Low Score	Fair Score	High Score	N	χ^2	*p* value
Incompatibilities	Malta	1 (1.5%)	19 (22.1%)	66 (76.4%)	86	6.87	0.10
	Germany	0 (0.0%)	10 (9.7%)	96 (90.3%)	103		
Wrong dose	Malta	9 (10.5%)	43 (50.0%)	34 (39.5%)	86	0.12	0.99
	Germany	11 (10.7%)	53 (51.5%)	39 (37.8%)	103		
Wrong duration	Malta	6 (7.0%)	23 (26.7%)	57 (66.3%)	86	7.03	0.09
	Germany	5 (4.9%)	24 (23.3%)	76 (73.8%)	103		
Wrong frequency	Malta	6 (2.8%)	25 (29.3%)	55 (63.9%)	86	3.86	0.30
	Germany	4 (3.9%)	20 (19.4.0%)	79 (76.7%)	103		
Wrong dosage form	Malta	2 (2.3%)	41 (47.7%)	43 (50.0%)	86	0.47	0.96
	Germany	3 (1.9%)	49 (47.6%)	52 (50.5%)	103		
Incomplete medical treatment	Malta	12 (14.7%)	42 (48.8%)	32 (37.2%)	86	6.04	0.19
	Germany	24 (23.3%)	40 (38.8%)	39 (37.9%)	103		

CHAPTER FOUR

DISCUSSION

4.1. Root Causes and Prescribing Errors - the Cause of Patient Harm

The medical use process is often not perceived by medical practitioners as a risk-prone process. Root causes that can lead to errors in the process, such as constant interruptions during patient consultation, time pressure or lack of information about the prescribed drug, are not perceived as a high risk which could have a serious impact. The effects of this attitude can be found on medical prescriptions as a prescribing error. Prescribing errors are manifold and can range from an incorrect dosage to lack of patient counselling. In the case of an error on the prescription, the community pharmacist is in the ideal position to recognise errors and to eliminate them. The pharmacist should also be aware of error root causes, because they might affect the pharmacist's intervention in the case of an erroneous prescriptions.

ADEs are a direct health risk to patients (Zhou and Rupa, 2018) and a significant economic burden to health care systems (Gyllensten et al, 2013). It is not possible to completely avoid ADEs, but the ultimate goal should be to reduce their occurrence as much as possible. This helps in protecting the patient and at the same time leads to a huge reduction in health expenditure. It is important to recognise any ADEs as early as possible in order to intervene early and quickly in the medical use process.

The aims of this research were: (1) to find and analyse the current status of causes for errors in an error-prone prescribing and pharmacists' error detection process in Malta and in Germany and; (2) to evaluate the potential risk of prescribing errors on medical prescriptions with the use of risk analysis tools. The error root causes were identified with a combination of interviews and data analysis. On the basis of two separate

questionnaires, one for medical practitioners and one for community pharmacists. The current status of root causes of prescribing error and suboptimal pharmacists' error intervention was determined. In addition to the causes, the potential risk of selected errors resulting from the causes was assessed with the help of the questionnaires. The questionnaire requested the opinion of medical practitioners and pharmacists about the role and ability of community pharmacists as the last element of error elimination.

A finding concerning the current status of errors showed a statistical difference in interruption rates between Maltese and German medical practitioners. Thirty-two percent (n=32) of medical practitioners in Germany admitted to often being interrupted during treatments with patients. This value is relatively low compared to the 66% (n=63) of the Maltese respondents. A very similar interruption rate in this study was found between Maltese (47%, n=40) and German (32%, n=33) pharmacists. It was shown that medical practitioners and pharmacists in Germany were less confronted with interruptions while working.

Studies show that it is not unusual to get distracted as a HCP (medical practitioner, pharmacist, nurse). For instance, pharmacists and nurses showed an interruption rate of once every 2 minutes (Relihan et al, 2010; Silver, 2010). Other studies highlighted the interruption rate of medical practitioners in community emergency departments which was quoted as once every 10 minutes (Chisholm et al, 2011; Weigl et al, 2017). HCPs think that colleagues, phone calls and patients themselves are the main source of interruptions. Studies found that HCPs were the main reason of interruptions and distractions by self-initiating talks and conversations with colleagues or other distractions (Fry and Dacey 2007; Relihan et al, 2010).

Interruptions can be defined as temporary suspensions of goal directed action by a secondary, unplanned task (Brixey et al, 2007). The risk of making errors increases when focussing on an unplanned task. Interruptions have an impact on the prospective memory and on the ability to remember performing a task (Relihan et al, 2010). The memory forms a cue to remind the person of the intention of the specific task in case of an interruption. People are less likely to remember their intention, if outside the context in which the cue was formed (Schaper and Grundgeiger, 2018). For instance, a medical practitioner wanted to check the blood pressure of the patient but got interrupted and had to leave the patient's room. The likelihood of remembering to go back to the patient and check the blood pressure is low. If people do remember and return to their task, some steps may be omitted, repeated, or the whole task might be repeated, because they might have forgotten what steps they already have been doing before the interruption. It was also shown that the working memory needs time to encounter the cue and to go back to the original task (Altman and Trafton, 2007). In case of stressful, time pressuring atmospheres, people do not give the working memory the time to fully encounter the cue and so risking making errors by rushing the tasks to finish up in time (Westbrook et al, 2010).

Interruptions are a threat to patient safety and have an impact on the quality of work of HCPs. The Institute for Safe Medication Practices give guidance on procedures to minimise errors in the medication use process. For instance, to establish a "no interruption zone" or to discuss "do-not-interrupt" rules with colleagues.[24]

[24] Institute for Safe Medication Practices. Side Tracks On The Safety Express. Interruptions Lead To Errors And Unfinished… Wait, What Was I Doing? 2012 [Internet] ISMP 2018 [cited 2018 May 31] Available from: http://www.ismp.org/NEWSLETTERS/acutecare/showarticle.aspx?id=37

To understand the difference in the interruption level between the two countries, one approach could be to look closer at cultural differences between Malta and Germany. Lewis (2006) characterised global cultures on the basis of a triangle model, where cultures are placed according to their dominant characteristics or their key characteristics among the three edges of a triangle. According to Lewis (2006), Maltese are placed very close to the multi-active culture edge as they are extroverted, do several things at once and frequently interrupt others. Germans are very high on the linear-active scale, since they attach great importance to analysing projects, tackling each problem one at a time in a linear way and are less likely to interrupts others. It remains unclear, whether this model according to Lewis (2006) can be used to analyse differences among medical practitioners and community pharmacists in this research.

The findings in this study together with the literature suggest that interruptions and distractions of medical practitioners and pharmacists while focussing on a task, despite cultural differences between Malta and Germany were an issue and awareness amongst HCPs of the negative effects of interruptions should be further highlighted.

Further analysis of the results shows that there was a difference in the perception of stress among community pharmacists in Malta and Germany. Around six percent (n=5) of pharmacists in Malta indicated to experience a low amount of stress compared to 22% (n=23) in Germany which would mean that pharmacists in Malta suffer more from stress or lack of stress management. The stress amount among medical practitioners did not differ significantly, as both groups indicated high work-related stress.

Stress at work or work-related stress often affects HCPs (Boran et al, 2012) and is often underestimated and poorly managed (Koinis et al, 2015). HCPs are exposed to stress factors such as increased workload, patient complaints or organisational issues (Ruotsalainen et al, 2015) which affect their stress perception. Studies have shown that community pharmacists are exposed to a higher amount of stress at work than the general workforce and other HCPs (Jacobs et al, 2014; Johnson et al, 2014).

Work-related stress is defined by the WHO as: "*the response people may have when presented with work demands and pressures that are not matched to their knowledge and abilities and which challenge their ability to cope".*[25] In community pharmacies, work-related stress can lead to dispensing errors and decreased error intervention (Boyle et al, 2016). Stress can negatively affect a person's well-being, both physically and mentally. This can lead to a reduction in job satisfaction, motivation or organisational commitments. Friends and family relationships can also be negatively affected (Jacobs et al, 2018). Causes leading to work-related stress were in studies by McCann et al (2009) and Johnson et al (2014), a high workload, lack of competence and loss of confidence, interruptions, lack of breaks, demanding and impatient patients, lack of privacy during the consultation or lack of professional development.

Further investigation would be necessary to determine to what extent the result is clinically relevant. The section of the questionnaire concerning work related stress was collected in relation to root causes of prescription errors and not primarily to determine the actual work-related stress. Although the questionnaire was validated by an expert

[25] World Health Organization. Stress at the workplace [Internet] WHO 2018 [cited 2018 May 31] Available from: http://www.who.int/occupational_health/topics/stressatwp/en/

panel, the stress found in this study is not measured using specific stress measurements such as the Perceived Stress Scale (PSS) of Cohen (1988) or a visual analogue scale (VAS). As a result, the questionnaire lacks data on the causes that lead to work-related stress and restricts statements regarding the stress difference found in Malta and Germany.

Jacobs and colleagues (2018) identified interventions and strategies to prevent and to manage work related stress in community pharmacies to support pharmacists and pharmacy staff. Strategies in community pharmacies through workshops to reduce stress is not required by law in Malta or Germany. Stress management strategies are therefore the responsibility of the persons in charge in the institutions. Currently the data available on the prevalence of stress management strategies in pharmacies is insufficient and limits the analysis of the different results in Malta and Germany (Balayssac et al, 2017).

Medical practitioners cumulatively perceive their work more burdensome and suffered from the effects of various stress factors, such as sleep loss, tiredness, fatigue and burn-outs (Bergner, 2004). Literature states that the occurrence of stress perception which is manifested in the mentioned stress factors, could be proven as a result of heavy workload and lack of time. On the one hand, the combination of the stress factors may adversely affect life satisfaction and may have adverse physical and mental health effects (Jurkat et al, 2001; Vliagoftis, 2016; Jacobs et al, 2018), on the other hand, stressful working conditions can be expressed in insufficient work outcomes and negative outcomes on the patient side and lead to a higher clinical uncertainty which reduces the ability to perform medical tasks adequately, responsibly and without errors (DeVoe et al, 2002; Gothe et al, 2007). As a result, the quality of care decreases, which

means an increase in costs for the individual medical practitioner, the institution in which they work and for the health care service as a whole (Gothe et al, 2007).

Long-term exposure to high work stress can result in burn-out. Maslach and Jackson (1986) understood burn-out as a three-dimensional construct consisting of emotional exhaustions, depersonalisations (for example negative and cynical attitudes) and reduced personal accomplishments. In particular, people with high work pressure and with a highly specialised profession are at risk of suffering a burn-out syndrome. Many medical practitioners found that their own personal needs are secondary (Gundersen, 2001), and they do not develop resources or strategies to counteract chronic fatigue. In the interviews conducted, none of the medical practitioners stated that they were at risk from burn-out syndrome. One specialist trainee reported to feel extremely stressed at the moment. The remaining medical practitioners reported that although they were exposed to high levels of stress, they reported better capability in coping with the effects of stress. It is estimated that about 22% of medical practitioners in Germany suffer from a burn out syndrome (Voltmer et al, 2010). In Malta 36% of family medical practitioners were found to suffer from a burnout of emotional exhaustions (Soler et al, 2008). The specific challenges for practising the medical profession are to manage stress factors, coping with workload and preventing burn-outs (Gothe et al, 2007). Medical practitioners who are exposed to stress factors in the workplace tend to treat patients both medically and psychologically inferior (Arnetz, 2001).

Considering the second section of the PEQs, which asked the medical practitioners and community pharmacists to rate the risks of specific prescribing errors according to the probability of occurrence and severity of consequences. From both rating scores,

probability and severity, the 'Risk Priority Number' (RPN) was calculated, which gives a numerical assessment of the risk of a particular process[26] (1 - 4 low risk) (6 medium risk) (8 - 16 high risk).

The results showed that medical practitioners in Malta rated the risk of a prescribing error due to illegible handwriting as a high risk with an average RPN of 6.81. Pharmacists in Malta estimate the risk even higher with an average RPN of 7.95. According to the RPN and the threshold of 8 as a high risk chosen in this study, measures should be considered to minimise the risk of illegible handwriting on a prescription in Malta. In Germany, this prescribing error was assessed with an average RPN of 1.15 among medical practitioners and 1.17 among community pharmacists. The calculated low numbers are considered as no risk and further measures will not be recommended. This low average RPN of HCPs in Germany resulted from the fact that 90% of the medical prescriptions are computer-printed. According to the IOM report in 2006, 7,000 people die in the US each year, because of illegible handwritten prescriptions by medical practitioners. Illegible medical prescriptions are a known and preventable cause of dispensing errors. Medical practitioners are responsible for the prevention of ADEs and are legally obliged to issue clearly intelligible prescriptions and to reduce ambiguity (Murray et al, 2009). It can be assumed that the focus of medical practitioners is more on diagnosing and the drug therapy than on the prescribing process. Trying to save time when writing a prescription per hand cannot be avoided, by writing quickly is expected

[26] Institute for Healthcare Improvement. Risk Priority Number (from Failure Modes and Effect Analysis) [Internet] IHI 2018 [cited 2018 May 31]. Available from: http://www.ihi.org/resources/Pages/Measures/RiskPriorityNumberfromFailureModesandEffectsAnalysis.aspx

to be wrong calculation (Legese, 2016). In two study conducted in countries, where handwritten prescriptions are still prevalent, it was shown that computerised prescriptions appeared to be associated with lower error rates, according necessary information and legibility of the prescription (Al Shahaibi NMS et al, 2012; Joshi et al, 2016). Handwritten prescribing errors can be avoided by using computerised prescriptions and supportive software (Jeetu and Girish, 2010).

Omissions of important information on a medical prescription is considered one of the most common type of prescribing error (Seden et al, 2013; Lavan et al, 2016). In this study, individual omissions were assessed, such as the omission of the prescriber's contact details or omission of the drug dose. It has been shown that the perception of medical practitioners and pharmacists differs with regard to the individual omissions in Malta and Germany. A statistically significant difference was indicated in the omission of the prescriber's contact details. Medical practitioners and community pharmacists in Malta have seen a higher risk of this individual prescribing errors than their counterparts in Germany. In both countries, it is regulated by law that medical prescriptions must include certain information about the prescriber including the contact details such as e-mail address or telephone number. A study in Malta showed that due to a vast number of hand-written prescriptions and no standard format for private prescription, 95% of private prescriptions had missing prescriber's contact information (Curmi, 2017). In such cases if any queries of the pharmacist occur and the phone number of the prescriber is not included on the prescription, difficulties to dispense the drug may be predictable. In Germany, prescriptions are mainly computerised, computer software programs are always involved which provides a standardised format of a prescriptions. Drugs can be

selected from a constantly updated list including dose and frequency. Some programs also provide drug-drug interaction alerts, if two drugs were chosen that are incompatible. On the pharmacist's side, similar programs exist for the dispensing process that include drug-drug interaction alerts and updated information about the individual drug that is being dispensed as an example. In Malta, such software programs are rarely used. Information about particular drugs are collected from certain websites. This includes another activity that one is unwilling to enter and thus accepts a prescription or delivery error.

Another issue was the question of whether medical practitioners were aware of having committed a prescribing error, as defined in the questionnaire. It was found that 89.3% of the participating practitioners in Germany were aware that they had once committed an error, 2.4% denied having made an error, before. In Malta, 72.2% confirmed an error and 16.7% denied which showed a statistically significant difference to Germany.

The proverbs "*everyone makes mistakes*" or "*no one is flawless*" fit well in this situation when it comes to taking a closer look at the results of the error awareness of medical practitioners. The US IOM report "*To Err is Human*" (Kohn et al, 2000) and a variety of other study results mentioned in this research, show that MEs are prevalent in the medication use process. The fundamental question that arises here is why prescribing errors were not perceived by 16.7% of medical practitioners in Malta and 2.4% in Germany in this research.

Klein et al (2013) distinguished error awareness in consciously awareness and remaining unrecognisable awareness that might only be noticed retrospectively when unpleasant

consequences were experienced like ADEs. Potential influences on the awareness are endogenous, such as lack of attention or lack of expertise and exogenous factors for example time pressure or ambiguous task situations.

According to Klein et al (2013), this would mean that the 16.7% of medical practitioners in Malta and 2.4% in Germany were unaware of their prescribing errors due to either endogenous or exogenous factors. Taking into consideration the results of the current root causes analysis in terms of the significant differences in interruption rates or more unorganised working atmospheres among medical practitioners in Malta, these exogenous factors could be causes of unrecognisable awareness. An explanation for the distinction in error awareness according to Klein et al (2013) regarding endogenous factors is a bit more complicated. Studies show that a vast portion of MEs remain frequently unreported due to voluntary reporting by health care providers (Elden and Ismail, 2016).[27] The reasons for under-reporting could help to explain exogenous factors of error awareness in this study. O'Hagan et al (2009) mentioned that 80 - 88% of MEs in seven industrialised countries, such as Canada, Germany, UK or the US stay under-reported. The under-reporting occurs in all medication use process stages including the prescribing process (Kang et al, 2017). Under-reporting of MEs is associated with a lack of knowledge (Alsulami et al, 2013) and a limited attitude towards the risk-prone medication use process of HCPs. Other factors MEs' under-reporting include miscommunication, blame culture, fear of punishment, lack of awareness of the reporting policies and potential termination from the job (Uribe et al, 2002). Klein et al

[27] World Health Organisation. Reporting and learning systems for medication errors:The role of pharmacovgilence centers [Internet] WHO 2014 [cited 2018 May 31] Available: http://apps.who.int/medicinedocs/documents/s21625en/s21625en.pdf

(2013) and Alsulami et al (2013) came to the same conclusion that exogenous error awareness was influenced by knowledge and the individual attitude towards an issue.

4.2. Limitations

The length of the questionnaire could have contributed to a low response rate among medical practitioners and community pharmacists. A higher response rate among both HCPs could have improved and strengthened the results of the current status of ME root causes and the potential risk of prescribing errors and would have assure a higher representativeness. Both questionnaires used closed-ended questions which could have contributed to biased response rates as responses are limited for this kind of questions. Another limitation was the five-point Likert scale, which was used in this study as a tool to analyse and assess root causes and risks of prescribing errors. The scale of this tool had only 5 options of choice, from 0 to 5. The chance of filling out the questionnaire randomly with a limited option of choice was high and could have led to bias. Participants could have also been influenced by previous answers and base their answer on responses given previously. The study was restricted to one metropolitan area in Germany which have limited the generalisation of the findings. The interviews conducted to identify root causes to develop the questionnaires included only medical practitioners. Including community pharmacist would have enhanced the root causes that decrease pharmacists' interventions in erroneous prescriptions. The findings of the questionnaires might also be influenced by selection bias. Responses to rank the prescribing error risks might not reflect real scenarios, as ideal answers might have been chosen instead

4.3. Recommendations for Further Work

The comparative research method to find causes that lead to dispensing errors and to assess the risk of prescribing errors risks was applied in Malta and in Germany. It is recommended with this developed method to compare more countries. The applied risk analysis to assess root causes of errors can be applied in medical practitioners' offices or in community pharmacies not only to identify and assess prescribing errors, but also to evaluate general procedures on their effectiveness or error rate.

4.4. Conclusion

This study developed a method of identifying and analysing the current status of processes that may lead to prescribing errors and suboptimal pharmacist interventions. The study assessed the risk of prescribing errors from a medical practitioner's and pharmacist's perspective.

This study showed that root causes, like interruptions or stress could lead to prescribing errors in Malta and Germany and in the case of community pharmacists, causes responsible for overlooking errors on prescriptions. Specific root causes of medical practitioners and community pharmacists were responsible for medication errors within Malta and Germany. The awareness of medical practitioners and community pharmacists should be increased, specifically to the root causes found in this study to avoid future errors. Causes of errors could have a correlation to cultural behaviour and should be taken in consideration when applying the developed method.

The potential risk of prescribing errors in Malta and Germany was assessed by undertaking a risk assessment exercise. Healthcare risk assessment methods are relatively new and have been used in high-risk industries such as the aviation industry. Considering the medication use process as highly risk-prone, it would be appropriate to apply risk assessment methods in this context. This study showed which prescribing errors are a high risk and which errors must be minimised with specific measures. Risk minimisation strategies to reduce the potential risk were addressed and can either be applied by health care professionals themselves or by implementing legal measures.

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APPENDICES

APPENDIX 1
Information Letter and Consent Form

Information Letter

DATE

Dear NAME,

This letter is an invitation to consider participating in a study I am conducting as part of my Doctoral degree in Pharmacy at the University of Malta. I would like to provide you with more information about the research and what your involvement would entail if you decide to take part.

This research will evaluate and analyse the current status quo of prescribing error causes by medical practitioners that have the potential to lead into dispensing errors by community pharmacists, and the ability of the pharmacist to intervene in such cases. The study will observe practitioners in their prescribing procedure and community pharmacy activities concerning dispensing medicinal products, in Malta and Germany.
Another aim of this research is to define and analyse potential risks that may occur in the process of prescribing and dispensing.

Participation in this study is voluntary. It will involve an interview of your prescribing or dispensing procedure. The interview will take approximately 45 minutes. You may decline to answer any of the interview questions if you so wish. You may decide to withdraw from this study at any time without any negative consequences. With your permission, the interview will be tape-recorded to facilitate collection of information and later transcribed for analysis. All information you provide will be treated in strict confidence and the anonymity of participants will be secured at all times. Your name will not appear in any thesis or report resulting from this study, however, with your permission anonymous quotations may be used. There are no known or anticipated risks to you as a participant in this study.

If you have any questions regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact me on: *0177 635 6348* (Germany) / *9999 3853* (Malta) or by e-mail: *Jeffrey.Kupka.15@um.edu.mt*

I look forward to speaking with you and thank you in advance for your assistance in this research.

Sincerely,

Jeffrey I. Kupka
Doctorate in Pharmacy Student
Department of Pharmacy, Faculty of Medicine & Surgery
University of Malta

Consent Form

I confirm that I have read the information presented in the information letter about the study being conducted by Jeffrey I. Kupka, a second year Doctorate in pharmacy student at the University of Malta. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I wanted.

I am aware that I have the option of allowing my interview to be tape-recorded to ensure an accurate recording of my responses.

I am also aware that excerpts from the interview may be included in the dissertation, with the understanding that the quotations will be anonymous.

I was informed that I may withdraw my consent at any time without penalty by advising the researcher.

With full knowledge of the above, I agree, of my own free will, to participate in this study.

YES ☐ NO ☐

I agree to have my interview tape-recorded.

YES ☐ NO ☐

I agree to the use of anonymous quotations in any thesis that comes of this research.

YES ☐ NO ☐

Participant's Name _____

Participant's Signature _____ Date _____

Researcher's Signature _____ Date _____

APPENDIX 2
PEQ_{med} Questionnaire

1. Demographics

1. How many years have you worked in your profession?

☐ 0 -5 years
☐ 6 -10 years
☐ 11 - 30 years
☐ > 30 years

Remarks:

2. What medical profession applies to you?

☐ Foundation Doctor
☐ Basic / Higher Specialist Trainee Area of specialisation _____
☐ Family Doctor
☐ Specialist / Consultant Area of practice _____
☐ Other (please specify) _____

3. What are your overall average working hours per week?

☐ < 40 hours
☐ 40 - 60 hours
☐ 61 - 80 hours
☐ > 80 hours

Remarks:

4. In which institution do you currently work? *(several possible answers)*

☐ Hospital
☐ Health centre
☐ Private clinic
☐ Others (please specify) _____

Remarks:

2. Root Cause Ranking

5. To what extent do you get interrupted while treating patients? (e.g. by colleagues, phone calls, other patients, relatives, emergencies)
Please rate your answer from 0 to 4 on the Likert scale below.

Very rarely →				Very often
0	1	2	3	4

Remarks:

6. Do you experience stress at your work?
Please rate your answer from 0 to 4 on the Likert scale below.

Very rarely →				Very often
0	1	2	3	4

Remarks:

7. How would you rate the atmosphere in your primary work area?
Please rate your answer from 0 to 4 on the Likert scale below.

Very calm				Very chaotic
0	1	2	3	4

Remarks:

8. How much time on average do you spend consulting a patient?

☐ < 10 minutes
☐ 10 - 20 minutes
☐ 21 - 30 minutes
☐ > 30 minutes

Remarks:

9. Do you have any kind of control-system that double checks the feasibility of the prescriptions before handing them to the patients?

☐ Yes
☐ No

a) If yes, what kind of control system do you use? (please specify)

_____

Remarks:

10. Do you use any kind of electronic medical records (EMR) for your patients at your primary work area?

○ Yes
○ No

Remarks:

11. Are you at all times informed about the following patient information?
Please rate your answer from 0 to 4 on the Likert scale below.

	Never →				Always →
	0	**1**	**2**	**3**	**4**
Medical History, previous illnesses					
Allergies					
Current and recently withdrawn or changed medication					
Vital signs (body temperature, blood pressure, pulse /heart rate, respiratory rate)					
Personal statistics (e.g. age, weight)					
Immunization status					
Specific laboratory test results					
Other (please specify) _____					

Remarks:

12. How many of your patients are regular?

☐ < 20 %
☐ 20 - 50 %
☐ 51 - 80 %
☐ > 80 %

Remarks:

13. Do you feel your medical knowledge is of high standard?
Please rate your answer from 0 to 4 on the Likert scale below.

Poor →				Excellent
0	1	2	3	4

Remarks:

14. Do you feel satisfied with your current medical affairs knowledge?
Please rate your answer from 0 to 4 on the Likert scale below.

Not at all satisfied → Extremely satisfied				
0	**1**	**2**	**3**	**4**

Remarks:

15. Which sources of information do you consult the most when prescribing?
Please rate your answer from 0 to 4 on the Likert scale below.

	Never → **Always**				
	0	**1**	**2**	**3**	**4**
Consultation with colleagues					
Consultation with a pharmacist					
International guidelines					
Peer-reviewed journals					
Drug company information					
Medical literature					
Reputable internet websites or apps (e.g. BNF, UpToDate)					
Other (please specify) _____					

Remarks:

16. **To what extent are you familiar with the following information of the drugs prescribed? Please rate your answer from 0 to 4 on the Likert scale below.**

	Not informed at all →				**Very well informed** →
	0	**1**	**2**	**3**	**4**
Registered indications					
Dose					
Frequency					
Duration of use					
Active ingredient(s)					
Contraindications					
Interactions					
Side effects					
Other (please specify) _____					

Remarks:

3. Prescribing Errors Risk Analysis

17. Please rate the following prescribing errors by their probability and severity as you think they appear in general

a) Omission of the prescriber's contact details

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

b) Illegible handwriting

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

c) Omission of dose

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

○	1	No impact on patient
○	2	Could lead to issues with patient, but no physical harm
○	3	Potential to physically harm patient
○	4	Will cause temporary harm

Remarks:

d) Omission of frequency

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

○	1	No impact on patient
○	2	Could lead to issues with patient, but no physical harm
○	3	Potential to physically harm patient
○	4	Will cause temporary harm

Remarks:

e) Omission of duration of use

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

f) Omission of the route of administration for a drug that can be given by more than one route

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

g) Omission of patient indication						
Probability						
	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity						
	○ 1	No impact on patient				
	○ 2	Could lead to issues with patient, but no physical harm				
	○ 3	Potential to physically harm patient				
	○ 4	Will cause temporary harm				

Remarks:

h) Using abbreviations						
Probability						
	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity						
	○ 1	No impact on patient				
	○ 2	Could lead to issues with patient, but no physical harm				
	○ 3	Potential to physically harm patient				
	○ 4	Will cause temporary harm				

Remarks:

i) Misspelling a drug name						
Probability	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity	○ 1 No impact on patient ○ 2 Could lead to issues with patient, but no physical harm ○ 3 Potential to physically harm patient ○ 4 Will cause temporary harm					

Remarks:

j) Prescribing by brand name rather than active ingredient						
Probability	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity	○ 1 No impact on patient ○ 2 Could lead to issues with patient, but no physical harm ○ 3 Potential to physically harm patient ○ 4 Will cause temporary harm					

Remarks:

k) Longer duration of short term use medication (e.g. Clopidogrel)

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

l) Prescribing a drug without informing the patient of its use

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

m) Prescribing contrary to treatment guidelines

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

n) Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified release formulations)

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

18. Are you aware of having made a prescribing error in the past?

☐ Yes
☐ No
☐ Do not know

b) If yes, which one? (please choose from the list below)
(several possible answers)

○	Omission of the prescriber's contact details
○	Illegible handwriting
○	Omission of dose
○	Omission of frequency
○	Omission of duration of use
○	Omission of the route of administration for a drug that can be given by more than one route
○	Omission of patient indication
○	Using abbreviations
○	Misspelling a drug name
○	Prescribing by brand name rather than active ingredient
○	Longer duration of short term use medication (e.g. Clopidogrel)
○	Prescribing a drug without informing the patient of its use
○	Prescribing contrary to treatment guidelines
○	Prescribing a drug for which there is no evidence of efficacy
○	Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified release formulations)
	Other *(please specify)* _____

Remarks:

4. Role of the Community Pharmacist

19. Do you think pharmacists could play a major role in recognising and correcting prescribing errors?
Please rate your answer from 0 to 4 on the Likert scale below.

Not at all →				All the time
0	**1**	**2**	**3**	**4**

Remarks:

20. What prescribing errors do you think a pharmacist is capable of recognising? Please rate your answer from 0 to 4 on the Likert scale below.

	Very unlikely →				Highly likely
	0	**1**	**2**	**3**	**4**
Allergies to medication prescribed					
Drug-Drug Interactions					
Duplicate Therapy					
Incompatibility					
Wrong Dose / Concentration					
Wrong Duration					
Wrong Rate					
Wrong Dosage Form					
Incomplete medical treatment					
Other (please specify) _____					

Remarks:

APPENDIX 3
PEQ_{pharm} Questionnaire

1. Demographics

1. How many years have you worked as a community pharmacist?

☐ < 2 years
☐ 2 -5 years
☐ 6 - 10 years
☐ > 10 years

Remarks:

2. What are your overall average working hours per week in a community pharmacy ?

☐ < 10 hours
☐ 10 - 20 hours
☐ 21 - 40 hours
☐ > 40 hours

Remarks:

3. Did you participate in any postgraduate study or advanced training courses concerning pharmacy practice after graduation?

☐ Yes
☐ No

c) If yes, please specify

_____

Remarks:

2. Root Cause Ranking

4. To what extent do you get interrupted while consulting patients or preparing patients medication? (e.g. by colleagues, phone calls, other patients)
Please rate your answer from 0 to 4 on the Likert scale below.

Very rarely →				Very often →
0	1	2	3	4

Remarks:

5. Do you experience stress at your work?
Please rate your answer from 0 to 4 on the Likert scale below.

Very rarely →				Very often →
0	1	2	3	4

Remarks:

6. How would you rate the atmosphere in your primary work area?
Please rate your answer from 0 to 4 on the Likert scale below.

Very calm				Very chaotic
0	1	2	3	4

Remarks:

7. How much time do you spend approximately for checking, interpreting and discussing issues related to the prescription with the patient??

☐ < 1 minutes
☐ 1 - 2 minutes
☐ 3 - 5 minutes
☐ > 5 minutes

Remarks:

8. Do you use any kind of pharmacy dispensing support software?

○ Yes
○ No

Remarks:

_____

_____

_____

9. Are you at all times informed about the following patient information?
Please rate your answer from 0 to 4 on the Likert scale below.

	Never →				Always →
	0	**1**	**2**	**3**	**4**
Patient details					
Medical History, previous illnesses					
Current and recently withdrawn or changed medication					
Personal statistics (e.g. age, weight)					
Specific laboratory test results					
Details of the prescribing doctor					
Other (please specify) _____					

Remarks:

---

10. How many of your patients are regular?

☐ < 20 %
☐ 20 - 50 %
☐ 51 - 80 %
☐ > 80 %

Remarks:

---

11. Do you feel your pharmaceutical knowledge is of high standard?
Please rate your answer from 0 to 4 on the Likert scale below.

Poor →				Excellent
0	**1**	**2**	**3**	**4**

Remarks:

---

12. Do you feel satisfied with your current medical affairs knowledge?
Please rate your answer from 0 to 4 on the Likert scale below.

Not at all satisfied				Extremely satisfied
0	1	2	3	4

Remarks:

13. Which sources of information do you consult the most when prescribing? Please rate your answer from 0 to 4 on the Likert scale below.

	Never →				Always →
	0	1	2	3	4
Consultation with colleagues					
Consultation with a prescribing practitioner					
International guidelines					
Peer-reviewed journals					
Drug company information					
Medical literature					
Reputable internet websites or apps (e.g. BNF, UpToDate)					
Other (please specify) _____					

Remarks:

14. To what extent are you familiar with the following information of the drugs prescribed? Please rate your answer from 0 to 4 on the Likert scale below.

	Not informed at all →				**Very well informed** →
	0	**1**	**2**	**3**	**4**
Registered indications					
Dose					
Frequency					
Duration of use					
Active ingredient(s)					
Contraindications					
Interactions					
Side effects					
Other (please specify) _____					

Remarks:

3. Prescribing Errors Risk Analysis

15. Please rate the following prescribing errors by their probability and severity as you think they appear in general

a) Omission of the prescriber's contact details

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

b) Illegible handwriting

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

c) Omission of dose

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

○	1	No impact on patient
○	2	Could lead to issues with patient, but no physical harm
○	3	Potential to physically harm patient
○	4	Will cause temporary harm

Remarks:

d) Omission of frequency

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

○	1	No impact on patient
○	2	Could lead to issues with patient, but no physical harm
○	3	Potential to physically harm patient
○	4	Will cause temporary harm

Remarks:

e) Omission of duration of use

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

f) Omission of the route of administration for a drug that can be given by more than one route

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

g) Omission of patient indication

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

h) Using abbreviations

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

i) Misspelling a drug name						
Probability	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity	○ 1 No impact on patient ○ 2 Could lead to issues with patient, but no physical harm ○ 3 Potential to physically harm patient ○ 4 Will cause temporary harm					

Remarks:

j) Prescribing by brand name rather than active ingredient						
Probability	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity	○ 1 No impact on patient ○ 2 Could lead to issues with patient, but no physical harm ○ 3 Potential to physically harm patient ○ 4 Will cause temporary harm					

Remarks:

k) Longer duration of short term use medication (e.g. Clopidogrel)

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

l) Prescribing a drug without informing the patient of its use

Probability

Never	1	2	3	4	Always
	○	○	○	○	

Severity

- ○ 1 No impact on patient
- ○ 2 Could lead to issues with patient, but no physical harm
- ○ 3 Potential to physically harm patient
- ○ 4 Will cause temporary harm

Remarks:

m) Prescribing contrary to treatment guidelines						
Probability						
	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity						
	○ 1	No impact on patient				
	○ 2	Could lead to issues with patient, but no physical harm				
	○ 3	Potential to physically harm patient				
	○ 4	Will cause temporary harm				

Remarks:

n) Prescribing a dose regimen that is not recommended for the formulation prescribed (e.g. modified release formulations)						
Probability						
	Never	1 ○	2 ○	3 ○	4 ○	Always
Severity						
	○ 1	No impact on patient				
	○ 2	Could lead to issues with patient, but no physical harm				
	○ 3	Potential to physically harm patient				
	○ 4	Will cause temporary harm				

Remarks:

4. Role of the Community Pharmacist

16. Do you think pharmacists could play a major role in recognising and correcting prescribing errors?
Please rate your answer from 0 to 4 on the Likert scale below.

Not at all →				All the time
0	**1**	**2**	**3**	**4**

Remarks:

17. What prescribing errors do you think a pharmacist is capable of recognising? Please rate your answer from 0 to 4 on the Likert scale below.

	Very unlikely →				Highly likely
	0	**1**	**2**	**3**	**4**
Allergies to medication prescribed					
Drug-Drug Interactions					
Duplicate Therapy					
Incompatibility					
Wrong Dose / Concentration					
Wrong Duration					
Wrong Frequency					
Wrong Dosage Form					
Incomplete medical treatment					
Other (please specify) _____					

Remarks:

APPENDIX 4
FIP Abstract

Pharmacist Perspective of Prescribing Errors

Jeffrey I. Kupka, Maurice Zarb-Adami, Maresca Attard Pizzuto, Anthony Serracino-Inglott

Background information: Errors on a medical prescription may lead to erroneous dispensing by the pharmacist. An assessment of causes that might lead to prescribing errors in Malta and Germany was undertaken.

Purpose: To assess root causes in the medical use process that have the potential to lead to prescribing errors from a pharmacist perspective.

Method: A questionnaire to assess root causes in the medical use process, was developed, validated and electronically disseminated to 338 pharmacists in Malta and to 188 pharmacies in Germany. Validation was undertaken by a panel of experts (N=14), comprising of 7 physicians, and 7 pharmacists using a structured communication method.

Results: One hundred eighty-nine pharmacists (86 Malta, 103 Germany) answered the questionnaire. Work environment factors, such as stress as a cause for errors, was significantly higher as claimed by pharmacists in Malta compared to pharmacists in Germany ($p < 0.05$). Interruption levels as a second factor, showed a statistically significant difference ($p < 0.05$). Pharmacists in Malta claimed to get interrupted more often while consulting a patient than pharmacists in Germany.

Dispenser-related factors, such as medical history, the information the pharmacist has of the patient, showed a statistically difference. German pharmacists claim to have a superior access to these information ($p < 0.05$).

Conclusion: The findings suggest that work environment and dispenser-related factors are an issue having negative effects on prescribing. Different work settings and technical equipment may have a positive impact in reducing the risk of errors and may be the cause of the differences in Malta and Germany.

Topic area: Community pharmacy

APPENDIX 5
ACCP Abstract

Risk Assessment of Prescribing Errors on Medical Prescriptions in Malta and Germany

Jeffrey Ikem Kupka, Maurice Zarb Adami, Maresca Attard Pizzuto, Anthony Serracino-Inglott

Introduction: Errors on a physician's prescription may lead to erroneous dispensing by the pharmacist. A risk assessment of errors arising from prescriptions in Malta and Germany was undertaken.

Research question or hypothesis: To assess the risk of prescribing errors by physicians from the perspective of physicians and pharmacists

Study design: Prospective qualitative and quantitative study design

Methods: Interviews with physicians were conducted to describe the medical use process in both countries.

Two questionnaires, one for physicians and one for pharmacists were developed and validated by 16 experts. Both professions were asked to assess root causes for errors that were discussed in physician's interviews and to rank potential prescribing errors on a scale of 1 (low score) - 4 (high score) by their probability and severity to get an overall 'Risk Priority Number' (RPN) (1 - 4 low risk) (6 medium risk) (8 - 16 high risk).

Results: One hundred and ninety-one physicians (94 Malta, 97 Germany) and 177 pharmacists (74 Malta, 103 Germany) answered the questionnaire respectively.

Prescribing errors due to illegible handwriting (RPN of 6.71 for physicians, 8.42 for pharmacists) and continuing the prescription for a longer duration than necessary (RPN of 5.69 for physicians, 7.82 for pharmacists) were rated as the two highest risks leading to potential dispensing errors in Malta. Physicians and pharmacists in Germany rated the continuing prescriptions as their highest risk with a score of 5.3 (physicians) and 7.42 (pharmacists).

Conclusion: In both countries an uncontrolled duration of a medication is seen as one of the highest risks. In Malta, the physician's handwriting is viewed as the main source of prescribing errors. This error is not an issue in Germany as prescriptions are issued electronically. Risk minimisation strategies to address these risks include the use of electronic software.