Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines

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Doctorate in Pharmacy

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To God be all the glory

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Abstract

Pharmacist's clinical reasoning and decision-making are critical competency areas that should be investigated due to the increasing clinical involvement of the profession. Clinical reasoning in pharmacy is a complex process that hinges on the pharmacist's capacity to integrate and apply accumulated knowledge, use and weigh evidence, evaluate all available arguments, and reflect upon the process to arrive to a clinical therapeutic decision.

The aim of this study was to investigate clinical reasoning process adopted by community pharmacists in Malta and Philippines when dealing with patients presenting with acute minor ailment concerns. The main outcome of this research was to provide recommendations based on implications in pharmacy education, practice, and research to effectively develop clinical reasoning and decision making competencies among pharmacists and future pharmacists.

A comparative qualitative ethnomethodology study was conducted, particularly using a retrospective think aloud technique to examine the patterns of clinical reasoning and decision making processes of community pharmacists. Community pharmacists in the Philippines (10) and in Malta (5) with at least 3-year work experience were observed in the workplace for an entire shift, and were subsequently interviewed. Interactions with adult patients concerning minor ailments, namely, headache, cold and flu, muscle pain, and cough, were documented. All verbal reports were audio/video recorded, transcribed and analyzed using protocol analysis. This study was approved by Faculty of

Research Ethics Committee of University of Malta and University of the Philippines Research and Ethics Board.

During the observation, 30 and 16 cases of pharmacists responding to minor ailments were observed in The Philippines and in Malta, respectively. Patient requests were classified into two: seeking specific medicine (n=33) or advice (n=13). Pharmacists performed clinical reasoning by collecting contextual patient information and analyze these using objective pharmaceutical knowledge and clinical experience leading to clinical actions to improve patient outcomes or maintain quality of life. Five predominant cognitive strategies when conducting clinical reasoning were identified: collect, assume, infer, act, and explain. When patients seek specific medicines, the pharmacists conducted reasoning only in 29% (Philippines) and 63% (Malta) of the cases, mostly through if/then and hypothetico-deductive approach, respectively. Majority of the specific active ingredients and brands requested by patients were dispensed as is, and about less than 33% were given a pharmaceutical equivalent, alternative or were reassessed. When patients sought for advice, pharmacists reasoned 100% of the time in which Filipino pharmacist utilized if/then approach (83%), whereas Maltese pharmacists tend to assess and decide medications by forward-chaining (50%).

Pharmacist's clinical reasoning approach mostly followed the analytical decision making, which critically varied according to patient's request at the onset of the interaction.

Chapter 1
Introduction

Chapter 1 Introduction

1.1 Community pharmacy practice

Pharmacists are regarded as the most accessible healthcare professional, but remain to be "underutilized" in the healthcare system (Stock, 1989; Mossialos et al, 2015). It was debated that pharmacy profession as a body of practice lacked a unifying crucial ingredient given the existence of many practice areas (Brodie, 1986). In order to overcome this identity issue, the patient-centered clinical role was proposed as the core function of the pharmacy profession. Decades after the philosophy of "pharmaceutical care" was introduced (Hepler & Strand, 1990) with a focus on putting forward the pharmacist core function to clinical interventions. Pharmaceutical care is defined as the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life" (Hepler & Strand, 1990). In line with the evolving philosophies of pharmacy practice, the World Health Organization² identified the role of community pharmacists which involves processing of prescriptions, clinically caring for patients, monitoring of drug utilization, performing small scale extemporaneous compounding, offering traditional and alternative medicines, responding to symptoms of minor ailments, providing drug information and health promotion, and conducting domiciliary services². Over the years, there has been a gradual progression of the pharmacy profession to incorporate more clinical involvement. From the traditional role of supply chain and dispensing of medicines, pharmacists have been proactively expanding their roles through services that would ensure cost-effective, accessible and rational use of medicines (de Melo & de Castro, 2017), promote health (Petrelli et al,

¹ Murray R. Community Pharmacy Clinical Services Review [Internet]. England; 2016 [cited 18 January 2019]. Available URL: https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2016/12/community-pharm-clncl-serv-rev.pdf
²World Health Organization. The Role of Pharmacist in the Healthcare System [internet]. Japan; 1994 [cited 29 January 2019]. Accessed URL: http://apps.who.int/medicinedocs/en/d/Jh2995e/1.6.2.html

2019), and improve health outcomes through direct patient and team-based care (Dalton & Byrne, 2017; Hwang et al, 2017). A pharmacist's practice highly differs according to national jurisdiction, but documented expansion of roles includes provision of emergency prescription refills, renewal/extension of prescriptions, collaborative prescribing, change of drug dosage/formulation, therapeutic substitution, prescribing in cases of minor ailments, initiation of prescription drug therapy, order and interpretation of lab tests and medicine administration (Mossialos, et al 2015; Hwang et al, 2017; Goode et al, 2019). Other emerging roles are being published to date such as vaccination (Kirkdale et al, 2016; Petrelli et al, 2019) and providing innovative pharmacy services (Vella et al., 2015; Wright et al, 2018; Attard Pizzuto et al, 2019). Some examples of professional services offered by community pharmacists include medication therapy management at the home care (Corsi et al, 2018), point-of-care testing for monitoring chronic diseases and aid in deciding during dispensing (Saldarriaga et al, 2017; Goble & Ricafort, 2017; Klepser & Klepser, 2018), smoking cessation interventions among adults (Carson-Chahhoud et al, 2019) and among pregnant patients (Barboza, 2018), and anticoagulant monitoring (Mifsud et al, 2019). This global trend is due to the increasing evidence of the value of pharmacist's interventions that contribute to healthcare savings in line with the escalating cost to address complex diseases (Dalton & Byrne, 2017) and health maintenance related to extension of life expectancy (Mossialos et al, 2015).

The pharmacy profession has come a long way since the 1980s. From focusing on production, to dispensing, to a much more patient-centered role, it continues to evolve to become more relevant and responsive to the needs of the patients and healthcare as a whole (Azzopardi, 2000). Recognition of pharmacists' capabilities highly vary from country to country which may be affected by multiple factors such as law, competency, training, and pharmacy education. Several examples have been cited as emerging roles and services, but it should be noted that only a few countries implement them. As an example, only 13 countries allow pharmacists to vaccinate according to International Pharmaceutical Federation in 2016³. Prescribing role is legal in countries like United Kingdom, Canada and in some states in the United States of America⁴. While the practice can be progressive in some countries, some societies continue to belittle the profession as merely "drug sellers" equivalent to salespersons offering common commodities. Important barriers to sustainably expand the scope of practice of community pharmacists include risk aversion (Rosenthal et al, 2010; Attard Pizzuto et al, following: 2016), lack of the state recognition, and the remuneration/reimbursement models (Houle et al, 2014; Mossialos et al, 2015), confidence to implement new services, funding and resources, support from employers, state, other healthcare professional (eg, physicians), and weak information systems (Mossialos et al, 2015). Community pharmacists must continue to publish scientific evidence that highlights their professional competency and contribution to health

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³ International Pharmaceutical Federation. An overview of current pharmacy impact on immunization: A global report [internet]. Netherlands; 2016. Available from: https://www.fip.org/files/fip/publications/FIP report on Immunisation.pdf

⁴Collins S. A tale of two countries: The path to pharmacist prescribing in the United Kingdom and Canada [internet]. US; 2014. Available from: https://www.pharmacist.com/article/tale-two-countries-path-pharmacist-prescribing-united-kingdom-and-canada

systems efficiency (Mossialos et al, 2013), as well as engage in policymaking in order to successfully empower them to perform more patient-centered care roles.

Self-care and pharmacist-led minor ailment service

Self-care is defined as "the ability of individuals, families and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without support of a healthcare provider".5 In this paradigm, patients treat selfrecognized illness or symptoms by using medicines at their own initiative, an activity referred to as self-medicating. Many patients utilize this method first to address minor ailments, before visiting a physician. Minor ailments are conditions considered less serious, such as cough, common cold, mild eczema, minor muscle pain, mild headache, oral thrush, heartburn, hay fever, skin rash, fungal infections and yeast infections.⁶ Pharmacists have been an important adviser on everyday health care issues, including minor ailments. Medicines required in these health cases are typically nonprescription drugs. Although considered safe, inappropriate selection and frequent use of these over-the-counter (OTC) medicines can potentially lead to adverse effects. Chrisholm-Burns et al (2010) documented that inappropriate self-medication with OTC contributes to hospital admission. Pharmacists are strategically positioned to promote responsible self-medication during dispensing, and are considered sources of reliable information (Dineen-Griffin et al, 2020).

⁵ World Health Organization. What do we mean by selfcare? [internet]. Geneva; 2020. Available from: https://www.who.int/reproductivehealth/self-care-interventions/definitions/en/

⁶ New Brunswick Pharmacists' Association. Minor Ailment Assessments [internet]. Canada; 2020. Available from: https://nbpharma.ca/minor-ailment-assessments

⁷ WHO Department of Essential Drugs and other Medicines. The role of the pharmacist in self-care and self-medication [internet]. Hague; 1998. Available from: https://apps.who.int/iris/bitstream/handle/10665/65860/WHO DAP 98.13.pdf?sequence=1&isAllowed=y

In 1996, Canadian pharmacists conducted a study to quantify and value their role in OTC medication of patients. Extrapolating the data gathered from 500 pharmacies to a national scale, it was estimated that pharmacists make 15 million OTC interventions on a per annum basis. It meant that if 25% of those patients consulted their physicians instead, the government will be charged \$169 million in physician billing (Loh, Waruszynski & Poston, 1996). In 2007, pharmacists prescribing prescription medicines for minor ailments began in Alberta, and subsequently adopted in 7 other provinces in Canada⁸. Although formulary is limited, pharmacists were legally permitted to give prescription medicines and were remunerated \$18 per each minor ailment prescribing (Taylor & Joubert, 2016). Within the context of self-care pharmacotherapy, community pharmacists are processing patient presentation and request and applying clinical reasoning to prepare a care plan for the patient that may include recommendation of non-prescription medicines, behavioral changes, advice as well as referral.

1.2 Defining clinical reasoning in health professions

Clinical reasoning and decision-making are critical competency areas that are much less explored in pharmacy compared to other health professions (Gregory & Austin, 2016, Croft et al, 2017; Wright et al, 2018). There are many definitions that have been put forward to define this concept. Clinical reasoning is utilizing both cognitive and noncognitive processes of collecting and interpreting patient information, considering benefits and risks, as well as patient preferences, to develop a diagnostic and therapeutic plan for improved patient outcomes (Townbridge et al, 2015). It is the capacity of a health professional to integrate and apply accumulated knowledge, use

⁸ Canadian Pharmacists Association. Pharmacists' Expanded Scope of Practice [internet]. Canada; 2020. Available from: https://www.pharmacists.ca/pharmacy-in-canada/scope-of-practice-canada/

and weigh evidence, evaluate all available arguments, and reflect upon the process to arrive to a clinical decision that is specific for the individual patient, whether it be a diagnosis or a therapeutic plan (Richir et al, 2008). Clinical reasoning is a discipline that elucidates the processes of thinking, problem-solving, and analysis leading to decision-making in the health professions (Lundgren-Laine & Salantera, 2010; Gregory & Austin, 2016). This complex process hinges upon the capability of humans to process, memorize, recall and synthesize knowledge, and also the level of experience in dealing with various clinical scenarios (Linn et al, 2012; Croft et al 2018). While it may seem overlapping, the critical difference of clinical reasoning and decision-making for physicians is that they emphasize on diagnosis, whereas for pharmacists, it is focused on ensuring therapeutic plans are optimized (Wright et al, 2018).

1.3 Clinical reasoning in community pharmacy

The investigation of clinical reasoning and decision-making in community pharmacy is needed to support the bringing to the forefront the real scope of pharmacists' work from product-oriented, drug-use control to the patient-centered clinical care role (Brodie, 1986; Toklu & Hussein, 2013). There are a few publications found regarding community pharmacist's clinical reasoning and clinical-decision making skills, all of which are exploratory in nature (Gregory & Austin, 2016; Sinopoulou et al, 2017; Nusair & Guirguis, 2017; Croft et al, 2018; Nusair et al, 2019). Previous studies relevant to clinical reasoning of pharmacists in the community setting involved 8-12 participants (Gregory & Austin, 2016; Nusair & Guirguis, 2017; Sinopopoulou, Summerfield & Rutter, 2017; Croft et al 2018).

Core thinking processes identified from the literature were: (1) considering prescription in context – nature of medicine, dose and indication appropriate for age of patient, compliance of prescription to pharmacy laws; (2) retrieving information through probing or checking patient profile (Sinopoulou et al, 2017; Croft et al, 2018), (3) identifying medication related issues - treatment adherence, control of surrogate marker, appearance of complications; (4) processing information – pattern recognition, distinguish and prioritize relevant information; (5) collaborative planning (Abuzour et al, 2018; Croft et al, 2018) (6) decision-making – rationalization of clinical action either as medication recommendation or referral (Sinopoulou et al, 2017; Croft et al, 2018); and (7) reflection – metacognitive skills (Croft et al, 2018). Pharmacists' motivation during patient consultation can either be product-based, diagnosis-based, or risk-aversion motivation (Sinopoulou et al, 2017). Product-based motivation means that pharmacist focuses on product selection based on the presenting signs and symptoms. Diagnosisbased motivation is focusing on the patient's complaints (eg, duration, location, severity of illness, patient history) to arrive to the proper treatment recommendation. Risk aversion motivation is when products are recommended based on suitability and less likely to potentially worsen a patient condition (Sinopoulou et al, 2017). The latter approach is aligned to one of the factors affecting decision-making of community pharmacists where safety was found to be the overarching consideration. In the risk aversion motivation approach, sales are justified even if there is no sufficient evidence on the products' effectiveness and target is to achieve placebo effect, for as long as there is no effect on safety (Hanna & Hughes, 2010). Although research on clinical reasoning of health practitioners is not conducted to judge their cognitive process as correct or incorrect (Ericsson & Simon, 1993), some unsuccessful decisions and behaviors by community pharmacists were identified in this area of research.

In a study conducted in Canada by Nusair & Guirguis (2017), their findings showed that pharmacists demonstrated the following themes in clinical reasoning: missed opportunities, depersonalized assessments, reliance on routines and use of nonspecific questions. In missed opportunities, pharmacists failed to gather information or engage patient due to assumptions held based on pattern familiarity and missed recognizing patient needs, respectively. Assessments were considered depersonalized as they tend to depend on patient profile rather than probe patients on their current conditions and needs. Reliance on routines were observed such as regularly checking safety and refill intervals rather than medication indication and effectiveness. Drug related problems may not be identified if pharmacists focus on technical dispensing routines. Utilizing nonspecific (and close-ended) questions during patient interaction were observed (Nusair & Guirguis, 2017). This can make patients disinterested in consulting their pharmacists (Hirsch et al, 2009).

Clinical reasoning and decision making in complex situations were explored by Gregory & Austin (2016) where they presented pharmacists with two ethically problematic hypothetical case scenarios and asked how these will be dealt. Three important tactics of community pharmacists were revealed. First, pharmacists consider education or relationship building as key to influencing patients to make the correct decisions. Participants believed that their responsibility as pharmacists was to deliver the best job in educating the patient to make their own decisions rather than to have

the best clinical outcome. Second is seeking advice deferring responsibility to others like physicians or "higher" authority for decisions rather than taking professional responsibility. Thirdly, pharmacists justified the aversion to the responsibility by interrelating their actions in compliance to regulation or laws. They concluded that the study showed pharmacist's "decision-making avoidance related to professional responsibility for patient outcomes" (Gregory & Austin, 2016). Another pertinent factor affecting decision making identified was providing recommendations based on personal beliefs rather than evidence-based medicine (Sinopolou et al, 2017). Accessible information and advice on medication that is grounded on evidence are expected from pharmacists (Ngwerume et al, 2015). The findings in the studies cannot be generalized due to the exploratory nature of the studies. As of present, no research has been conducted on clinical reasoning and decision-making of community pharmacists dealing with acute minor ailments in actual patient care setting.

As the practice of pharmacy continues to evolve, pharmacists' extended scope of practice of clinical interventions require them to perform more clinical reasoning and make clinical decisions either independently, or collaboratively with other healthcare professions (Gregory & Austin, 2016; Wright et al, 2018). These competencies can be applied in clinical scenarios such as community pharmacy triage, self-care with non-prescription medications, medication therapy management of chronic medical conditions, and interdisciplinary management of acute illness in hospitalized patients (Tietze, 2018). It is important to note that pharmacists' clinical reasoning, and consequently decision-making, can ultimately affect patient safety and health outcomes (Croft et al, 2017). Especially in the community pharmacy which may be the first point

of contact for patients within the healthcare system, pharmacists must be able to appropriately attend to patient concerns and provide appropriate clinical actions such as recommendation of non-prescription drugs (Melton & Lai, 2017) or referral to other health care professionals².

1.4 Clinical reasoning in other health professions

Clinical reasoning research among cognitive scientists began in the 1980s to differentiate experts from novices (Glaser, 1984). Clinical reasoning has been identified as the "central component of physician competence" and its mastery can be found in medical schools, licensing bodies, and specialty societies (Norman, 2005). It is the core of both medical practice and education. It is comprised of a complex series of steps and cognitive processes that also constitute higher level of thinking to identify real clinical issues, evaluate evidence, and finally come up with decisions that will determine patient's physiological and psychosocial state (Lateef, 2018). It varies in the different domains of medicine. For example, surgical expertise — manual dexterity, visual-spatial coordination, radiology — anesthesiology, and critical care, will all require different set of cognitive skills to arrive at their course of action (Norman, 2005). According to Graber in 2005, approximately 75% of diagnostic failures may be due to thinking failure (Croskerry, 2009).

In the nursing profession, effective clinical reasoning skills was found to have positive impact on patient's health outcomes⁹. It is an expected element of expert and

²World Health Organization. The Role of Pharmacist in the Healthcare System [internet]. Japan; 1994 [cited 29 January 2019]. Accessed URL: http://apps.who.int/medicinedocs/en/d/Jh2995e/1.6.2.html

⁹ University of Newcastle. Clinical Reasoning: Instructor Resources [online]. Available from: https://www.utas.edu.au/ data/assets/pdf file/0003/263487/Clinical-Reasoning-Instructor-Resources.pdf

competent practice (Banning, 2008). There are main eight steps in clinical reasoning cycle as described by the University of Newcastle: look, collect, process, decide, plan, act, evaluate and reflect. It is recognized that clinical reasoning is a dynamic process that warrants nurses to often combine one or more phases or move back and forth between them to come up with a decision or action or to evaluate outcomes (Levett-Jones et al, 2010).

Early researches exploring clinical reasoning in physical therapy focused on the diagnostic perspective of their practice, similar to the physicians (Edwards et al, 2004). Rotor and Capio (2018) from the UP College of Allied and Medical Professions described the clinical reasoning of Filipino physical therapists in a qualitative inquiry of 10 physical therapists employed in different areas of the practice. They found that procedural reasoning was common in PTs working in home health, outpatient clinic and hospital, and that physician referral affected the extent of their clinical reasoning (Rotor & Capio, 2018).

1.5 Information processing theory

Pioneering the information processing theory to explain human problem solving by experts was introduced by Newell & Simon in 1972. After a decade of research, it is claimed that the theory represents the human thought process and information highway. It was employed to investigate how cognitive processing occurs during problem-solving, decision-making, skill acquisition and expertise, learning and perception (Hoffman, 2007). According to this theory, there are two main memories, namely, short term memory and long-term memory. Whenever there is an incoming

stimulus, it enters and subsequently processed in the short-term memory. This was described as having small working capacity, but it is very fast and accessed almost immediately. The information processing theory stipulated that human's capacity for information processing is limited by the structure of human memory. Since short term memory can only process seven items plus and minus two (Miller, 1956) grouping or chunking items may overcome the limited working capacity (Miller, 1956; Newell & Simon, 1972). Without organizing large sets of information that are bigger than the memory capacity, these will be lost and less likely remembered. When information is successfully organized, knowledge and experiences accumulated throughout life may be stored in long term memory. Whether it is conceptual, declarative (facts), or procedural, the presence of similar base or patterns between a new information and the ones in the long-term memory store facilitates how it shall "fit" in with previous experience (Newell & Simon, 1972). As more experiences are encountered, the chunks of information become larger and numerous, which then will affect how future occurrences will be processed (Bartels, 2013). In order to solve a problem, cognitive strategies, called operators, are needed to create links between one knowledge state to another, and to transform each one as required (Ericsson & Simon, 1984). When these operators are aggregated, it forms the process that represents clinical reasoning (Hoffman, 2007).

1.6 Dual process theory

Another area of cognitive psychology relevant in this dissertation is dual process theory. Recent studies use the Platonic-Aristotelian tradition of Greek philosophy, the two fundamental approach that has long been recognized, known as the dual process theory of human cognition; namely, the intuitive reasoning (System I) and analytical

reasoning (System II). It is a controversial discussion regarding who uses what System, in what combination or ratio, and which type of clinical scenario demands an appropriate approach of thinking. Considering work environment and context, there will always be a shift between the two systems (Lateef, 2018). There is no literature in any field of practice that suggests a specific approach would be better than the other. Particularly in pharmacy, the nature of clinical reasoning approach may differ based on the specific task at hand (Nusair et al, 2019).

1.6.1 Intuitive reasoning

Intuitive reasoning (System I) is a type of reasoning described as intuitive, automatic, fast, narrative, experiential and affect-based. Physician's early diagnostic impressions are formed consciously or subconsciously by integrating factors and/or being influenced by patient's physical appearance and behaviour, workplace environment (i.e. workload, priority), resource issues (i.e. reference), and other overarching issues (i.e. professional, ethics) (Croskerry, 2009). Practitioners who use this approach require little mental effort, and act non-systematically on assumptions, feelings or hunches (Nusair et al, 2019). Some researchers of clinical reasoning in the field of medicine compared this intuitive system to 'gut feeling' (Stolper et al., 2015). While this approach is frequently right, it still fails occasionally, particularly in patients presenting atypical symptoms, or when the condition was mistaken for another (Croskerry, 2009). Critiques question the reliability of this approach as it may be more prone to error primarily due to contextual and affective factors (Croskerry, 2009; Pelaccia et al, 2017), which lead to cognitive biases (Croskerry, 2013).

1.6.1.1 Pattern recognition

Pattern recognition is a type of intuitive reasoning approach that non-analytically matches clinical condition to a pattern previously formed or encountered stored in memory. Critical to its retrieval is recognition of key features resembling clinical patterns (Arocha, Patel & Patel, 1993; Yazdani, Hosseinzadeh, & Hosseini, 2017). Classical example often cited is how a physician can assess and diagnose a patient in five minutes. After attending hundreds of patients in the past, a clinical picture can easily be drawn based on a presenting pattern. Typically, this approach is identified in the data when "match" is generated as an operator (Nusair, 2009).

1.6.2 Analytical reasoning

Analytical reasoning (System II) is a thinking process that is analytical, deliberate, systematic, and rational. It is effortful, conscious, and time consuming (Epstein, 1994; Cate & Durning, 2018). In this process, data is gathered, systematically evaluated, and logically decided. System II is considered as resource intensive since a lot of cognitive work is required to perform identification and interpretation of cues, generation of hypothesis, and to test the hypothesis. While this process is slower than System I, it can be less prone to error (Croskerry, 2009). Medical literature published preliminary conclusions as to when System II is most likely to be utilized in situations such as when time permits, outcomes are considered high-stake, situation is complex, problems are considered ambiguous, non-routine or ill-defined, or the uncertainty is high (Croskerry, 2008; Moulton et al, 2007; Pelaccia et al, 2017; Lateef, 2018). Novice practitioners tend to use System II thinking

by integrating informative factors such as academic knowledge, limited personal experience, and also anticipating patient preference (Lateef, 2018).

1.6.2.1. Forward-chaining

Forward chaining is one of the types of analytical reasoning. In 1988, Jones initially defined forward chaining, also known as goal-driven reasoning, as a type of System II approach that collects data and cues to generate a hypothesis (Hoffman, 2007). Expert decision makers use this thinking process, which results in more accurate diagnoses (Botti & Reeve, 2003).

In data gathering, the operators are found in the following order: 1) "verify" or "review; then 2) "explain"; then 3) "act" or "collect"; then 4) "infer"; then 5) "conclude" (Hoffman, Aitken & Duffield, 2009; Nusair et al, 2019).

1.6.2.2 Hypothetico-deductive

Contrary to forward-chaining, hypothetico-deductive approach starts with a hypothesis on preliminary cues obtained, which is continuously modified as new information is encountered (Yazdani, Hosseinzadeh, & Hosseini, 2017). Gathering of cues are performed to support the initial hypothesis and to identify possible causes or other possible conditions (Botti & Reeve, 2003). Novice decision-makers are hypothesized to utilize more backward reasoning or mean end reasoning due to less domain-specific knowledge and that information sought is targeted based on and only if the issue is identified (Kahney, 1993).

It was found that operators are in the following order: 1) "conclude" or "infer"; then 2) "review" or "act"; then 3) "explain"; then 4) "predict" (Hoffman, Aitken & Duffield 2009; Nusair, 2019).

1.6.2.3 If-then

If a pharmacist's decision is based on a single criteria or particular condition, this was categorized as if/then approach. There is no prerequisite number or order of operators, but when segments are analyzed, the identifying instances appeared as "if... then...". (Hoffman, Aitken & Duffield 2009; Nusair, 2019).

1.7 Ethnomethodology using think-aloud technique

Think-aloud technique was referred to as one of the most effective ways to assess higher level thinking (Olson et al, 1984). When using think-aloud, participants verbalize their thoughts while carrying out procedures or solving problems that are videotaped. Data collection involves observation and recording of the participant's introspection. The problem of this method is that subjective interpretation of the cognitive processes as a product of the introspection are not always manifested in the observable behaviour (Ericsson & Simon, 1993). In order to address this limitation, thinking aloud requires the researcher to collect and measure what the participant is saying as against the observable action. There are two possible designs for this process: concurrent or retrospective technique. Retrospective technique is implemented by videotaping the participants and speak their thoughts after the task is performed. Qualitative exploration of clinical reasoning among health professions in previous

studies involves less than 12 respondents (Gregory & Austin, 2016; Nusair, 2016; Sinopopoulou, Summerfield & Rutter, 2017; Croft et al, 2018; Abuzour, Lewis & Tully, 2018).

Findings in exploratory studies cannot be used to generalize and extrapolate the results too broadly. In addition, the qualitative ethnomethodology as a study design does not aim to measure or quantify clinical reasoning and decision-making skills. Sampling does not require thousands of participants. Other methods can be effectively and efficiently utilized in order to achieve quantification, such as script concordance testing or problem-based learning with appropriate scoring system.

1.8 Setting of the study

This study was conducted in two countries: Philippines and Malta.

1.8.1 Philippines

Philippines, a country comprised of 7,100 islands divided geographically into Luzon, Visayas and Mindanao, is recognized as the 12th most populous country in 2010. The islands are further subdivided into 17 regions, 80 provinces, 167 cities, and 16 highly urbanized cities. The country was ranked 60th in overall healthcare efficiency by WHO in 2000.⁹ According to Institute of Health Metrics and Evaluation (2017), lower respiratory tract infection is the third cause of mortality, while low back pain (1st), headache disorders (2nd), other musculoskeletal disorders (6th) are highly ranked problems causing disability in the Philippine population¹⁰.

¹⁰Institute for Health Metrics and Evaluation. Philippines [online] (cited 9 March 2020). Available from: http://www.healthdata.org/Philippines

⁹Tandon, A,. Murray, CJL, Lauer, JA, Evans, DB. Measuring overall health system performance for 191 countries (GPE Discussion Paper Series: No. 30) [online]. World Health Organization. Geneva; 2000 (cited 9 March 2020). Available from: http://who.int/healthinfo/paper30.pdf

Pharmacy education in the Philippines is 4-year program in most colleges and schools of Pharmacy, while some implement a 5-year program. In order to comply to the international standards for pharmacy education which should be at least 5-years, some universities offer an additional 1-year clinical pharmacy program (BS Pharm Major in Clinical Pharmacy)^{11,12}, while others developed a 2-year professional post-baccalaureate Doctor of Pharmacy course^{12,13}. A shift to a 5-year pharmacy program was developed which included changes in the curricular topics and internship strategies that was supposed to be implemented in 2018 (Ongpoy et al, 2019). However, this was not pushed through and instead, the curriculum remained as a 4-year programme and its content was modified. A national licensure examination must be passed before graduates are awarded the license to practice. The majority of the pharmacy graduates in the Philippines (77%) go into community pharmacy followed by 15% in the hospitals, 7% industry and 0.5% academia (Loquias & Robles, 2012).

According to GlobalData, the Philippine pharmaceutical market is forecast to grow at 3.3B Euros by 2025¹⁴. There are 32,443 community pharmacies in the country as reported by FDA in 2016¹⁵, which serves about 109M Filipinos all over the country. The latest documented pharmacist to population ratio was found at 6:10,000.¹⁶

11 .

¹¹ University of Santo Tomas. Bachelor of Science in Pharmacy Major in Clinical Pharmacy. 2017. (cited 13 Mar 2020). Available from: http://www.ust.edu.ph/academics/programs/bachelor-of-science-in-pharmacy-major-in-clinical-pharmacy/

¹² University of Immaculate Conception. Proscpectus. (cited 13 Mar 2020). Available from: https://www.uic.edu.ph/pharmchem/prospectus/
¹³ Centro Escolar University. Programs Offered (Pharmacy) [online]. (cited 13 Mar 2020). Available from: https://manila.ceu.edu.ph/pharmacy-programs-offered

¹⁴ Balfour, H. New opportunities for Indian pharma industry in the Philippines, finds study [online]. European Pharmaceutical Review. UK. (cited 13 Mar 2020). Available from: europeanpharmaceuticalreview.com/news/107476/new-opportunities-for-indian-pharma-industry-in-philippines-finds-study/

¹⁵ Robles, Y & Rosado, H. Philippines. In: An Overview of Current Pharmacy Impact on Immunisation [online]. FIP (cited 13 Mar 2020). Available from: https://www.fip.org/www/streamfile.php?filename=fip/publications/FIP report on Immunisation.pdf

¹⁶Anderson C & Roy T. 2012 FIP Global Pharmacy: Workforce Report [internet]. Netherlands; 2012 [cited January 2020]. Available from: https://apps.who.int/medicinedocs/documents/s20206en/s20206en.pdf

Pharmacy customers' buying power extremely varies, and many patients buy their medications by piece instead of the whole regimen. "Tingi retail modality", which refers to the piecemeal purchases due to budget constraints or convenience (Romo & Digal, 2009), became a consumer habit among Filipinos stemming from the period of World War II as a survival strategy. In fact, Spanish chroniclers from the 16th century already observed the "sachet marketing" among retailers selling to Philippine natives (Sy-Changco et al, 2011). This is important to note since it can potentially affect the quality of pharmaceutical care given due to long queues and favoring less those with low value purchases. Few over-the-counter medications such as anti-inflammatory, vitamins and antacids, may be obtained free of charge from the "Pharmacy of the Nation" (Botika ng Barangay) program of the Department of Health in partnership with local government units¹⁷, otherwise, patients have to pay from their pockets.

1.8.2 Malta

Malta, comprised of two islands called Malta and Gozo, is an independent State located in the Mediterranean and is a member of the European Union. It was estimated in 2018 that there were 493,559 residents in the islands, comprised of local and international residents.¹⁸ It was ranked 5th out of 191 countries in terms of overall healthcare services by World Health Organization (2000)⁹. In a 2017 health statistics, leading problems that results in disability were low back pain (1st), headache (3rd), and

⁹Tandon, A,. Murray, CJL, Lauer, JA, Evans, DB. Measuring overall health system performance for 191 countries (GPE Discussion Paper Series: No. 30) [online]. World Health Organization. Geneva; 2000 (cited 9 March 2020). Available from: http://who.int/healthinfo/paper30.pdf

¹⁷Department of Health. DOH relaunches 'Botika ng Bayan' (online). Manila; 2018 (cited 13 Mar 2020). Available from: https://pia.gov.ph/news/articles/1010499

¹⁸Macdonald V. Malta's population growth largest in EU – by far. Malta; 2019 (cited 15 Mar 2020). Available from: https://timesofmalta.com/articles/view/maltas-population-growth-largest-in-eu-by-far.720748

neck pain (4th), and lower respiratory tract infection ranked 5th as the top cause for morbidity, and 7th in premature death.¹⁹

Qualified pharmacists in Malta must be able to complete the 4-year Bachelor of Science in Pharmaceutical Science and a 1.5 year of Master of Pharmacy degree at the University of Malta. Pharmacists may proceed to postgraduate courses, namely, Master in Advanced Clinical Pharmacy (M. ACP – Level 7) and Doctorate in Pharmacy (Level 8 professional doctorate). ²⁰ In line with Directive 2005/36/EC²¹, pharmacy diplomas taken in an EU university shall be recognized in Malta, and a warrant to practice will be awarded by the Pharmacy Council upon submission of documents. Based on records, there are about more than1500 registered pharmacists and 245 pharmacies in the country. ²² There are 25 pharmacists for every 10,000, which was highest ration compared to 82 countries and territories that participated in a 2012 pharmacy workforce survey. ¹⁶

The pharmaceutical market value of Malta was estimated to be 77 million euros in 2007.⁵ Over-the-counter medications for acute conditions may be given for free for qualified patients (through a Means Test or one of the eligibility requirements) through the Schedule 2, known as the Karta r-Roża or pink card.^{23,24} However, most sales for

¹⁶Anderson C & Roy T. 2012 FIP Global Pharmacy: Workforce Report [internet]. Netherlands; 2012 (cited January 2020). Available from: https://apps.who.int/medicinedocs/documents/s20206en/s20206en.pdf

¹⁹Institute for Health Metrics and Evaluation. Malta [online]. USA; 2017 (cited 15 Mar 2020). Available from: http://www.healthdata.org/malta

²⁰ University of Malta. Degree Courses Offered (online). Msida; 2020 (cited 15 Mar 2020). Available from: https://www.um.edu.mt/ms/pharmacy/courses

²¹Recognition of Professional Qualifications, Directive 2005/36/EC of the European Parliament and the of the Council (Sept 7 2005).

²² Malta Medicines Authority. Licensed Pharmacies in Malta and Gozo [online]. Malta; 2020 (cited 9 Feb 2020). Available from: http://www.medicinesauthority.gov.mt/licensed-pharmaceutical-activities

²³Social security. Għajnuna Medika b'xejn (Karta r-Roża) Free Medical Assistance (Pink Card). Malta (cited 9 Feb 2020). Available from: https://socialsecurity.gov.mt/en/Documents/INF%20-%20FreeMedicalAidMT.pdf

²⁴ Directorate for Pharmaceutical Affairs. Out-patients Formulary List. Ministry for Health, Malta; 2020 (cited 9 Feb 2020)..Available from: https://deputyprimeminister.gov.mt/en/pharmaceutical/Documents/GFL/out patients gfl jan 2020.pdf

over-the-counter medicines are on out-of-pocket basis. As per Directive 2001/83/EC,²⁵ medications must be supplied with a patient information leaflet, hence, sales should be sold by the box and not by piece or blister.

1.8.3 Comparison of Maltese and Philippine community pharmacy

The community pharmacy practice operations in Malta and Philippines have similar organizational structure, such that a pharmacist is supported by pharmacy assistant(s). Maltese community pharmacy practice has been chosen to be compared with Philippine community pharmacists as they have robust community pharmacy practice, highly rated by consumers for their ability to provide patient counselling on how to take their medications, how medicines work, answer health related questions, and provide diagnostic testing thru point-of-care tests (Wirth et al, 2011). One of the factors may be attributed to the high percentage of the pharmacy education curriculum in Malta dedicated to medicinal sciences and sufficient pharmacy internship hours (Atkinson & Rombaut, 2011).

Conducting a comparative analysis provides an opportunity to describe the complex and multidimensional knowledge and skills of community pharmacists to assess minor ailments and treat with the appropriate over-the-counter medicine from two different countries. This may present a learning and collaborative opportunity for both countries, although coming from two different continents. The focus of the study was to describe the practice in both countries. This should provide a better understanding on the cognitive skills from two different contexts.

 $^{^{25}}$ Community code relating to medicinal products for human use, Directive 2001/83/EC of the European Parliament and the of the Council (Nov 6 2001).

1.9 Aims of the study and research question

The primary objective of this study was to explore and investigate the clinical reasoning process and decision making of experienced pharmacists. It aimed to address the following specific objectives:

- A. Describe the clinical actions generated by pharmacists as a result of their clinical reasoning during patient consultation and counselling sessions.
- B. Identify conceptual and behavioral cues that manifests from pharmacists during their clinical reasoning.
- C. Describe the interrelationship of the conceptual and behavioral cues with the clinical actions generated by the pharmacists as a result of their clinical reasoning.
- D. Recommend strategies to effectively develop or enhance clinical reasoning and decision-making competencies in education, research, and policy.

The primary research question that was explored in this project was:

How did pharmacists perform clinical reasoning?

Specifically, these sub-questions were intended to be explored in order to identify the phenomena embedded in the entire process:

What were the clinical actions generated by pharmacists as a result of their clinical reasoning?

What were the constructs generated when pharmacists perform clinical reasoning?

How did these constructs interrelate to constitute a clinical decision?

Chapter 2 Methodology

Chapter 2 Methodology

This chapter describes the methodology undertaken to implement the data collection and analysis of this research.

2.1 Research design

The research design of the study was a comparative qualitative ethnomethodology that particularly utilized a retrospective think aloud technique to examine the patterns of clinical reasoning and decision-making processes between community pharmacists practicing in Metro Manila, Philippines and Malta. A pilot study was conducted primarily to refine tools and to identify logistical issue. Subsequently data was collected from the community pharmacies over a period of 3 months. The design is outlined in Figure 2.1.

2.2 Sampling

This study employed purposive and convenience sampling. Five pharmacists from Malta and 10 from Metro Manila, Philippines (a total of 15) were recruited to participate. The sample size used in this study was similar to the previous studies of similar nature to study clinical reasoning.

The inclusion criteria for pharmacists who participated in the study had at least 3-year cumulative work experience as a licensed pharmacist in community pharmacy and must devote most of the time in direct patient-care. The three-year cumulative experience working in the community pharmacy ensured that the participants gained the minimum experience to be able to acquire "competence" level.

Inclusion criteria for patient cases to be recorded were also established. Only patients or their proxy of 18 years and above were invited to participate. Minor ailments were considered for this study, prioritizing headache, cough, muscle pain, or cold and flu, and must have not visited a physician prior to the consult. Mothers of children with minor ailments who consulted the pharmacists were also considered.

2.3 Study site selection

Participating community pharmacies with pharmacists who agreed to join this study have an adequate and conducive space for observation and were serving a community with high intake of patients with minor ailments. Study sites were consenting pharmacies with practicing community pharmacists who were willing to participate in studies for the betterment of community pharmacy practice. Some pharmacy chains and pharmacists were hesitant to allow observation in their operation and practice, and hence, participation was voluntary.

2.4 Ethics approval

Approval from ethics committee was sought before implementing data collection. The study protocol was approved by University of the Philippines Manila Research Ethics Board (UPMREB Code: 2019-405-01) and the Faculty of Research and Ethics of the Faculty of Medicine and Surgery in University of Malta (FRECMDS 1819 067).

2.5 Data Collection

Data collection for the study consisted of two parts. The first part was workplace observation, in which the researcher stayed with the participant in the pharmacy and recorded interactions with patients. The second part was a semi-structured interview with the pharmacist which occurred immediately after a number of cases were recorded, or another visit was scheduled if time did not permit.

2.5.1 Workplace observation

Pharmacists were observed in the workplace for 4-8 hours, in some instances, were visited more than once for the observation. An AV recording of the patient-pharmacist interactions were obtained, with particular focus on the angle of the pharmacist. The researcher took note of verbal, nonverbal and environmental cues from the interaction. Each participant was recorded for a minimum of 2 to maximum 9 patients presenting for minor ailments.

A data collection sheet was used to facilitate data gathering. In the observation, patient's identity (and face) was not part of the recording. A patient consent form was obtained prior to recording. Clinical scenarios that were recorded were only with patients whose circumstances qualified within the inclusion criteria.

2.5.2 Semi-structured interview

A 60 minutes semi-structured interview was carried out with each pharmacist participant. In this interview, a clip from the AV recording of a particular case was shown

to the pharmacist to discuss the clinical reasoning and decision making that occurred.

The pharmacist participant reviewed the AV recording of his/her own interaction. The questions asked by the researcher were based on the specific case highlighted.

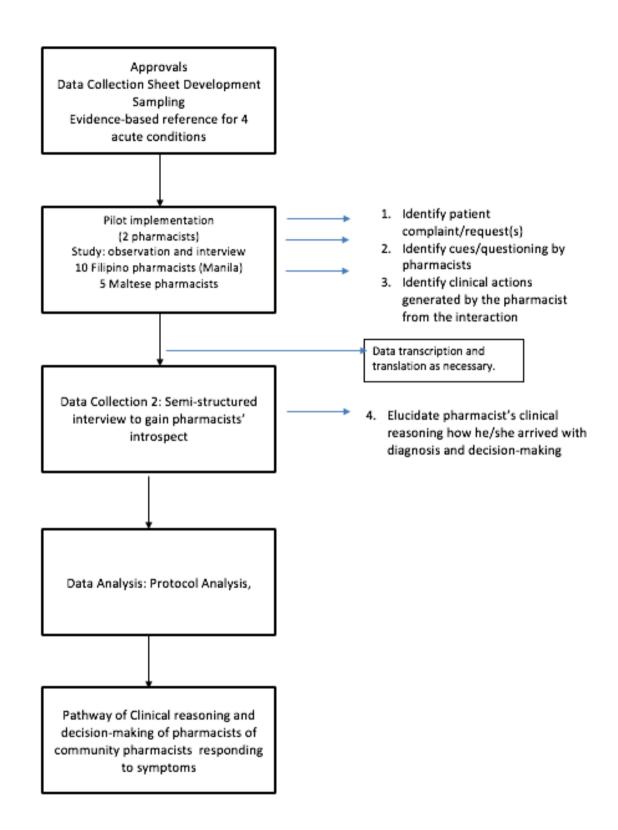


Figure 2.1 Flowchart of methodology

2.6 Data handling and management

Audio and video recorded clips were transcribed and translated. Semi-structured interviews were also audio recorded and transcribed. Pharmacist participant reviewed the transcriptions to verify accuracy. AV recorded clips were deleted after the analysis of the data.

2.6.1 Assigning codes

For pharmacists in the Philippines, the first two characters were PH while for Maltese pharmacist, MT was used. These were followed by two numerical numbers according to their nth sequence in the data collection schedule.

For patient participants, the first character used was M or F to represent whether patient was male or female. The following character were as follows: "W" for cough, "X" for common cold, "Y" for headache, and "Z" for any pain related. Two numerical numbers were also assigned according to their nth sequence as they arrived in the pharmacy. For example, a male patient with cough came. This was assigned with M_W_01. If the patient was a child accompanied by a parent, "c" came after the code for sex. For example, a female child patient came with her mother to complain of cough, this was assigned with Fc_W_02. "O" was added if customer was buying for another patient.

Personal identification of the pharmacists and patients were excluded in the transcripts and manuscript of the research. Patient identity was not recorded in the AV recording. Data was accessible only to the researcher and was destroyed when thorough analysis was completed.

This study complied to Data Privacy Act of 2012 in the Philippines and the General Data Protection Regulation (GDPR) in the European Union. Under the provisions of these acts, participants had the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

2.6.2 Data analysis

To systematically analyse the verbal data, protocol analysis was used. This ensured scientific footing of the analysis as it had been used in the past to look into processing models of human reasoning to find connection between thinking and verbalization to ultimately understand the decision making of experts. Protocol analysis, ultimately, describes the thinking path of the participant and allowed the researcher to gain an insight into the decision-making process (Lundgren-Laine & Salantera, 2010). To perform protocol analysis, three steps were performed: (1) referring phrase analysis, (2) assertional phrase analysis, (3) script phrase analysis. The protocol analysis conducted in this research was guided by the work of Nusair (2020) and Hoffman (2009).

Each phrase was analyzed to identify "concepts" that the pharmacist participant used or concentrated upon during patient care and interview. These were pharmaceutical concepts that were considered and processed to arrive at a clinical decision.

Table 2.1 Sample of transcription and concept identification

Transcription	Concept
Case: Patient buying paracetamol	
Patient: Can I buy 4 pieces of Biogesic (paracetamol)?	Patient choice
PH01: We have a generic of paracetamol. It is similar (to Biogesic).	Drug: Pharmaceutical equivalent
Case: Two customers asked for appropriate medicine for cough	
Patient: Hello! I am here to take my drops. MT05 Hello, how are you? Patient2: I have cough and catarrh here.	Disease: Signs/Symptoms
MT05: okay. Patient1: sugar-free you have? MT05 shows the medicine. Ambroxol. Patient2: let me look at it because oh yes, once I had it before.	Patient choice
MT05: So you had it before. Patient2: Yes, i have catarrh because of the cigarettes. Is this the one that you said	Medication taken
Patient1: Yes, it is liquidizing. MT05: That means it is a mucolytic	Drug information: mechanism of action

Cognitive strategies used by the pharmacist's reasoning were identified. These are called "operators". For example, if the pharmacist asked questions to gather information about the condition of the patient, it was labeled as "collect". Operators used in this study were adapted from previous publications (Hoffman, 2009; Nusair et al, 2019). Original operators developed for the pilot study were listed below:

Table 2.2 List of original operators used

Operator	Definition
Retrieve	Information gathering
Verification	Confirmation of facts
Assumption	Judgement based on hunch or culture
Therapeutic planning	Therapeutic care or monitoring plan
Inference	Assessment by connecting evidence
Reflection	Retrospectively identify what could have been done better

Frequency of use of each operator term was estimated and grouped for comparison. Applicable concepts for operators were mapped as relevant. Analysis of operators and concepts were tabulated as identified from the actual case scenarios or during the semi-structured interviews.

After identifying the operators in each patient case, the order by which they appeared determined the clinical reasoning approach. As an example described by Nusair et al (2019), it can be expected that if forward-chaining approach was used by the pharmacist, "collect", "review" and "explain" should come before "infer" and "act".

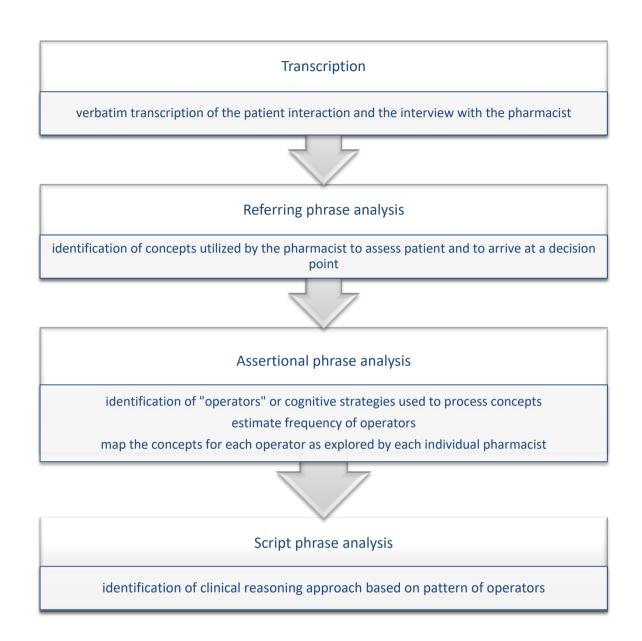


Figure 2.2 Summary of protocol analysis adopted for data analysis

Chapter 3
Results

Chapter 3 Results

3.1 Study participants

A total of 15 pharmacists agreed to be part of the study. Ten pharmacists were recruited in Manila, Philippines, and 5 were from Malta. In both countries, the majority of the respondents were female, with an average age of 37.7 (range: 26-62 years) and 29.4 years (range: 28-37 years) for the Philippines and for Malta respectively.

Table 3.1. Demographic data of pharmacist respondents (n=15)

Demographic variable	Count		
	Philippines	Malta	Overall
Sex			
Female	8	4	12
Male	2	1	3
Age			
Less than 35	4	1	5
35 or more	6	4	10
Highest Educational			
Attainment			
Bachelor	10	0	10
MS/MPharm	0	3	3
PharmD	0	2	2
Years of Practice			
3-5	2	4	6
6-10	4	-	4
≥11	4	1	5
Employment Position			
Staff Regular	3	-	3
Managing Pharmacist	-	3	3
Locum Pharmacist	-	1	1
Pharmacist's Owner	7	1	8
Currently studying			
Yes	-	1	1
No	10	4	14
Program currently enrolled	NA	PharmD	
Attends CPD programs			
Yes	10	5	15

In the Philippines, all of the respondents have bachelor's degree as it is the minimum qualification, in addition to a State licensure exam, in order to practice the profession of pharmacy. As for Malta, three of the respondents have MPharm, while one completed a post-graduate PharmD and another was currently enrolled in the PharmD program. Contrary to Philippines, the minimum qualification to work in the community pharmacy in Malta is a Master of Pharmacy degree. In terms of years of practice, majority of the respondents in the Philippines (8 out of 10) had community pharmacy work experience of 6 years and above and most of them were also pharmacy owners (7 out of 10). Pharmacists in Malta in this study had relatively less years of work experience of 3-5 years (4 out of 5), and only one was a pharmacy owner. It was easier to recruit pharmacy owners of independent pharmacies in the Philippines who had absolute control of operations, whereas in Malta, even if most of them were hired, their pharmacy owners gave them independence to decide to participate in research. All of the respondents claimed to attend continuing education seminars.

3.2 Workplace observation

Total recorded cases during workplace observation in Manila, Philippines and Malta were 30 and 16, respectively. The cases were categorized based on the initial interaction of the patient with the pharmacist; whether an advice was sought, or a specific medicine was requested. When customers ask for a medicine that is most appropriate for their condition, the pharmacist asks or confirms signs and symptoms before making any recommendation. When patients request for a specific medicine, two different scenarios took place: either dispense immediately as requested or ask questions to confirm appropriateness.

Table 3.2. Cases recorded during workplace observation

	PH	%	MT	%
Total no. of cases recorded	30	_	16	_
No. of cases patients seeking advice	5	16%	8	50%
No. of cases patients seeking specific medicine	25	83%	8	50%
Intervention by Pharmacist when:				
Patients sought advice	5/5	100%	8/8	100%
Patients sought specific medicine	9/25	36%	5/8	63%

3.3 Clinical actions generated in the study

Table 3.3.1 summarizes the clinical actions performed by pharmacist observed in the workplace whether patients sought medicine or advice. Each medicine dispensed was counted as one, and not per case encountered by the pharmacist. For example, a pharmacist serving a patient with cold and flu may dispense cold and flu tablet and nasal spray. This was counted as two instead of one.

Table 3.3.1 Summary of clinical actions generated when patients sought for medicine

Clinical Action	Frequency		
	Philippines	Malta	
	N=34 (%)	n= 8(%)	
Dispensed medication*			
As requested by patient	23 (67%)	6 (75%)	
Pharmaceutical equivalent	5 (14%)	1 (12.5%)	
Pharmaceutical alternative	1 (3%)	1 (12.5%)	
Reassessed and recommended	2 (6%)		
another medicine			
Did not dispense	3 (8%)	-	
Referred to physician	-	-	

^{*}each medication counts as 1 clinical decision

Pharmacists dispensed majority of the medications as requested by clients (67% in Philippines and 75% in Malta). Pharmaceutical equivalent was offered when the brand requested was unavailable. This was particularly prevalent in pharmacies carrying mostly true

generic medicines and less of innovator branded ones. Pharmaceutical alternatives were only offered once (in both countries) when the requested medicine and its equivalent were out of stock. There were instances when the requested medicine was deemed inappropriate, reassessments were conducted and a different medicine was recommended (6%). For example, a patient requested carbocisteine which upon probing by the pharmacist it transpired that was actually nonproductive cough, and butamirate was dispensed as being more appropriate. Failure to make a sale was observed in 3 cases in the Philippines.

Table 3.3.2 Summary of clinical actions generated when patients sought for advice

Clinical Action	Frequ	ency
	Philippines n (%)	Malta n (%)
Assessed and dispensed*	6 (100%)	10 (90%)
Did not dispense	-	-
Referred to physician	-	1 (10%)

^{*}each medication counts as 1 clinical decision

When patients seek advice for their condition, each was assessed by the pharmacist and the corresponding clinical actions were dispensing of medication(s) and/or referral to physician. Patients seem to be more open-minded to accept the clinical decisions made by the pharmacist in this context, compared to when they have specific medications preferred. Although minor ailment cases were observed, referral to physician was warranted in presence of comorbidities or severe conditions. Only one case was referred (in Malta) as the actual patient was a child suffering from moderate to severe symptoms of asthmatic cough.

3.4 Concepts generated in the study

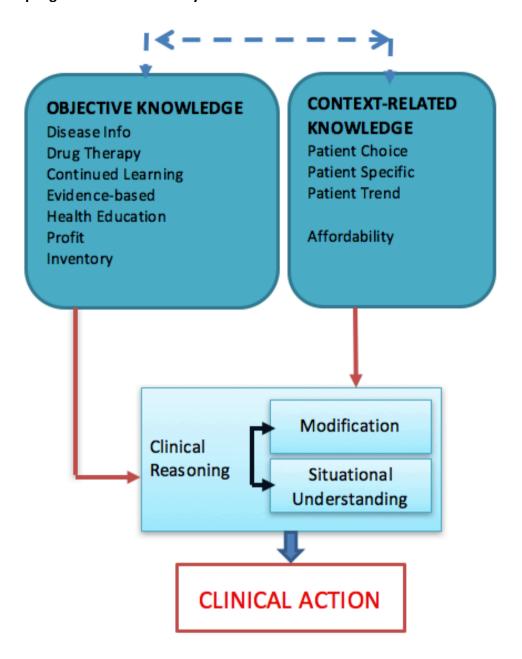


Figure 3.1. Themes and concepts occurring during clinical reasoning at dispensing medications for minor ailments leading to a clinical action. Adapted and modified pharmacist's decision-making diagram (Bartels, 2013).

In order to arrive at a clinical action, pharmacist integrated objective and context related knowledge in the process of performing clinical reasoning. Bartels' (2013) proposed diagram was adapted to illustrate the concepts generated in this study.

3.4.1 Theme 1: Objective knowlegde

Objective knowledge of pharmacists refers to knowledge on chemistry, medicinal science, pharmaceutical technology, evidence-based research, protocols, therapeutics using both prescription and nonprescription medicines, nonpharmacological treatment, cost, and relevant health information that will improve patient outcomes. Knowledge in this domain is based on facts, and relatively does not change from patient to patient. Evidence-based guidelines and protocols change in a timely manner according to research, insights and opinion by key experts, but this do not occur overnight.

3.4.1.1. Concept 1: Disease

During interviews, it was emphasized that pharmacists must establish the condition, or its cause based on the presenting signs and symptoms. Important subconcepts under disease are history of present illness, duration, and frequency of symptoms. Pharmacist knowledge on objective measures to confirm the condition helps in the assessment. Understanding the universe of signs and symptoms is important, most especially that the conditions chosen for this research are symptomatically managed by pharmacists. Red flag signs are the basis for referral to other healthcare professionals.

Vulnerable population, which includes pregnant/lactating women, elderly, children, and those with chronic conditions, are always assessed in caution. For example, an asthmatic patient with cough was referred as the signs and symptoms may be an indication of exacerbation rather than viral infection.

3.4.1.2 Concept 2: Drug therapy

Pharmacist must be able to choose the right drug according to the needs of the patient. Pharmacist should be knowledgeable on the medicines that are found in the pharmacy's inventory. If the medicine requested is out of stock, a pharmaceutical equivalent or alternative must be offered. Dosage form can affect adherence, as it may be more convenient to the context of the patient. Medicines or supplements that can improve safety or efficacy may also be offered (eg, vitamin C in iron supplementation). Medication taken for chronic conditions affects clinical decision to prevent potential drug interaction or simply to avoid duplication. Inappropriate self-medication must be detected by the pharmacist and intervened with the patient. Anecdotal experience of patients, even by pharmacist themselves, towards use of specific products influence pharmacist's choice to dispense. In the Philippines, equivalence of innovator and popular branded medicines versus true generics are considered by pharmacists.

3.4.1.3 Concept 3: Continued learning

All of the pharmacists (n=15) participating in the study agreed that practitioners should attend continuing education sessions, especially treatment guidelines are always updated. What is valid today, may be scientifically invalid tomorrow. Pharmacist respondents who took pharmacy education decades ago mentioned that many of the new courses (i.e., patient counseling) were not part of the old curriculum, and hence, continuing education is beneficial for their practice.

3.4.1.4 Concept 4: Evidence-based recommendation

Updated treatment protocols should be made available to practitioners, which helps in their clinical reasoning. Not all pharmacists have ready access to databases and journals. Providing access to treatment algorithms as they are updated will help them make the best clinical decisions in their practice.

While some pharmacists do not prefer herbal medicine due to the lack of evidence on its efficacy, some would prefer to dispense them as first line on the basis of perceived safety or when requested by patients. This poses an ethical dilemma due to the limited evidence on the efficacy of herbal medicines.

3.4.1.5 Concept 5: Health education

Pharmacists must educate patient on the disease, medicines, and device. Regular monitoring and side-effects of maintenance medication must be kept in mind during minor ailment treatment. A simple dry cough may actually be a side-effect of angiotensin-converting enzyme inhibitor. In the context of the Philippines, since patients buy medicines a few pieces at a time, some would expect that taking one capsule or tablet will relieve the symptoms. Especially when the dose and timing are incorrect, patients do not maximize the therapeutic benefit of the medicine. Advice should not be limited to medicine treatment, but also mention non-pharmacologic management. Accurate information on its use should be relayed to the patient.

3.4.1.6 Concept.6: Profit

Pharmacist must make the business sustainable by maximizing profit in an ethical manner. This means that the pharmacist must identify and offer products that would address all patient needs, but not to the point that they cannot afford it. It does not also mean that unnecessary items are pushed to patients. Medicines that give better margin were preferred by pharmacists, unless the patient articulates that cheaper medicines. In the context of the Philippines, some generic medicines yield more profit than branded products.

3.4.1.7 Concept 7: Product inventory

Pharmacist decision is also affected by the availability of stock in the pharmacy. A pharmacist cannot offer what she does not have on stock. In both countries, more than 90% of the clinical decision was to dispense. An alternative medicine is recommended should the first choice is unavailable, only if it does not compromise therapeutic needs and goals of the patient.

Television advertisements heavily influence patient choice, and advertised medicines are likely requested in the pharmacy. Pharmacists should be vigilant with new products and trends among patients. It was mentioned that some products become more popular; for example, throat spray becomes more in demand compared to a lozenge.

3.4.2 Theme 2: Context-related knowledge

Contextual-related knowledge refers to information specific to the individual and unique context of the patient. This includes age, comorbidities, hypersensitivity to excipients, chemicals, health trends, and patient's cultural, health, religious and lifestyle beliefs. Patient's preference is also accommodated for as long as it does not cause patient harm.

3.4.2.1 Concept 1: Patient choice

While a pharmacist's assessment and recommendation are important components of treating minor ailment, it is still the patient who is making the final decision for his own health. Table 3.1 shows that 67% (Philippines) and 75% (Malta) of the specific medicines requested (active ingredient and brand) were dispensed. Even the dosage form is important to make a successful sale for the customer's convenience and compliance. Cultural beliefs also played an important influence on both patients and pharmacist. Patients believe that only specific products will work on them. This is called "hiyang". If the medicine is unavailable, the patient may likely to refuse any alternatives.

3.4.2.2 Concept 2: Patient specific

Some patient specific restrictions can affect clinical actions by the pharmacist. If a patient is lactose intolerant, may require gluten free, or halal medicines, these should be known and respected by the pharmacist. Hypersensitivity to some active ingredients, like ibuprofen, should be ruled out. Religious beliefs should be respected, as well as lifestyle choices (eg, vegan).

3.4.2.3 Concept 3: Patient trend

A patient's medical history is important when deciding the appropriate over-thecounter medicine. This is particularly important in dispensing OTC in patient with existing comorbidities. For example, non-steroidal anti-inflammatory drugs should not be given in patients with severe or uncontrolled hypertension or asthma. Pseudoephedrine or phenylephrine, a common sympathomimetic decongestant in Malta and Philippines, in the oral form should not be given in patients with severe hypertension.

3.4.2.4 Concept 4: Affordability

Pharmacists were still conscious of making sure that patients would be able to afford their medications, while balancing the profitability of the business. In Philippines, customers buy medicines by piece, due to limited financial capacity. Pharmacists try to recommend cheaper generic equivalent so that patient can maximize the budget, while at the same time, there can be better margins for them compared to a branded one.

3.4.3 Clinical reasoning

As previously defined, clinical reasoning is the capacity of an individual to integrate knowledge, evaluate evidence, and weigh arguments to arrive at a clinical decision. Information made available to the pharmacist are understood and modified to fit into the situational context of the patient.

3.4.3.1 Modification

According to Bartels, integrating objective and contextual related knowlegde is crucial to successfully choose the most appropriate treatment for the patient. Being able to do so means providing a patient-centered care approach. In dealing with minor

ailments in the community pharmacy setting, many of the patients do not have official diagnosis of physicians. If patients can avoid paying the doctor's professional fee, they would prefer to save it. A pharmacist works on the available information collected from patients, and hence, the right questions must be asked in order to gather objective and contextual related knowledge. In some instances, patients cannot articulate themselves well, there is language barrier, or status of chronic conditions are unknown. The pharmacist must assess whether there is enough information to lead in a clinical decision. If the situation is judged as out of scope to what a pharmacist can legally offer, this will require referral to another healthcare professional. Inadequate information, both in objective and context related knowlegde, may warrant referral as well.

3.4.3.2 Situational understanding

A community pharmacist working in a single pharmacy for a period of time will likely establish rapport with patients. After encountering them multiple times, a pharmacist gets to know their unique circumstances such that it becomes easier for them to make drug therapy clinical decision. For example, even seemingly harmless multivitamin supplements, which can contain vitamin K, cannot be given without questioning as it can harm patients taking warfarin. This can be overlooked and never mentioned to the pharmacist during the short interaction. Modified objective and contextual related knowledge comprise the pharmacist's situational understanding unique to that patient.

3.4.4 Clinical action

Clinical actions generated were listed in tables above (Table 3.3.1 and Table 3.3.2). The majority of the decisions were to dispense medication. Pharmacists provide assessment and recommendations when patients seek for it. If patients seek for medicines, either pharmacist confirms appropriateness through a series of questions or immediately dispense in a transactional manner.

Table 3.4.1 Frequency of concepts utilized by pharmacists in Philippines and Malta during workplace observation in the community pharmacy setting

Theme	Philippines n=56	Malta n=44
Concept		
Objective	(82%)	(54%)
Drug	41%	38%
Disease	28%	34%
Inventory	9%	-
Health Education	22%	22%
Evidence-based	-	6%
Context Related	(18%)	(46%)
Patient choice	70%	17%
Patient trend	10%	74%
Patient specific	10%	9%
Affordability	10%	-

Concepts that were utilized by the pharmacists during workplace observation were tabulated in table 3.4.1. In practice, pharmacists looked more into the drug aspects of the case more than the disease. Pharmacists in the Philippines paid attention to inventory, since some of the pharmacies they worked for carried true generic medicines and must be able to offer generic equivalent. Pharmacists in both countries offered health

education to patients. Maltese pharmacists recommended medications that were evidence-based or according to protocols.

For context related concepts, Filipino pharmacists dispensed medicines with patient choice as the primary consideration. Maltese pharmacists' choice of recommendation were mostly based on patient's personal trend – comorbidities, past medical history, age, and point-of-care test results (eg, current blood pressure). Affordability was a huge consideration for Filipino patients such that some of them would afford only for a dose for a day.

Table 3.4.2 Frequency of concepts utilized by pharmacists in Philippines and Malta during semi-structured interview in the community pharmacy setting

Theme Concept	Philippines	Malta (n=47)
Objective	(73%)	(57%)
Drug	26%	26%
Disease	41%	39%
Evidence-based	-	13%
Continuing education	10%	11%
Health education	4%	3%
Profit	5%	3%
Inventory	4%	5%
Context Related	(26%)	(42%)
Patient trend	41%	61%
Patient choice	29%	10%
Patient specific	6%	26%
Affordability	23%	18%

Frequency of concepts as mentioned during interview were also tabulated. The researcher decided to distinguish concepts that were mentioned as a reflection of the pharmacist's practice vis-a-vis to those that are relevant to the actual case. This was done to compare whether there is reconstruction of thoughts, which indicates that they are retrieving knowlegde from long-term memory stimulated by the case being questioned at hand. It can be observed that concepts related to disease were more explored compared to the drug therapy. Consistently, participants from the Philippines did not speak about evidence-based recommendations but appear to choose medicines based on local culture and practice. A concept that did not appear during actual dispensing was profit (5%). This was still balanced by the context-related knowledge, such that pharmacists consider buying capacity of patient and ensuring they can still afford (23%) their medication. In both countries, consideration for patient trend had the highest proportion compared to patient choice. For Filipino participants, the hierarchy of concepts was dissimilar to the result of observation. Maltese participants were more consistent in observation and practice.

3.5 Operators

The second part of the protocol analysis is called assertional analysis. In this part, operators used by the pharmacist to conduct clinical reasoning were identified. Some definitions were modified as found appropriate in the acute care setting. For example, "verify" was originally defined as *confirmation of accuracy of a specific fact*. However, to clearly differentiate with the operator "collect", the former was modified to mean

confirmation through objective observations. This was aspects of the patient that the pharmacist can measure, see, hear, feel or smell during consultation.

Table 3.5.1 Frequency of the final list of operators utilized by pharmacists to perform clinical reasoning during workplace observation

Operators	Description	Frequer	ncy n (%)
		PH	MT
Collect	Information gathering from patient	35 (28%)	23 (35%)
Assume	Judgment based on hunch or culture	16 (13%)	3(4.6%)
Infer	Assessment by connecting evidence and making a choice	13 (10.1%)	12 (18%)
Act	Describing what the pharmacist or thinking of doing	36 (28%)	14 (21.5%)
Explain	Giving reasoning for what they are doing, or how things work	18 (14%)	11 (17%)
Review	Naming facts, context or objects in relation to medicine or patient pertinent to the case	6 (4.7%)	-
Verify	Confirming of facts objectively	1 (0.8%)	3 (4.6%)
Reflect	Retrospectively identifying what could have been done better	1 (0.8%)	3 (4.6%)
Plan	Describing plan that will be taken in the future (eg, if symptoms persist)	2 (1.5%)	1 (1.5%)
Match	Making connection between current situation and past situation or current patients to past patients	1 (0.8%)	1 (1.5%)

The most frequent operators in this study were the following: collect, act, infer, assume, and explain. Since pharmacists were recorded in an actual patient care setting, it can be observed that the highest frequent operator is *collect*, which may be expected in order to understand objective and contextual related knowledge. *Act* also came in very high, which represents the pharmacist taking action to the case. In purely transactional

interactions, pharmacists readily dispense medicines without conducting clinical reasoning. In this circumstance, assumptions are being made, either because it is believed that the medicine is safe, low in side effects, or considered "mild". In addition, the cultural concept of "hiyang" or agreeableness towards a specific brand either due to actual patient's belief, or as perceived by the pharmacist towards the patient, preventing potential clinical intervention. *Inference* were performed in scenarios where pharmacists utilized collected evidence to act on a decision.

Verification is distinguished from collection (or data gathering) such that the former looks into health parameters that can objectively be demonstrated to the pharmacist. It may not be necessarily observable during patient care that pharmacist is objectively verifying facts. This became apparent in the retrospective think aloud when the pharmacist was asked to verbalize the patient case. In some instances, pharmacist made the same clinical decisions based on a previous similar case encountered. This became apparent to the researcher when the pharmacist verbalized that the medicine was recommended since the same was prescribed by a physician to a patient having the same signs and symptoms. In hindsight, there were instances when pharmacist mentioned questions or tasks they would have performed to the patient. This is considered as "reflection". In all of the cases when pharmacists reflected, the researcher asked if doing so would have changed their decision. The responses were the same clinical decisions would still be made. Compared with a research methodology where the patient case is highly controlled, it would be easy to categorically identify right and wrong

decisions. However, that is not the objective of this research, but only to describe how it is performed in actual scenario. Finally, when pharmacists advised patients how to monitor the condition and what possible next step should be done, this was tagged as "plan". Mainly, pharmacist would say "if symptoms persist after 3 or 7 days, visit the doctor", or "come back if the condition progressed or side-effects appear".

Box 1: Example of *Hypothetico-deductive during interview*

PH07, 3 years experience, summary of thoughts during case referring to Fo_W_04

"So when the patient said cough, all the different classification of medicines registers in my mind like mucolytic, expectorant, and antitussive [infer]. From there, it proceeds [act]. I would ask questions to determine which would fit best, if there is phlegm that can't go out, or if it was dry cough [retrieve].

The operators used were (1) infer (2) act, (3) retrieve

When one of the respondents was asked to be verbalize her thoughts regarding one of the cases, it was mentioned that all of the medicine classification was thought of. It meant that the respondent began with a hypothesis already, which is cough, and eliminating other medicines based on incoming information. It was difficult to interpret that the pharmacist inferred right away at the onset of her interaction with the patient without sharing her thoughts during the interview. The pharmacist asked further questions to the patient to ultimately confirm that she was making the right decision to dispense the requested medicine.

Box 2: Example of pattern recognition during interview

PH01, 4 years experience, question on physician referral

"For example, for cough and colds, usually those are cases that goes to physician if the duration exceeds 1 week because there is tuberculosis we've encountered, right? [match] It's a possible symptom if the condition persists. If ever after a week it (medicine) did not take effect and the cough stayed the same [infer], it's better that the patient goes to physician to check what is causing the symptoms and may be given the right medicine [act]."

The operators used were (1) match (2) infer, (3) act

Pharmacists were also asked to reflect on other scenarios to demonstrate how they would go about a case. These were also analyzed to determine any forms of clinical reasoning and compare if they really apply concepts and cognitive strategies during actual patient interaction.

Table 3.5.2 Percentage of pharmacists performing operators and exploring concepts during observation and retrospective think aloud interview

Operators and	Philippines (n=10)		Malta (n=5)	
applicable concepts	Observation	Interview	Observation	Interview
COLLECT				
Establish disease/cause	8	9	5	5
Patient signs and symptoms	9	10	5	5
Past medical history	0	5	5	5
Medications taken	1	6	4	5
Allergy	1	3	2	3
Age	2	5	4	4
VERIFY				
Physical aspect	1	7	4	3
Point of care	-	2	-	5
ASSUME	6	10	1	1
INFER	8	10	5	5
ACT				
Patient choice	10	10	5	5
Cost	-	9	-	4
REFLECT	2	-	2	-

Although the frequency of operators reveals which strategies are performed much higher by pharmacists, it does not give meaningful information as to what concepts were explored and the actual proportion of pharmacists performing them. This is deemed necessary to present, especially pharmacist respondents had different number of recorded cases (uncontrolled as this was exploratory study). The categorical data in this

table is intended to merely describe how participants explored selected concepts during his reasoning, and not to represent a score – 100 being the ideal.

It can be observed that pharmacists gather information on the signs and symptoms to establish the condition, and whether this merited referral to another physician. It is notable, however, that Filipino pharmacists do not consider past medical history, medications taken, or age of the client. Allergy was less likely to be asked in both countries. During data collection, none of the pharmacist did any point-of-care test in relation to any minor ailment. Verification of physical aspects, such as checking of physical appearance or listening to sound of cough, were less likely to be performed by Filipino pharmacists in actual patient setting.

As can be referred in the table, there is a discrepancy in the proportion of pharmacists in each operator when comparing between observation and interview. This is because during the interview, pharmacists were able to reconstruct their thoughts especially after the interaction with the patient. As an example, respondents would say past medical history is important to collect, but in the actual observation, none of them asked patients about comorbidities.

3.6 Clinical Reasoning Approach

After identifying the operators, the clinical reasoning approaches were determined according to the order by which operators appeared during the interaction with the patient. The retrospective think aloud data pertinent to the case were also included.

Table 3.6. Clinic reasoning approach observed during workplace observation (n=53) *

	Philippines		Malta		
System 1 (intuitive)	MEDICINE	ADVICE	MEDICINE	ADVICE	
Pattern Recognition	1 (3%)	-	_	1 (10%)	
System 2 (analytical)	System 2 (analytical)				
Hypothetico-deductive	2 (8%)	1 (15%)	5(62.5%)	1 (10%)	
Forward chaining	-	-	-	5 (50%)	
If/Then	8 (27%)	5 (85%)	-	3 (30%)	
No observable CR demonstrated	16 (55%)		3 (37.5%)	-	

^{*1} count per clinical decision demonstrated

The data was stratified based on the patients seeking advice or specific medicines. In both scenarios, analytical approach or System II was predominantly used. When patients seek for medicines, pharmacist tend to not perform clinical reasoning half of the time in the Philippines, and a third of the time in Malta. If clinical reasoning was conducted, pharmacists in Malta used hypothetico-deductive approach whereas, Filipino pharmacists used if/then. If/then was classified when the pharmacist collected one information, usually indication, to infer the appropriate medication. Hypothetico-deductive usually begins with the operator *infer*, succeeded by *act*, followed by a series of *collect*, which indicate more probing questions in a backward analytical manner.

Chapter 4 Discussion and Conclusion

Chapter 4 Discussion

In this chapter, the results of the study in exploring clinical reasoning among community pharmacists dealing with minor ailments in Manila, Philippines and Malta are discussed. This research attempted to elucidate the pharmacist's cognitive actions as it occurred when dealing with patients concerning minor ailments. As of writing, publications on the community pharmacist's clinical reasoning were conducted in a simulated environment using validated clinical vignettes with cases of a patient with prescription (Gregory & Austin, 2016; Nusair & Guiguis, 2017; Sinopoulou et al, 2017) or with predefined consultation scenarios (Akhtar & Rutter, 2015; Haider & Leutsch, 2019). This was the first project to look into clinical reasoning and decision making in an actual patient care setting with community pharmacists catering to acute conditions namely, cold, cough minor muscle pain, and headache.

One of the long-established roles of pharmacists has been to care and respond to patient's minor ailment. In order to do that, pharmacy academicians have been trying to elucidate the tacit cognitive skill called clinical reasoning to understand how it is performed in practice. This study focused on how community pharmacists' make clinical decisions during assessment, treatment and referral in cases of minor ailments. Community pharmacists' thinking process is triggered by two major cues based on patient's request: buying a specific medicine or consulting for appropriate medication based on their condition. There were more requests for medicines than advice from Filipino pharmacists, which may be attributed to the general perception of patients that pharmacists are mere medicine sellers (Douglas & Salenga in Ud Babar, 2017). In the observed cases in the Maltese setting, patients are as much likely to ask for medicine or advice

towards the pharmacist. This may be associated to the positive perception of patients towards pharmacist's capacity to help them with their minor ailments (Wirth et al, 2011).

Pharmacists provided the full scope of patient care process in all customers who consulted their minor ailment. When patients request for medicines, pharmacists tend to dispense without assessment of therapeutic appropriateness. Pharmacists respondents mentioned several reasons for the lack of intervention when there is a preferred medicine. These include prejudice towards non-acceptance to recommendation, underestimating harmful effects of inappropriate OTC use (considering it as "minor condition" and medicine is generally safe), and the low quantity of ordered medicine will less likely to harm patients. Despite having established safety profile over years in the market, nonprescription medicines can still cause harm with irrational use. As an example, Schmiedl et al. (2014) in a drug safety study in Germany identified aspirin, paracetamol, and ibuprofen, either as a single agent or in combination with other prescription drugs, have previously caused hospitalization to self-medicating patients. Pharmacist must ensure correct use of OTC, especially extending more guidance to patients taking prescription medicines concomitantly.

Appropriate assessment to dispense the right medicine is reliant on the questioning skills of the pharmacist to determine patient needs (Rutter, 2013). It was observed that in both countries, there was no structured framework or strategy to gather patient information during patient assessment. Rutter and Harrison's (2020) latest publication recommends veering away

from the use of protocol and mnemonics to facilitate patient self-care due to low acuity of treatment when the goal is to manage symptoms. Nevertheless, purposeful and direct questioning should be employed to arrive at a proper diagnosis and treatment recommendation (Sinopoulou, Summerfield & Rutter, 2017; Rutter & Harrison, 2020). Respondents in both countries did not present an organized approach to identify and refine patient problem during assessment.

Majority of the clinical actions, whether it was advice or medicine sought, was to dispense medicines (Table 3.3.1 and 3.3.2). When the interaction became purely transactional, the patient receives the exact requested OTC medicine as long as it was in the pharmacy inventory. Although only one case of referral to physician was observed, all of the pharmacists were vigilant towards red flag signs and symptoms that should be considered severe and would require referral.

4.1 Themes, Concepts and Operators

In the course of textual analysis, the concepts generated were aligned to previously identified concepts (Bartels, 2003; Nusair & Guirguis, 2017; Croft, at al 2017). These concepts were regrouped and categorized based on the PhD dissertation of Bartels (2003) on clinical reasoning of pharmacists in the ambulatory setting. Her proposed framework for clinical decision making was adapted and modified as it clearly organized and represented the concepts found during the referring phrase analysis.

Similar to the original proposed model, concepts were grouped into major themes, namely, objective and contextual-related knowledge. In the original model, objective knowledge included drug/disease information, alternative to drug therapy, continued learning, evidencebased, cost and health education. Context-related knowledge, data related to patient situation, include patient choice, specific, and trend. In the modified and adapted clinical reasoning and decision-making model, several changes are proposed. Cost was transferred to context-related knowledge and the term was changed to "affordability". It is argued that affordability is dependent on the patient's capacity to pay, which is variable to the context of the patient. When an average individual's resources are limited, a good becomes unaffordable when it is beyond the total budget that can be spared for all basic needs (Niens & Brouwer, 2013). Mathematically, affordability in medicines is computed based on price of medicine over daily wage of lowest-paid unskilled government worker (WHO/HAI, 2008). It was deemed important to clearly distinguish affordability to "profit", a concept that was added to the objective knowledge domain. Realistically, community pharmacists have to ensure profitability (Tootelian, Wertheimer & Mikhailitchenko, 2012), but at the same time should not compromise the treatment of patients. There are patients who prefer innovative or branded medicines, while others can only afford generic medicines one piece at a time. "Alternative to drug therapy" was deleted since health education is sufficient to cover non-pharmacotherapeutic advice for minor ailment cases.

Frequency of concepts were tabulated based on its occurrence in workplace observation and interview (Table 3.4.1 and Table 3.4.2). This was done to identify if the data gathered in two activities corroborated, or if participants were merely reconstructing thoughts on their practice. Filipino pharmacists utilize more objective knowledge than context-related ones, while

pharmacists in Malta weigh on both domains almost equally to make clinical decisions. In both countries, drug and disease information comprised the largest amount of objective data. This implies that in dealing with minor ailments, the thinking process is heavily focused on objective data consistent to previous literature (Bartels, 2003; Nusair et al, 2019). As for the context-related knowledge, Filipino pharmacists accommodate patient choice significantly more than the other concepts in practice. In theory, however, the largest amount of context-related data perceived to be utilized was patient trend. This is further highlighted when selected details of concepts were cross tabulated with operators (Table 3.6). For example, past medical history was not collected by any of the Filipino pharmacist respondents during observation, but 5 (out of 10) of the pharmacists mentioned its importance during the interview. Another notable finding in this study was that Filipino community pharmacists did not utilize evidence-based medicine as a tool to support recommendations. As for pharmacists in Malta, frequency scores were consistent between the two data collection procedure. As previously mentioned, objective and contextrelated knowledge were almost equally weighed when making clinical decisions. Patient trend was also consistently highly utilized when reasoning. As for affordability and inventory, these were emphasized during interview, but were not apparent considerations in practice.

It is also proposed in the adapted model that majority of the cognitive strategies, also known as operators, occur at the modification level. These are the activities that are cognitively performed by pharmacists during the reasoning process to integrate the objective and context-related knowledge. It was revealed that there are 10 operators conducted when dealing with patients with minor ailments; namely, collect, assume, infer, act, explain, review, verify, reflect,

plan and match. Collect was the mostly used operator as can be expected to gather objective and context-related information. This is followed by act, which is the product of the clinical decision of the pharmacist. Assume was prevalent among Filipino pharmacists that held on to cultural belief of "hiyang" or agreeableness of the medicine to the patient. In addition, when pharmacists dispensed immediately without even a single question, they relied on assumptions previously mentioned, such as safety of OTC and presumption that patient is knowledgeable on the use of requested medicine. Objective verification through physical assessment and point-of-care test to support clinical decisions were activities not routinely performed by community pharmacists in the Philippines but was found to be a normative practice in Malta.

As there are only few literature available on clinical reasoning in pharmacy, no single process or approach was deemed most appropriate (Nusair et al, 2019). In this thesis, operators were merely described, but it is not suggested that all of the activities should be cognitively performed in order to arrive at an appropriate clinical action. In the cross-tabulation of selected concepts and operators, it can be observed for Filipino pharmacists that the frequency of the concepts in observation was lower compared with the interview. This may mean that pharmacists are retrieving knowledge from long term memory, reconstructing their answers rather than describing thoughts occurring at the short-term memory space. It can also indicate that Filipino pharmacists appear to know the importance of the concepts theoretically but does not apply them in actual patient care. Based on Miller's clinical skills hierarchy (Miller, 2003; Muse & McManus, 2013), it suggests that some participants in this study know (level 1 knowledge) concepts that are relevant to clinical reasoning at the cognition level, but do not demonstrate or

show the skill in practice (level 4 action). Other respondents did not show much difference between observation and interview, which indicates that pharmacists are able to translate knowledge to practice. These pharmacists were able to demonstrate a process that is comprised of multitude of concepts, which can be simple or complex depending on the patient's unique context. This shows important implication to the quality of care rendered in the patient care process as it is more important what reflects in their actions on a daily basis to display professional authenticity.

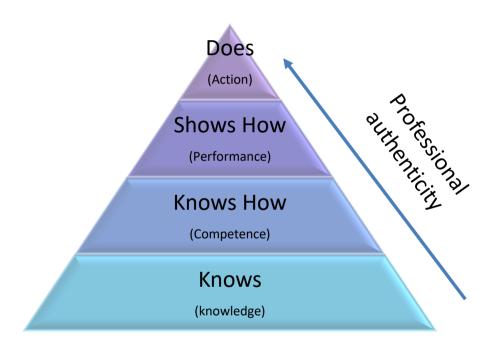


Figure 4.1 Miller's Hierarchy of Clinical Competence (1990) adapted by Mehay and Burns (2009)

4.2 Clinical reasoning among Filipino pharmacists

After operators were identified, the order by which they appeared during textual analysis of the patient interaction led to the identification of the clinical reasoning approach. Filipino

pharmacists mostly used analytical thinking particularly, if/then approach, regardless if medicine or advice was sought. It was apparent that therapeutic indication mostly determined the pharmacist's decision. For example, headaches would be given paracetamol, toothaches will be treated with mefenamic acid, or paracetamol in combination with ibuprofen is dispensed when it was body pain. The simplistic conditional approach may potentially compromise patient safety. In many of the cases, pre-existing comorbidity or patient's age were not confirmed. This is important, for example, to non-steroidal anti-inflammatory such as ibuprofen as it is contraindicated in many conditions. Due to the sachet marketing, a buying culture in which patients buy few piece medicines at a time, it can be argued as to how much 1 pill can harm a patient. However, patients can buy a piece on a daily basis from different pharmacies, and an intervention will less likely to occur if this will be the mindset of every pharmacist and staff. Adverse drug reaction from the use of Ibuprofen was detected as early as on the 8th day of use (Schmiedl et al, 2014). When tediously done right, pharmacist's professional guidance would reduce preventable medication errors. For the same reason stated, it is argued that it can potentially cause more harm when clinical reasoning is not performed at all as observed in more than half of the case in patients asked for medicines.

Hypothetico-deductive approach was demonstrated in both patient groups, but more predominantly among those when medicine was requested. At the onset of the interaction when patients request for a specific medicine, pharmacists already infer the minor ailment based on the indication, and proceeds to "collect" more information such as other signs and symptoms, probable cause, etc. Compared to if/then that considers only one concept (disease indication),

hypothetico-deductive occurs when the appropriateness of the medicine was repeatedly tested through a series of questioning.

Based on the observation, despite differences in years of practice, type of employment or number of CPD attendance, it appears that the clinical reasoning capacity is similar across all participants. This may be attributed to the pharmacy educational curriculum, client expectation, as well as culture and pharmacy practice. There is an opportunity to strengthen clinical reasoning among community pharmacists. It is highlighted at this point that generalization among Filipino community pharmacist's capacity for clinical reasoning to address minor ailments cannot be concluded based on this exploratory analysis.

4.3 Clinical reasoning among Maltese Pharmacists

In this study, Maltese pharmacists' decisions were made based on analytical thinking approach. All of the pharmacists exhibited good questioning skills, which enabled them to gather sufficient objective and contextual related knowledge to understand patient concerns. If at the onset, the cue of the patient was a medicine request, hypothetico-deductive reasoning was found to be the utilized the approach. In the same category, a third of the patients were not assessed as the product was assumed to be safe. These are still probable missed opportunities to intervene avoidable adverse effects. If the patient asked for advice, forward-chaining was implemented half of the cases, followed by if/then approach. Forward-chaining is distinguished with if-then approach if several information were collected to build on a hypothesis. For example, a mother with a child with a croupy cough came to consult with the pharmacist. If pharmacist collected information on history of present illness, comorbidities, and medication being taken, while also

physically assessing patient by listening to the sound of the cough and taking note of the appearance (paleness). With the information, a hypothesis was generated leading to a clinical action, which was referral. This example demonstrated how operators and concepts were combined during modification step to get a good situational understanding. Pattern recognition was recognized only during the retrospective think aloud interview when the pharmacist self-reported on giving the same recommendation from a similar case encountered.

Pharmacist participants from Malta are more homogenized in terms of clinical reasoning skills which can be ascribed to high proportion of biomedical sciences courses in the pharmacy curriculum (Atkinson & Rombaut, 2011) that is provided by the only university, as well as culture and client expectations. Pharmaceutical education and practice exposure through the internship program may have significantly contributed to their skills in pharmaceutical care.

4.4 Limitations

As with other research studies, there were difficulties and limitations encountered during the study. Thorough analysis of data can only be performed with proper recording or documentation using reliable equipment. Recorders are commended to be as less intrusive as possible to avoid discomfort at the end of the participant. In this study, two of the Maltese participants requested to voice record, instead of audio-video recorded. In such scenarios, some cues may have been missed (such as reaction of nonverbal cues of patient and how pharmacist responded). Language barrier is a difficulty anticipated, especially some patients preferred to speak to the pharmacist in the local language. Researcher requested assistance for translation

from native language speakers without breaching the confidentiality agreement with the respondents.

As an exploratory study, it cannot be extrapolated to all of the pharmacists practicing in the community in the two countries. This study provides an insight to the reasoning approaches developed throughout education and years of practice in the respective countries. Think aloud method relies on the capacity of the participants to coherently and extensively explain their thoughts. Details describing what the medicine is for or why it was chosen may be deemed by the participants as unnecessary since the researcher is also a pharmacist. Participants were asked thoroughly and repeatedly, which may have triggered them to retrieve more stored knowledge rather than thoughts that occurred during dispensing in order to satisfy the researcher. One of the criticisms of think aloud method is that participants may be over performing due to Hawthorne effect (Russo et al, 1996; Nusair et al, 2019). To overcome these, data was presented such that concepts referring to the actual case was segregated to reflection answers. They were also encouraged to work as if the researcher was not present, and that during the interview, they answer freely as if talking to a first-year pharmacy student. Rapport with the pharmacist respondent was also established by exerting as much effort so they feel comfortable during data collection. Pharmacist respondents were also interviewed immediately after a number of cases have been collected to avoid reconstruction of answers. The advantage of conducting the study in an actual patient care setting is that concepts, operators and approach obtained were actual as it occurred, no matter how simplified or complicated the process may be.

4.5 Recommendations for future study

To further improve the study, think aloud exercises may be given to participants prior to data collection so that they will be at ease to elaborately describe their thoughts. Other clinical reasoning study designs may also be employed. Evaluation of the pharmacist's thought process in conducting assessment while simultaneously determining appropriateness of the clinical action (Akhtar & Rutter, 2015) may be conducted. It is important to determine factors affecting effective clinical reasoning among pharmacists. Comparison of clinical reasoning between novice and expert practitioners may be useful to establish continuing education needs. Clinical reasoning among pharmacy students may also be explored to assess their preparedness for practice and efficacy of teaching methodologies employed.

It is also recommended to conduct structural equation modeling to test proposed clinical reasoning and decision-making models in pharmacy to determine relationships of identified variables and latent constructs. Conducting this study will help determine what directly contributes to clinical competency (eg, basic science, pharmacy aptitude).

4.6 Study Implications

This study provided an insight how community pharmacists conduct clinical reasoning as it happens in actual patient care setting. With this understanding, implications to standards, practice, and education are discussed as follows.

4.6.1 Streamlining entry to practice requirements, pharmacy professional goals and practice standards

Expanded roles and changing expectations towards pharmacists to perform more clinical roles have been repeatedly discussed in conferences and seminars. However, clear and defined actions to achieve this should be instituted as moral and professional responsibility of pharmacists to their patients and the society. Pharmacy councils and professional groups must work together to streamline standards and practice goals to continuously develop/enhance clinical reasoning capabilities of pharmacists. For example, in the UK, the Royal Pharmaceutical Society developed General Level Framework for general level of practice, and also the Foundation Pharmacy Framework to define advanced practice level²⁶. To ensure that pharmacist can provide better clinical service upon entry to the workforce, competency requirements as measured by professional licensure exam or prior to the awarding of the warrant should be established.

4.6.2 Continuing professional development (CPD) focus on development/enhancement of clinical reasoning skills

In line with 4.6.1, pharmacists should be able to find opportunities to hone their clinical reasoning abilities to improve their patient care. CPD course curriculum and design should be encouraged for the attainment of this skill. Filipino pharmacists are required to accumulate 45 credit units before their practice license can be renewed in accordance to

²⁶Royal Pharmaceutical Society. The RPS Foundation Pharmacist Framework 2019 (internet). United Kingdom. Available from: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Foundation/RPS%20Foundation%20Pharmacy%20 Framework.pdf?ver=2019-11-13-134125-950

²⁷Professional Regulatory Board of Pharmacy Resolution No. 279 S. 2017. Operational Guidelines on the Implementation of RA 10912. Available from: prc.gov.ph/sites/default/files/PRB%20of%20PHARMACISTS%202017-279 101017 1.PDF

Republic Act 10912, 40% should be dedicated to enhancement of professional practice and technical competence²⁷. In Malta, CPD is also available although not mandatory, respondents positively welcome courses which will refresh and enhance their skills. These are untapped areas of opportunity that can be maximized to advocate for its advancement.

4.6.3 Changes in pharmacy curriculum and teaching strategy

Development of clinical reasoning should begin in the University years. Methodologies to develop clinical reasoning skills should be incorporated into various courses. This includes illness script development, script concordance testing, and problem-based learning.

4.7 Conclusion

This qualitative research study strived to elucidate clinical reasoning and decision making of community pharmacists attending to minor ailments in an actual patient care setting. Pharmacist's clinical reasoning approach mostly followed the analytical decision-making, which critically varied according to patient's request at the onset of the interaction. Ensuring that pharmacy decisions are made by considering important objective and contextual-related knowledge during clinical reasoning will result in the highest quality of care and falling short could have implications to patient safety and health outcomes.

This is an innovative dissertation because this is the first research in community pharmacy to study clinical scenarios where pharmacist had complete autonomy to make clinical decisions on the treatment of patients. Hence, this may be the closest to real life description of clinical reasoning and decision-making of community pharmacists treating minor ailments. Furthermore, this study was conducted in two countries from different continents. Although pharmacists in these settings greatly differ in their pharmacy education and background, professional obligations and expectations to provide the highest quality of care are the same. This study provides value to the profession for identifying opportunities for growth, while at the same time exhibiting capacity to clinically reason and recommend evidence-based treatments in such a short period of interaction with patients.

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Appendix 1. Data Collection

Appendix 1.1 Data Collection Sheet

Research Title: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

DATA COLLECTION SHEET DURING OBSERVATION

(PHASE 2)		
Pharmacist Participant Code: Years of Practice as a Community Pharmacist:	Date of Data Collection:	
Position in the company:		
Highest Educational Attainment in Pharmacy (complete	ad degree).	
PhD PharmD	.a acg. cc/.	
MS BSC		
Currently Studying? No Yes, degree program: Attends CPD programs: No Yes, area of topics attended:		
Patient Number:	Time of recording:	
Chief complaint:	Observations:	
Patient Information provided:		
	Clinical Desiries of Pharmacists	
	Clinical Decision of Pharmacist:	

Appendix 1.2. Semi-structured Interview Questions Addressed to Pharmacist (Phase 4)

Pharmacist participant will be shown a chosen clinical interaction and intervention recorded during the observation (Phase 2). Below is the list of questions that will be asked of the pharmacist using the AV recording as the main context of the discussion.

2.5.1.1 Based on the video:

- 1. Can you summarize the task and the outcomes of your actions? What did you do and what were the outcomes for the patient?
- 2. Talk me through your thoughts after you received the patient request/complaint.
- 3. What came to mind when you were undertaking the initial assessment of the request/complaint?
- 4. Discuss the process you went through to dispense the medication for the patient.
- 5. What are the cues you needed to make that product recommendation for the patient? Do you think it's the appropriate product for the presenting conditions of the patient? (if applicable)
- 6. What environmental cues presented/observed that led you to refer to the physician? (if applicable)
- 7. Include questions that further investigate specific actions of behaviours of the participant that were not raised spontaneously during the discussion:
 - a. Why did you look up that information?
 - b. What was the rationale for asking that question?
 - c. Why did you take that POCT in relation to an acute condition presenting symptom? *blood glucose test, blood pressure test, influenza test
 - d. How did you arrive at that information?

2.5.1.2 Based on reflection:

- 1. Discuss any challenges that you identified/needed to overcome in supplying this medication to the patient.
 - a. Did you have enough time?
 - b. Did you have access to resources to make the right recommendation?
- 2. Discuss the information sources used to consider the appropriateness of the prescribed medicine.

C. Conclusion

- 1. Do you have any further information that you feel would assist with our understanding of the decision-making process that are required when supplying medications?
- 2. Are there any further comments you would like to make?

Appendix 1.3 Data Collection Protocol given to participants

Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines

Data Collection Protocol

Phase 1: Observation

- Pharmacists shall be AV recorded as they perform their work with a consulting patient in the community pharmacy.
- II. Researcher will record ONLY interactions with patients who have given their informed consent to recording. Researcher will ask the patient first while waiting or before being served by the pharmacist what chief complaint they will consult with. If the patient qualifies, he/she will be asked to sign an informed consent form.
- III. Patients with only the following minor ailments shall be asked to take part in the study: headache, cough, common cold and muscle pain. Patient must at least be 18 years old.
- IV. Researcher will observe and record at least 2 patient cases.
- V. In the observation, the researcher shall utilize a data collection sheet to take note of the following as it happens:
 - i. Identify patient complaint/request
 - ii. Record cues from Pharmacist
 - a. Questions asked
 - b. Physical examination
 - c. Access to any resources
 - iii. Record clinical action of the pharmacist
 - a. Point-of-care test conducted
 - b. Clinical decision (eg, product recommendation, referral, counselling)
- VI. The researcher will not document any pharmacy administrative and legal concerns of the pharmacy. Only the pharmacist and related clinical reasoning will be documented.

Phase 2: Semi-structured interview

This phase is the second and last data collection point.

- I. From the recorded videos, the researcher will play one clinical scenario, which shall be the main point of discussion in the semi-structured interview.
- II. Questions regarding the clinical reasoning and decision-making will be asked.
- III. The duration of the interview shall not be more than 30 minutes. The interview can be scheduled before or the during shift (during idle times), or as convenient to the pharmacist.
- IV. The interview will be audio recorded. The participant can request a transcript as needed.

Note:

Pharmacist participant can correct the transcription should there be any gross error in the process.

Pharmacist participant can request to delete a video or to exclude cases as they wish to do so. Pharmacist participant upon exercising his/her clinical judgment during dispensing, and in the process decides to dispense rx medicine without prescription, he/she can request to exclude those patients as part of the study.

Appendix 2.1 Ethics Approval from University of the Philippines Manila Research Ethics Board



UPMRED FORM 4/B/DDF-CERTIFICATION OF APPROVAL

CERTIFICATION OF APPROVAL

This certifies that the University of the Philippines Manila Research Ethics Board (UPMREB) Review Panel 1 which is constituted and established, and functions in accordance with the requirements set by the University of the Philippines Manila, the Philippine Health Research Ethics Board (PHREB); and in compliance with the WHO Standards and Operational Guidance for Ethics Review of Health-related Research with Human Participants (2011)) the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (2016), and the National Ethical Guidelines for Health and Health-related Research (2017), has approved the following study protocol and related documents:

TYPE OF SUBMISSION: Initial	
UPMREB CODE: UPMREB 2019-405-01	
STUDY PROTOCOL TITLE: Comparative	Analysis of Clinical Reasoning and Decision
Making of Community Pharmacists during of	
PRINCIPAL INVESTIGATOR: Ms. Arianne	
TYPE OF REVIEW: Expedited Review	
SPONSOR/FUNDING AGENCY: Investiga	tor
APPROVAL DATE: 07 October 2019	EXPIRY OF ETHICAL CLEARANCE*: 31 October 2020 Study protocols are reclassified as <i>Inactive</i> after expiry of ethical clearance.
DUE DATE OF APPLICATION FOR RENEWAL OF ETHICAL CLEARANCE (30 days before expiry): 30 September 2020 Submit application using the UPMREB FORM 3(B): Continuing Review Application Form.	FREQUENCY OF CONTINUING REVIEW: Yearly
APPROVED SITE/S: Community pharmacy Pharmacy, Calma Drugstore	y - branches of Generika Drugstore, AIO

- Comparative Analysis of Clinical Reasoning and Decision-Making of Community Pharmacists during dispensing in Malta and the Philippines version 2.0 dated 25 September 2019;
- Informed Consent Form for Pharmacists (English) version 2 dated 25 September 2019;
- Informed Consent Form for Pharmacists (Filipino) version 2 dated 25 September 2019;
- Informed Consent Form for Patients (English) version 2 dated 25 September 2019;
 and
- Informed Consent Form for Patients (Filipino) version 2 dated 25 September 2019.

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UPMREB 2019-405-01_Approval_Aninon



TECHNICAL DOCUMENTS INCLUDED IN THE REVIEW:

- Curriculum Vitae and Research Ethics Training certificate of Ms. Arianne Diane Aninon as principal investigator;
- Curriculum Vitae and Research Ethics Training certificate of Prof. Edwin Rumaero as co-investigator; and
- 3. Curriculum Vitae and GCP training certificate of Ms. Cristan Agaceta.

RESPONSIBILITIES OF PRINCIPAL INVESTIGATOR WHILE STUDY IS IN PROGRESS (Please note that forms may be downloaded from the UPMREB website:

- reb.upm.edu.ph):
 Register research study in the Philippine Health Research Registry upon approval (http://registry.healthresearch.ph)
 - Progress report using the attached UPMREB FORM3(B)2012: Continuing Review
 Application Form, as indicated above, which includes the following: (NOTE: In
 view of active ethical clearance, this report is mandatory even if the study has not started
 or is still awaiting release of funds.)
 - a. Date covered by the report
 - b. Protocol summary and status report on the progress of the research
 - c. Philippine Health Research Registry ID
 - d. Number of participants accrued
 - e. Withdrawal or termination of participants
 - f. Complaints on the research since the last UPMREB review
 - Summary of relevant recent research literature, interim findings and amendments since the last UPMREB review
 - h. Any relevant multi-center research reports
 - i. Any relevant information especially about risks associated with the research
 - j. A copy of the informed consent document
 - Any amendment/s in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, and revisions in the informed consent, must be submitted or reported using UPMREB FORM3(A)2012: Study Protocol Amendment Submission Form.
 - Report of non-compliance (deviation/violation), whether minor or major, at the soonest possible time up to six (6) months after the event, using UPMREB FORM 3(D)2012: Study Protocol Non-Compliance (Deviation/Violation) Report.
 - Reports of adverse events including from other study sites (national, international)
 using the UPMREB FORM 3(G)2012: Suspected, unexpected serious adverse
 event/reaction/s report, with timelines for submission guided by the GL 02
 Version 2.0: Guideline on Reporting Serious Adverse Events; or list of reportable

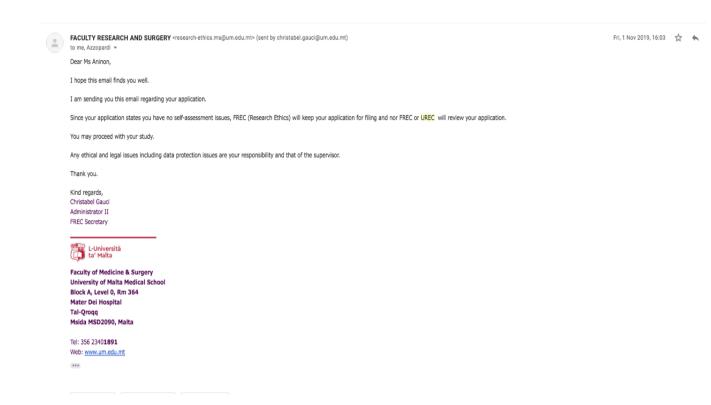
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Appendix 2.2 Ethics approval from Faculty of Research Ethics Committee under University of Malta

Electronic correspondence with FREC Secretary regarding approval of the study.



Appendix 3. Requirements for Informed Consent

Appendix 3.1 Philippines

Appendix 3.1.1. Informed Consent Form for Pharmacists

CONSENT FORM FOR THE PHARMACIST

Research Title: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

I, Arianne Diane A. Aninon, a third year Doctorate of Pharmacy student at the University of Malta, am doing a research-based dissertation entitled "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines" as part of my course requirements. Prof. Lilian Azzopardi from the University of Malta is my principal supervising investigator while, Asst. Prof. Edwin C. Ruamero Jr., from University of the Philippines, College of Pharmacy and Cristan C. Agaceta, RPh are my co-investigators in this study.

Background

Clinical reasoning and decision-making are critical competency areas that are much less explored in pharmacy compared to other health professions. Learning clinical reasoning and decision making in the actual patient care setting will allow us to understand the processes involved in performing such cognitive activities and will provide insight on how knowledge should be constructed to pharmacists or pharmacy students especially those who are expected to fulfil a more clinical role in the community. This study is a comparative qualitative ethnomethodologic research that will particularly utilize a retrospective think aloud technique to examine the patterns of clinical reasoning and decision-making processes. The methodology mainly consists of observation (with recording) of interaction with patients and subsequently, a semi-structured interview to talk about one clinical scenario encountered. We would like to stress that our goal is to map out the cognitive processes that happens as you interact with the patient, provide intervention, and make clinical decisions. There will be no assessment or judgment of whether your practice was right or wrong.

Participant Selection and Voluntary Participation

You are being invited to be one of the 10 pharmacists to take part in this research because your experience as a community pharmacist (cumulative community pharmacy experience of at least 3 years) can contribute much to our understanding and knowledge of clinical reasoning and decision making among community pharmacists. Your participation in this research is entirely voluntary.

Procedures

On the day of the observation, interactions with patients presenting presenting either headache, cough, muscle pain, or common colds will be audio-video recorded. The consent of patient/s (at least 18 years old) will be obtained. The face of the patient will not be captured in the video. The interaction will be transcribed and will be preliminary analyzed. The second part of the research is a semi-structured interview. Transcription will be sent for your approval, and list of questions will be sent prior to the interview. During the interview, one of your recorded clips will be shown to you, which shall be the context of the questions to be asked. The semi-structured interview shall also be audio recorded for transcription.

Duration

The research takes place over in one of your work shifts (on the schedule of your preference) in the community pharmacy. During that time, I will be in the pharmacy to install a recorder and seek patient consent for recording the interaction. There will be no additional time required of patients nor of you during the observation. A follow-up interview will be requested on your preferred time to talk about one of the clinical scenarios, which had been pre-analyzed prior to the interview. The follow-up interview shall not be more than an hour.

Risks and Benefits

If you feel that the recorded interaction should not be part of the analysis, for whatever reason you think is important, you can say immediately, and the clip will be deleted. There will be no direct benefit to you, but your participation will

help us how to construct and teach clinical reasoning and decision making in the pharmacy curriculum both for Philippines and Malta.

Reimbursements

You will not be provided any incentive by participating in this research, but findings of this research will be shared with you. There will be no reimbursements, even travel expense. A snack will be provided after the semi-structured interview.

Confidentiality

We will not be sharing information about you to anyone outside of the research team. Your identity will not be revealed in any manuscript or publication later on. A participant code shall be assigned during data processing and analysis. Video/audio recordings will be encrypted and Microsoft Office files related will be password protected. Under Under the Data Privacy Act of 2012, participants have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

Right to Refuse or Withdraw

If you feel that you do not wish to continue while the data gathering is in process, you may stop participating and you do not need to explain your reasons. You can also ask for any information gathered from you to be deleted without any questions or penalty.

I have been invited to participate in research about the clinical reasoning and decision-making of community pharmacists, a study being conducted by a PharmD student at the Department of Pharmacy, University of Malta. By signing this form, I certify that I approve the following:

- 1. patients (who gave their consent to participate) presenting one of the identified acute conditions with the pharmacist in the pharmacy will be audio-video recorded
- 2. the follow-up semi-structured interview will be audio recorded
- 3. transcripts in both cases (observation and interview) will be produced
- 4. transcripts will be sent to me and I will be given the opportunity to correct any factual errors
- 5. the transcript will be analyzed by Arianne Diane Aninon as the research investigator
- transcript will be limited to Arianne Diane Aninon and academic colleagues and researchers whom she might collaborate as part of the research process
- 7. any summary interview content, or direct quotations from the interview, that are made available through academic publication or other academic outlets will be anonymized so that I cannot be identified, and care will be taken to ensure that other information in the interview that could identify yourself is not revealed
- the actual recording will be destroyed, and transcripts will not contain personal identification of myself and of my patient
- 9. any variation of the conditions above will only occur with my further explicit approval.
- 10. A Copy of the signed ICF is given to me.

This study complies with the Data Privacy Act of 2012. Under the provisions under this act, I have the right to obtain access to, rectify, and where applicable ask for the data concerning me to be erased. This consent form is valid until the end of the study. (Check the following below if you agree:)

I have read the foregoing information. I have ha have been asked to have been answered to my sati I consent voluntarily to be a participant in this stu I consent to be audio and video recorded for this	ıdy.
Print Name of Participant	
Participant's Signature	Date
Researcher's Signature	_ Date

Contact Information

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Principal Investigator: Arianne Diane Aninon, RPh, PharmD in progress

Doctorate of Pharmacy Student, Department of Pharmacy

Faculty of Medicine and Surgery, University of Malta Contact information: 09773842160 /

arianne.aninon.17@um.edu.mt

Principal Supervisor: Prof. Lilian Azzopardi

Department Head, Department of Pharmacy Faculty of Medicine and Surgery, University of Malta Msida Campus, Msida, Malta

Email: lilian.m.azzopardi@um.edu.mt

Co-investigator: Edwin C. Ruamero Jr., RPh, MPH

Assistant Professor, College of Pharmacy, UP Manila College of Pharmacy, University of the Philippines Manila Taft Avenue, cor. Pedro Gil, Ermita, Manila

E-mail: ecruamero1@up.edu.ph

Co-investigator: Cristan C. Agaceta, RPh

Senior Technical Advisor, Management Sciences for Health

Email: ykistan.gmail.com

This proposal has been reviewed and approved by UP Manila Research Ethics Board (UPMREB), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the UPMREB, contact:

Dr. Jacinto Blas Mantaring Address: 2/f Paz Mendoza 547 Pedro Gil St Ermita 1000 Manila

Email: upmreb@post.upm.edu.ph

Tel: +63 2 5222684

Mobile: +639273264910 or +639153080212

Appendix 3.1.2 Consent form for Pharmacist [Filipino Version]

CONSENT FORM PARA SA PARMASYUTIKO

Titulo ng Pananaliksik: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

Mabuhay! Ako po ay si Arianne Diane Aninon, kasalukuyang nag-aaral sa Unibersidad ng Malta, at nag-aaral ng Doctorate ng Pharmacy degree. Bilang parte ng aking programa, nangangailangan akong magsagawa ng isang pananaliksik. Iniimbitahan ko po kayong maging parte ng pag-aaral na ito. Si Propesora Lilian Azzopardi mula sa Unibersidad ng Malta, Assistant Propesor Edwin Ruamero, Jr. mula sa Unibersidad ng Pilipinas at Cristan C. Agaceta, RPh ang kasama sa grupo na nagsasaliksik.

Background

Ang clinical reasoning at decision making ay mga kakayahang hindi naaral at "ineexplore" sa propesyon ng parmasiya kumapara sa ibang propesyong pangkalusugan. Ang pag-aaral ng clinical reasoning at decision making sa aktwal na pagbibigay ng serbisyo sa pasyente ay magbibigay ng daan paano nagproproseso ng impormasyon ang parmasyutiko. Ito ay mahalaga upang mapag-isipan paano dapat ito mas mapabuti at paano dapat ituro lalo na tumataas ang pangangailangan sa clinical role. Ang pag-aaral na ito ay isang *comparative qualitative* ethnomethodologic research na gagamit ng retrospective think aloud technique na may layuning imbestigihan ang patterns ng clinical reasoning at decision-making ng parmasyutiko. Ang metodolohiya ay dalawang proseso: isang obserbasyon sa trabaho at pagkatapos ay panayam na semi-structured. Gusto nating bigyang diin na layunin nating gawan ng mapa ang pag-iisip ng parmasyutiko habang nagbibigay ng serbisyo sa pasyente, at nagdedesisyon sa tamang kagamutang ibibigay. Gusto nating bigyan ng sagot ang "paano", at hindi para hatulan kung tama o mali ang serbisyo.

Pagpili sa parmasyutiko at ang boluntaryong pagsali

Ikaw ay iniimbitahang sumali <u>upang maging isa sa sampung parmasyutiko na kasali</u> sa pagsasaliksik na ito dahil sa iyong karanasan sa pagttrabaho sa botika ng 3 taon at may direktang pag-aalaga sa pasyente. Ikaw ay may potensyal na magbigay ng malaking kontribusyon sa pag-intindi at kaalaman ukol sa clinical reasoning at decision making sa konteksto ng parmasiya sa comunidad. Ang pagsali sa pag-aaaral na ito ay boluntaryo.

Pamamaraan

Sa araw ng pag-oobserba, ang pakikipag-usap sa pasyente na may isa sa 4 na karamdaman: ubo, masakit na kalamnan, sakit ng ulo, o sipon, AT hindi pa bumibisita sa doctor, ay bibidyuhan na may pahintulot ng pasyente. Ang pasyente ay dapat labingwalong taong gulang o mas higit. Ang mukha ng pasyente ay hindi isasama sa recording. Ang interaction ay isasalin sa panunulat (transcription), at paunang susuriin bago ang panayam. Sa araw ng panayam, isa sa mga recording ay ipapalabas, at ang mga katanungan ay base lamang sa "clinical scenario" na iyon. Ang panayam ay irerecord muli upang maisalin sa sulat para masuri.

Tagal ng pamamaraan

Ang obserbasyon ay magaganap sa isa sa iyong work shift sa botika. Sa panahong yan, ako ay sasama upang magrecord at humingi ng pahintulot sa mga pasyente. Walang karagdagang oras ang hihingin mula sa pasyente o sa iyo para tapusin ang isang transaksyon. Tayo ay mag-iiskedyul ng panayam na hindi lalagpas ng isang oras.

Gantimpala sa pagsali

Walang gantimpala sa pagsali sa pagsasaliksik na ito, pero ang resulta ay ibabahagi sa inyo. Walang ibibigay na bayad na pamasahe. Isang simpleng token ng pasasalamat ay ibibigay matapos ang panayam.

Pagiging kompidensyal

Hindi naming ibabahagi ang impormasyon patungkol sa iyo sa labas ng research team. Ang iyong pagkakakilanlan ay hindi ilalabas sa manuscript or pablikasyon. Lahat ng kasali ay bibigyan ng participant code sa pagpproseso at pag-aanalisa ng datos. Lahat ng bidyo at audio recording ay ieencrypt, at ang lahat ng Microsoft office files ay lalagyan ng password. Sa ilalim ng Data Privacy Act ng 2012, lahat ng kasali ay may karapatang makita, baguhin at burahin ang impormasyong may kinalaman sa kanilang sarili.

Karapatang humindi o umatras sa pagsali

Kung nais na hindi magtuloy habang nagkokolekta ng datos, maaring umatras sa pagsali at hindi kailangang magbigay ng paliwanag. Maaring hilingin na burahin ang impormasyon na may kinalaman sa iyo, na walang tanong o parusa.

Ako ay naimbitahang sumali sa pagsasaliksik tungkol sa clinical reasoning at decision-making ng mga parmasyutiko sa komunidad, isang pag-aaral na isinasagawa ng PharmD student ng Departamento ng Parmasiya ng Unibersidad ng Malta. Sa pagpirma sa form na ito, ako ay nagbibigay ng sertipikasyon na ako ay pumapayag sa mga sumusunod:

- 1. na ang mga pasyente kong may acute minor ailment (ubo, sipon, sakt sa kalamnan at sakit ng ulo) na nagbigay ng pahintulot ay ibibidyo
- 2. ang susunod na semi-structured na panayam ay irerecord ang boses
- 3. ang obserbasyon at panayam ay isasalin sa sulat
- 4. ang mga pagsalin sa sulat ay ibibigay sa akin at mayroon akong oportunidad na itama ang unamang pagkakamali
- 5. ang pagsalin sa sulat ay aanalisahin ni Arianne Diane Aninon bilang pangunahing mananaliksik
- 6. ang pagsalin sa sulat ay makikita at magagamit lamang ni Arianne Diane ay ng kanyang research team na kasama nya sa pagsasaliksik
- 7. ang buod ng nilalaman, at direktang sipi mula sa panayam na ilalabas sa pablikasyon at iba pang academic outlets ay hindi bibigyan ng pagkakakilanlan (anonymized), at sisiguraduhing ang ibag impormasyon ay hindi magbibigay daan para makilala ang iyong pagkakakilanlan
- 8. ang bidyo at audio recording ay buburahin pagkatapos, at ang pagkasalin sa sulat ay hindi maglalaman ng personal na pagkakakilanlan ko bilang parmasyutiko at ng aking mga pasyente
- 9. ang paglabag sa lahat ng nakasulat dito ay tahasang paglabag sa aking inaprubahan
- 10. ako ay nabigyan ng kopyang pinirmahang informed consent form

Ang pagsasaliksik na ito ay sumusunod sa Data Privacy Act ng 2012. Ayon sa probisyon ng batas na ito, ikaw ay may karapatang makita, itama, o burahin ang lahat ng may kinalaman sa iyo. Ang pahintulot na ito ay matatapos hanggang matapos ang pag-aaral. (Lagyan ng tsek kung ikaw ay sumasang-ayon:)

Nabasa ko ang lahat ng nakasulat sa dokumentong ito.

Ako ay binigyan ng pagkakataong magtanong at lahat ng katanungan ay nasagot ng buo ayon sa aking pangangailangan. Pinahihintulutan ko ang researcher na bidyuhan ako at ang aking pasyente.

Ako ay sumasali ng boluntaryo sa pag-aaral na ito.

Pangalan ng Parmasyutiko:	_
Pirma ng Parmasyutiko:	Date
Pirma ng Mananaliksik:	Date

Kung kayo po ay may katanunagan, maaring magtanong ngayon o pagkatapos ng pagpunta sa botika. Maaring kontakin ang mga sumusunod:

Principal Investigator: Arianne Diane Aninon, RPh,

PharmD in progress

Doctorate of Pharmacy Student, Department of

Pharmacy

Faculty of Medicine and Surgery, University of Malta

Contact information: 09773842160 / arianne.aninon.17@um.edu.mt

Co-investigator: Edwin C. Ruamero Jr., RPh, MPHAssistant Professor, College of Pharmacy, UP Manila
College of Pharmacy, University of the Philippines

Manila

Taft Avenue, cor. Pedro Gil, Ermita, Manila

E-mail: ecruamero1@up.edu.ph

Co-investigator: Cristan C. Agaceta, RPh

Senior Technical Advisor, Management Sciences for

Health

Email: ykistan.gmail.com

Ang proposal na ito ay sinuri at inaprubahan ng UP Manila Research Ethics Board (UPMREB), ang komite na magsisigurado na ang mga sasali ay protektado mula sa kapahamakan. Kung nais mas makilala ang UPMREB, maaring kontakin ang sumusunod:

Dr. Jacinto Blas Mantaring Address: 2/f Paz Mendoza 547 Pedro Gil St

Ermita 1000 Manila

Email: upmreb@post.upm.edu.ph

Tel: +63 2 5222684

Mobile: +639273264910 or +63915308021

Appendix 3.1.3. Informed Consent for Patient Participants [English Version]

CONSENT FORM FOR PATIENTS/CUSTOMERS IN PHARMACY

Research Title: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

I am Arianne Diane A. Aninon, a second year student at the University of Malta, currently reading for Doctorate of Pharmacy degree. To fulfill the aims of my course, I am required to complete a research-based dissertation. We are asking you to be in a research study. You do not have to be in the study. If you say yes, you can quit the study at any time. Please take as much time as you need to make your choice. Your medical care will NOT change in any way if you say no.

Why are you doing this research study?

We want to learn more about how pharmacists process information that you will provide regarding your minor ailment and decide on the recommendation to be given to you. This study will help us learn more about clinical reasoning and decision making of community pharmacists as they serve you in the pharmacy. We are asking people like you who have cough, muscle pain, headache OR common cold with no prior consultation with a physician to help us.

What happens if I say yes, I want to be in the study? If you say yes, we will:

We will audio-video record your consultation with the pharmacist. We will make sure your face will not be caught in video. Your name or any personal information to identify you will not be recorded and will not be part of the study. We are only interested on the interaction with the pharmacist and how the pharmacist provides the health service that you need.

How long will the study take?

There will be no additional time that will be taken from you in the pharmacy as patient/customer. We intend to record the interaction and service provision as it happens in reality. It can be as short as 5 minutes, or as long as the pharmacist needs to complete your transaction. On the other hand, the duration of the study until completion will be a year.

What happens if I say no, I do not want to be in the study?

No one will treat you differently. You will not be penalized. The care you get from your pharmacist will not change.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. If at any point you decide you would not like to have your consultation recorded, we can delete the video clip. The care you get from your pharmacist will not change.

Who will see my video and my answers?

The only people allowed to see your video will be the principal investigator and the supervising team. Your health information, video recording, transcripts, and a copy of this document will be locked in our files. After the research analysis, we will delete the video. We will not tag your personal identification in our transcripts or your answers into your medical record. When we share the results of the study by publication or presentation in conferences, we will not include your name. We will make sure no one outside the study will know you are a part of the study.

Will being in this study help me in any way?

Being in the study will not help you immediately, but by documenting and explaining the process, we can help community pharmacists reflect on their own practice and identify how they can provide better service with you. We also hope that this may help pharmacy educators with improving how clinical reasoning and decision making is taught to future pharmacists.

Will I be paid for my time?

No. There is no reward or incentive in participating. Your approval will be highly appreciated. You will not be reimbursed for any expenses you have incurred in the pharmacy, including travel expenses. However, a simple snack will be provided after recording.

This study complies with the Data Privacy Act of 2012. Under the provisions under this act, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased. This consent form is valid until the end of the study.

What if I have questions or concerns regarding the study? What if I decided to withdraw my participation after I leave the pharmacy? Please call the head of the study, Arianne Diane at 09773842160.

I am a Filipino citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled: *Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines*. (Check below, if you agree:)

The purpose and details of the study have been explained to me by *Arianne Diane A. Aninon* and any difficulties which I have raised have been adequately clarified.

I give my consent to the Principal Investigator to take a video of my consultation and transaction with the pharmacist and/or to make the applicable observations. I am aware of any inconveniences which this may cause.

I understand that the results of this study in which I am participating may be used for medical or scientific purposes and that the results of this study may be reported/published. However, I shall not be personally identified in any way, either individually or collectively, without my expressing written permission. Under the Data Privacy Act of 2012, I have the right to obtain access to, rectify, and where applicable ask for the data concerning me to be erased.

I am under no obligation to participate in this study and am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. Access to a video recording of my interaction with the pharmacist is limited to the Principal Investigator, academic/clinical study supervisors, and the research team for the study duration, and all data collected will be securely disposed of at end of the study.

Print Name of Participant _		
Participant's Signature	Date	
Researcher's Signature	Date	

Contact Information

If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following:

Co-investigator: Cristan C. Agaceta, RPh

Email: ykistan.gmail.com

Senior Technical Advisor, Management Sciences for Health

Principal Investigator: Arianne Diane Aninon, RPh, PharmD in progress

Doctorate of Pharmacy Student, Department of Pharmacy
Faculty of Medicine and Surgery, University of Malta

Contact information: 09773842160 / arianne.aninon.17@um.edu.mt

Co-investigator: Edwin C. Ruamero Jr., RPh, MPH

Assistant Professor, College of Pharmacy, UP Manila College of Pharmacy, University of the Philippines Manila Taft Avenue, cor. Pedro Gil, Ermita, Manila

E-mail: ecruamero1@up.edu.ph

This proposal has been reviewed and approved by UP Manila Research Ethics Board (UPMREB), which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the UPMREB, contact:

Dr. Jacinto Blas Mantaring Address: 2/f Paz Mendoza 547 Pedro Gil St Ermita 1000 Manila

Email: upmreb@post.upm.edu.ph

Tel: +63 2 5222684

Mobile: +639273264910 or +639153080212

Appendix 3.1.4. Informed Consent for Patient Participants [Filipino Version]

CONSENT FORM PARA SA PASYENTE/CUSTOMER SA BOTIKA

Titulo ng Sinasaliksik: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

Mabuhay! Ako po ay si Arianne Diane Aninon, kasalukuyang nag-aaral sa Unibersidad ng Malta, at nag-aaral ng Doctorate ng Pharmacy degree. Bilang parte ng aking kurso, nangangailangan akong magsagawa ng isang pananaliksik. Iniimbitahan ko po kayong maging parte ng pag-aaral na ito. Kapag kayo po ay sumang-ayon, meron pa rin kayong pagkakataon na bawiin ang inyong pahintulot kahit kailan niyo gustuhin. Ang pagbibigay ng serbisyo ng parmasyutiko ay di magbabago kahit kayo po ay hindi sumali sa pagsasaliksik na ito.

Bakit isinasagawa ang pag-aaral na ito?

Gusto naming alamin kung paano nagproproseso ng impormasyon ang parmasyutiko patungkol sa inyong sakit at nagdedesisyon sa tamang kagamutan na ibibigay sa inyo. Ang pag-aaral na ito ay tutulungan kaming aralin ang "clinical reasoning at decision making" ng parmasyutiko habang kayo ay binibigyan ng serbisyo. Iniimbitahan naming ang pasyenteng katulad mo na mayroong isa sa apat na sakit na ito: ubo, masakit na kalamnan, sakit ng ulo, or sipon, at hindi pa kayo bumibisita sa doctor.

Anong mangyayari kapag ako ay pumayag? Kung ikaw ay pumayag:

Amin pong kukuhaan ng bidyo ang pakikipag-usap nyo sa parmasyutiko. Sisiguraduhin naming na hindi makukuhaan ang inyong mukha, at hindi naman kailangan kuhain ang mga personal na impormasyon na makakapagbigay ng inyong pagkakakilanlan. Kami po ay interesado sa isasagot ng parmasyutiko sa inyong konsultasyon, at kung ano ang pag-aalaga na ibibigay sa inyo.

Gano katagal ang pag-aaral?

Wala pong karagdagang oras ang hihingiin sa inyo bilang pasyente o customer. Gusto po naming makita ang pang-araw araw na paraan na pagbibigay ng serbisyo nang parmasyutiko sa kanyang mga customer na nangyayari sa realidad. Ito ay maaring maging 5 minuto o kahit gano kahabang oras kelangan para matapos ang iyong transaction sa parmasyutiko. Ang buong pag-aaral ay tatakbo ng isang taon.

Paano kung ako ay hindi sumali sa pag-aaral na ito?

Bibigyan pa rin kayo ng serbisyo katulad ng inaasahan ninyo sa kahit saang botika. Walang magbabago at walang pagpaparusa kung kayo po ay hindi sumali.

Paano kung ako ay sumali pero magbago ang aking isip?

Maari pong itigil ang pagbibidyo sa inyo sa kahit anong oras nyo gusto. Maari rin pong burahin ang bidyo kung napagisipan ninyong ayaw nyopala sumali. Ang serbisyo ng parmasyutiko ay hindi magbabago.

Sino ang makakakita ng aking bidyo at nang aking mga sagot?

Ang maaari lang makanood ng inyong bidyo ay ang pangunahing mananaliksik, at ang kanyang kasamahan sa pag-aaral na ito. Ang inyong impormasyong pangkalusugan, bidyo, at pagsasalin sa sulat mula sa recording ay maayos na itatago at hindi basta ipamimigay or i-lalagay sa internet. Kapag kami ay magbabahagi ng resulta ng pag-aaral na ito, walang pangalan ang lalabas. Wala pong makakaalam na kayo ay naging bahagi ng pagsasaliksik na ito.

Ako ba ay matutulungan sa pagsali sa pag-aaral na ito?

Sa ngayon, walang benepisyo ang matatanggap sa pagsali, ngunit kayo po ay makakatulong sa mga parmasyutiko sa komunidad na lalong pag-ibayuhin ang kanilang serbisyo sa pagbibigay nang magandang pag-aalaga. Inaasahan po natin na makakatulong sa ating mga kaguruan pano tamang ituro ang clinical reasoning and decision making sa susunod na henerasyon ng parmasyutiko.

Ako po ba ay babayaran sa pagsali?

Wala pong bayad sa pagsali sa pag-aaral na ito. Ang inyong pagsali ay pinasasalamatan ng buong puso. Hindi babayaran ang kahit anong gastos ninyo, kasama na ang pamasahe. Mayroong simpleng snack na ibibigay pagkatapos ng pagbibidyo. Ang pagsasaliksik na ito ay sumusunod sa Data Privacy Act ng 2012. Ayon sa probisyon ng batas na ito, ikaw ay may karapatang makita, itama, o burahin ang lahat ng may kinalaman sa iyo. Ang pahintulot na ito ay matatapos hanggang matapos ang pag-aaral.

Ako ay Pilipino at nasa labingwalong taong (18) gulang pataas. Ako ay naimbitahan sumali sa pagsasaliksik na may titulong: *Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines*. (Lagyan ng check ang mga sumusunod)

Ang kahalagahan at detalye ng pag-aaral na ito ay pinaliwanag ni Arianne Diane A. Aninon sa akin, at lahat ng katanungan ay nasagot ng buo ayon sa aking pangangailangan.

Binibigay ko ang pahintulot sa pangunahing mananaliksik na kuhaan ng bidyo ang konsultasyon at transaction ko sa parmasyutiko/a at mag-obserba sa amin. Alam at naiintindihan ko ang abala na maaring isanhi ng pag-aaral na ito sa akin.

Naiintindihan ko rin na ang resulta ng pagsali sa pag-aaral na ito ay gagamitin sa medical o siyentipikong kadahilanan at maaring ibahagi at maipublish ang resulta nito. Subalit hindi ilalabas ang kahit anong personal na pagkakakilanlan sa akin, lalo na kung walang pahintulot. Ayon sa Data Privacy Act ng 2012, ako ay may karapatang makita, baguhin, at kung kinakailangan burahin ang lahat ng may kinalaman sa akin.

Ako ay sumasali ng boluntaryo at hindi ako inobliga na sumali. Ako ay maaring umatras sa pagsali kahit kailan, kahit hindi magbigay ng rason. Ang paggamit ng bidyo na kinuhaan sa pakikipag-usap ko sa parmasyutiko ay limitado sa pangunahing mananaliksik at ang kanyang kasamahan sa pag-aaral na ito. Lahat ng datos ay maingat na buburahin pagkatapos ng pag-aaral.

Pangalan ng Pasyente/Customer:		
Pirma ng Pasyente/Customer:	Date	
Pirma ng mananaliksik:	Date	
Kung kayo po ay may katanunagan, maaring	g magtanong ngayon o pagkatapos ng	g pagpunta sa botika. Maaring kontakin
ang mga sumusunod:		

Principal Investigator: Arianne Diane Aninon, RPh, PharmD in progress

Doctorate of Pharmacy Student, Department of Pharmacy Faculty of Medicine and Surgery, University of Malta

Contact information: 09773842160 / arianne.aninon.17@um.edu.mt

Co-investigator: Edwin C. Ruamero Jr., RPh, MPHAssistant Professor, College of Pharmacy, UP

Manila College of Pharmacy, University of the Philippines

Taft Avenue, cor. Pedro Gil, Ermita, Manila

E-mail: ecruamero1@up.edu.ph

Manila

Co-investigator: Cristan C. Agaceta, RPh

Senior Technical Advisor, Management Sciences for Health

Email: ykistan.gmail.com

Ang proposal na ito ay sinuri at inaprubahan ng UP Manila Research Ethics Board (UPMREB), ang komite na magsisigurado na ang mga sasali ay protektado mula sa kapahamakan. Kung nais mas makilala ang UPMREB, maaring kontakin ang sumusunod:

Dr. Jacinto Blas Mantaring Address: 2/f Paz Mendoza 547 Pedro Gil St Ermita 1000 Manila

Email: upmreb@post.upm.edu.ph

Tel: +63 2 5222684

Mobile: +639273264910 or +63915308021

Appendix 3.2.1. Information Sheet and Informed Consent for Pharmacists in Malta

Pharmacist Participant Information Sheet

I am Arianne Diane A. Aninon, a second year student at the University of Malta, currently reading for Doctorate of Pharmacy degree. To fulfil the aims of my course, I am required to complete a research-based dissertation. The research topic I have chosen is entitled, "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines".

Background

Clinical reasoning and decision-making are critical competency areas that are much less explored in pharmacy compared to other health professions. Learning clinical reasoning and decision making in the actual patient care setting will allow us to understand the processes involved in performing such cognitive activities and will provide insight on how knowledge should be constructed to pharmacists or pharmacy students especially those who are expected to fulfil a more clinical role in the community. This study is a comparative qualitative ethnomethodologic research that will particularly utilize a retrospective think aloud technique to examine the patterns of clinical reasoning and decision making processes. The methodology mainly consists of observation (with recording) of interaction with patients and subsequently, a semi-structured interview to talk about one clinical scenarios encountered. We would like to stress that our goal is to map out the cognitive processes that happens as you interact with the patient, provide intervention, and make clinical decisions. There will be no assessment or judgment of whether your practice was right or wrong.

Participant Selection and Voluntary Participation

You are being invited to take part in this research because your experience as a community pharmacist (cumulative community pharmacy experience of at least 3 years) can contribute much to our understanding and knowledge of clinical reasoning and decision making among community pharmacists. Your participation in this research is entirely voluntary.

Procedures

On the day of the observation, interactions with patients presenting presenting either headache, cough, muscle pain, or common colds will be audio-video recorded. The consent of patient/s (at least 18yrs) will be obtained. The face of the patient will not be captured in the video. The interaction will be transcribed, and will be preliminary analyzed. The second part of the research is a semi-structured interview. Transcription will be sent for your approval, and list of questions will be sent prior to the interview. During the interview, one of your recorded clips will be shown to you, which shall be the context of the questions to be asked. The semi-structured interview shall also be audio recorded for transcription.

Duration

The research takes place over in one of your work shifts (on the schedule of your preference) in the community pharmacy. During that time, I will be in the pharmacy to install a recorder and seek patient consent for recording the interaction. There will be no additional time required of patients nor of you during the observation. A follow-up interview will be requested on your preferred time to talk about one of the clinical scenarios, which had been preanalyzed prior to the interview. The follow-up interview shall not be more than an hour.

Risks and Benefits

If you feel that the recorded interaction should not be part of the analysis, for whatever reason you think is important, you can say immediately and the clip will be deleted. There will be no direct benefit to you, but your participation will help us how to construct and teach clinical reasoning and decision making in the pharmacy curriculum both for Philippines and Malta. There will be no remuneration from participating in this research, but findings of this research will be shared with you.

Confidentiality and GDPR

We will not be sharing information about you to anyone outside of the research team. Your identity will not be revealed in any manuscript or publication later on. Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of the said Regulation, participants have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased.

Consent form for the Pharmacist

Research Title: "Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines"

I have been invited to participate in research about the clinical reasoning and decision-making of community pharmacists, a study being conducted by a PharmD student at the Department of Pharmacy, University of Malta. By signing this form, I certify that I approve the following:

- 11. patients (who gave their consent to participate) presenting one of the identified acute conditions with the pharmacist in the pharmacy will be audio-video recorded
- 12. the follow-up semi-structured interview will be audio recorded
- 13. transcripts in both cases (observation and interview) will be produced
- 14. transcripts will be sent to me and I will be given the opportunity to correct any factual errors
- 15. the transcript will be analysed by Arianne Diane Aninon as the research investigator
- 16. transcript will be limited to Arianne Diane Aninon and academic colleagues and researchers whom she might collaborate as part of the research process
- 17. any summary interview content, or direct quotations from the interview, that are made available through academic publication or other academic outlets will be anonymized so that I cannot be identified, and care will be taken to ensure that other information in the interview that could identify yourself is not revealed
- 18. the actual recording will be destroyed and transcripts will not contain personal identification of myself and of my patient
- 19. any variation of the conditions above will only occur with my further explicit approval.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of the said Regulation, I have the right to obtain access to, rectify, and where applicable ask for the data concerning me to be erased.

I have read the foregoing information. I have had the opportunity to ask questions about it and any questions				
have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study.				
				
Date				

Contact Information

This research has been reviewed and approved by the University Research and Ethics Committee of the University of Malta. If you have any further questions or concerns about this study, please contact:

Name of researcher: Arianne Diane Aninon

Mobile: 99682809

E-mail: arianne.aninon.17@um.edu.mt

Principal Supervisor: Prof. Lilian Azzopardi Email: <u>lilian.m.azzopardi@um.edu.mt</u>

Appendix 3.2.2. Information Sheet and Informed Consent for Patients in Malta [English Language]

PATIENT INFORMATION SHEET

Study Title: Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines

I am Arianne Diane A. Aninon, a second year student at the University of Malta, currently reading for Doctorate of Pharmacy degree. To fulfill the aims of my course, I am required to complete a research-based dissertation. We are asking you to be in a research study. You do not have to be in the study. If you say yes, you can quit the study at any time. Please take as much time as you need to make your choice. Your medical care will NOT change in any way if you say no.

Why are you doing this research study?

We want to learn more about how pharmacists process information that you will provide regarding your minor ailment and decide on the recommendation to be given to you. This study will help us learn more about clinical reasoning and decision making of community pharmacists as they serve you in the pharmacy. We are asking people like you who have cough, muscle pain, headache OR common cold with no prior consultation with a physician to help us.

What happens if I say yes, I want to be in the study? If you say yes, we will:

We will audio-video record your consultation with the pharmacist. We will make sure your face will not be caught in video. Your name or any personal information to identify you will not be recorded and will not be part of the study. We are only interested on the interaction with the pharmacist and how the pharmacist provides the health service that you need.

How long will the study take?

There will be no additional time that will be taken from you. We intend to record the interaction and service provision as it happens in reality.

What happens if I say no, I do not want to be in the study?

No one will treat you differently. You will not be penalized. The care you get from your pharmacist will not change.

What happens if I say yes, but change my mind later?

You can stop being in the study at any time. You will not be penalized. If at any point you decide you would not like to have your consultation recorded, we can delete the video clip. The care you get from your pharmacist will not change.

Who will see my video and my answers?

The only people allowed to see your video will be the principal investigator and the supervising team. Your health information, video recording, transcripts, and a copy of this document will be locked in our files. After the research analysis, we will delete the video. We will not tag your personal identification in our transcripts or your answers into your medical record. When we share the results of the study by publication or presentation in conferences, we will not include your name. We will make sure no one outside the study will know you are a part of the study.

Will being in this study help me in any way?

Being in the study will not help you immediately, but by documenting and explaining the process, we can help community pharmacists reflect on their own practice and identify how they can provide better service with you. We also hope that this may help pharmacy educators with improving how clinical reasoning and decision making is taught to future pharmacists.

Will I be paid for my time?

No. There is no reward or incentive in participating. Your approval will be highly appreciated.

Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of the said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning you to be erased.

What if I have questions or concerns regarding the study? What if I decided to withdraw my participation after I leave the pharmacy? Please call the head of the study, Arianne Diane at 99682809.

Appendix 3.2.3 Information Sheet for Patients in Malta [Maltese Language]

INFORMAZZJONI GHAL TAL-PAZJENT

Titlu tal-Istudju: Analiżi komparattiva tar-raġunament kliniku u t-teħid ta' deċiżjonijiet tal-ispiżjara tal-komunità wagt li jingħataw f'Malta u fil-Filippini

Jiena Arianne Diane A. Aninon, studenta tat-tieni sena fl-Università ta' Malta, bħalissa qeda fit-tieni sena' tad-Dottorat tal-Farmaċija. Biex nilħaq l-għanijiet tal-kors tiegħi, jiena meħtieġa li nlesti dissertazzjoni bbażata fuq irriċerka. Aħna qed nitolbuk biex tkun fi studju ta' riċerka. M'hemmx għalfejn tkun fl-istudju. Jekk tgħid iva, tista' tieqaf mill-istudju kwalunkwe ħin. Jekk jogħġbok ħu il-ħin tiegħek biex tagħmel l-għażla tiegħek. Il-kura medika tiegħek MHUX se tinbidel bl-ebda mod jekk tgħid le.

Għaliex qed tagħmel dan l-istudju ta' riċerka?

Aħna rridu nitgħallmu aktar dwar kif l-ispiżjara jipprocessaw informazzjoni li inti ser tipprovdi dwar is-sintomi tiegħek u niddeciedu dwar ir-rakkomandazzjoni li għandha tingħata lilek. Dan l-istudju ser jgħinna nitgħallmu aktar dwar ir-raġunament kliniku u t-teħid tad-decizjonijiet tal-ispizjara fil-komunità waqt li jservuk fil-farmacija. Qed nitolbu l-għajnuna ta' nies bħalek li għandhom sogħla, uġigħ fil-muskoli, uġigħ ta' ras JEW riħ komuni u li għadhom ma marrux għand it-tabib.

X'jigri jekk ngħid iva, irrid inkun fl-istudju? Jekk tgħid iva, aħna:

Ħa nirrekordjaw il-konsultazzjoni tiegħek mal-ispiżjar b'mezz ta' awdjo-vidjo. Aħna se niżguraw li wiċċek ma jinqabadx fil-vidjow. Ismek jew kwalunkwe informazzjoni personali biex tidentifikak mhux se jiġu irreġistrati u mhux se jkunu parti mill-istudju. Aħna interessati biss fuq l-interazzjoni tiegħek mal-ispiżjar u kif hu / hi jipprovdi s-servizz tas-saħħa li għandek bżonn.

Kemm se jdum l-istudju?

Mhux se jkun hemm ħin addizzjonali biex tieħu sehem fl-istudju. Aħna beħsiebna nirrekordjaw l-interazzjoni u s-servizz li jingħatalek.

X'jiġri jekk ngħid le, ma rridx nkun fl-istudju?

M'intix ser tigi penalizzat. Il-kura li tingħata mill-ispizjar tiegħek mhux se tinbidel.

X'jiqri jekk ngħid iva, imma nibdel l-opinjoni tiegħi aktar tard?

Tista' tieqaf milli tkun fl-istudju fi kwalunkwe ħin. M'intix ser tiġi penalizzat. Jekk fi kwalunkwe punt tiddeċiedi li ma tkunx tixtieq li tirreġistra l-konsultazzjoni tiegħek, nistgħu nħassru l-'video clip'. Il-kura li tingħata mill-ispiżjar tiegħek mhux se tinbidel.

Min se jara l-vidjow tiegħi u t-tweġibiet tiegħi?

L-unići nies li se jithallew jaraw il-vidjow tieghek se jkunu n-nies li jahdmu fuq l-istudju. L-informazzjoni dwar is-sahha tieghek, ir-reģistrazzjoni tal-vidjow, it-traskrizzjonijiet, u kopja ta' dan id-dokument se jigu msakkra fil-fajls taghna. Wara l-analiżi tar-rićerka, ahna nhassru l-vidjow. Ahna mhux se nxandru l-identifikazzjoni personali tieghek fit-traskrizzjonijiet taghna jew fit-twegibiet tieghek fir-rekord mediku tieghek. Meta naqsmu r-riżultati tal-istudju bil-pubblikazzjoni jew bil-preżentazzjoni f'konferenzi, ahna mhux se ninkludu ismek. Ahna se niżguraw li hadd barra mill-istudju ma jkun jaf li inti parti mill-istudju.

Il-partecipazzjoni tieghi f'dan l-istudju ghinni b'xi mod?

Il-partećipazzjoni tieghek fl-istudju mhux ser jghinek immedjatament, imma billi niddokumentaw u nispjegaw il-pročess, nistghu nghinu lill-ispiżjara tal-komunità jirriflettu fuq il-prattika taghhom stess u nidentifikaw kif jistghu jipprovdu servizz ahjar lilek. Nisperaw ukoll li dan jista' jghin lill-edukaturi tal-farmacija jtejbu ir-ragunament kliniku u t-tehid tad-deciżjonijiet li huma mghallma lill-ispiżjara futuri.

Inkun imħallas għall-ħin tiegħi?

Le. M'hemm l-ebda premju jew incentiv għall-partecipazzjoni tiegħek. L-approvazzjoni tiegħek ser tkun apprezzata ħafna.

Taħt ir-Regolament Ġenerali dwar il-Protezzjoni tad-Data (GDPR) u l-leģislazzjoni nazzjonali li timplimenta u tispeċifika aktar id-dispożizzjonijiet relevanti ta 'limsemmi Regolament, għandek id-dritt li tikseb aċċess għal, tikkoreġi, u fejn applikabbli titlob li d-data li tikkonċerna lilek titħassar.

X'jiġri jekk għandi mistoqsijiet jew tħassib rigward l-istudju? X'jiġri jekk iddeċidejt li nirtira l-parteċipazzjoni tiegħi wara li nħalli l-ispiżerija? Jekk jogħġbok ċempel lill-kap ta' l-istudju, Arianne Diane f' 99682809.

Appendix 3.2.4 Consent Form for Patients [English Language]

I am a Maltese citizen and I am over eighteen (18) years of age. I have been asked to participate in a research study entitled: Comparative analysis of clinical reasoning and decision-making of community pharmacists during dispensing in Malta and the Philippines.

The purpose and details of the study have been explained to me by <u>Arianne Diane A. Aninon</u> and any difficulties which I have raised have been adequately clarified. I give my consent to the Principal Investigator to take the required samples and/or to make the applicable observations. I am aware of any inconveniences which this may cause.

I understand that the results of this study in which I am participating may be used for medical or scientific purposes and that the results of this study may be reported/published. However, I shall not be personally identified in any way, either individually or collectively, without my expressing written permission. Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of the said Regulation, I have the right to obtain access to, rectify, and where applicable ask for the data concerning me to be erased.

I am under no obligation to participate in this study and am doing so voluntarily. I may withdraw from the study at any time, without giving any reason. Access to a video recording of my interaction with the pharmacist is limited to the Principal Investigator, academic/clinical study supervisors, and the medical team for the study duration, and all data collected will be securely disposed of at end of the study.

<u>I am not</u> receiving any remuneration for participating in this study. In case of queries during the study I may contact Arianne Diane Aninon at 99682809.

Signature of participant	
Name of participant	
Signature of Principal Investigator	
Name of Principal Investigator	
Email of Principal Investigator	
Contact number of Principal Investigator	
Name of Principal Supervisor	
Email of Principal Supervisor	
Contact number of Principal Supervisor	
Date	

Appendix 3.2.5 Consent Form for Patients [Maltese Language]

PROPOSTA GHALL-FORMULA TAL-KUNSENS

Jien/a cittadin/a Maiti/ja u gnaiaqt tmintax-ii sena.		
Talbuni biex nieħu sehem fi studju ta' riċerka bl-isem ta':		
L-għanijiet u d-dettalji tal-istudju spejga(t)homli <i>Arian</i> għamilt.	<i>ne Diane A. Aninon</i> li wkoll iċċara(t)li xi mistoqsijiet li	
Nagħti l-kunsens tiegħi lill-persuna responsabbli għal osservazjonijiet li hemm bżonn u nifhem li dan jista' jkun	din ir-riċerka biex j(t)ieħu l-kampjuni u/jew j(t)agħmel l- ta' skomdu għalija.	
hekk jiena b'ebda mod ma nista' nkun identifikat/a, indiv tieghi bil-miktub. Taħt ir-Regolament Ġenerali dwar il-	w għal skopijiet xjentifiċi u jistgħu jiġu ppubblikati; jekk isir idwalment jew bħala parti minn grupp, mingħajr il-kunsens Protezzjoni tad-Data (GDPR) u l-leġislazzjoni nazzjonali li vanti ta 'limsemmi Regolament, għandek id-dritt li tikseb tikkonċerna lilek titħassar.	
Jiena m'għandi l-ebda dmir li nieħu sehem f'dan l-istud meta rrid ma nkomplix nieħu sehem f'dan l-istudju ming	iu u dan qiegħed/qiegħda nagħmlu minn rajja. Jiena nista' najr ma' nagħti raġuni.	
L-aċċess għal reġistrazzjoni tal-vidjow tal-interazzjoni tie superviżuri tal-istudju akkademiku / kliniku, u l-istudju - i mormija sewwa fl-aħħar tal-perjodu tal-aħħar studju.	għi mal-ispiżjar huwa limitat għall-investigatur prinċipali, is- t-tim mediku għar-riflessjoni, u se jinġabar għal dejta	
Jiena mhux qed nithallas biex niehu sehem f'dan l-istudju Arianne Diane Aninon f'99682809.	ı. Fil-każ ta 'mistoqsijiet matul l-istudju nista' nikkuntattja lil	
Firma tal-partecipant		
Isem tal-partecipant		
Firma tal-persuna responsabbli għal din ir-riċerka		
Isem tal-persuna responsabbli għal din ir-riċerka		
Email tal-persuna responsabbli għal din ir-riċerka		
Numru tal-mowbajl tal-persuna responsabbli għal din ir-	riċerka	
Isem tas-superviżur principali		
Email tas-superviżur principali		
Numru tat-telefon tas-superviżur principali		
Data		

Appendix 4. Dissemination Results

Oral Presentation

Aninon AD & Azzoprardi LM. Clinical reasoning of community pharmacist when responding to minor ailments (*Accepted for oral presentation at FIP World Congress Seville 2021*).

Poster Presentation

Aninon AD, Azzoprardi LM, Gauci M, Agaceta CC, Ruamero Jr., E. Clinical reasoning of community pharmacists for self-care recommendations. (Submitted for poster presentation at ASHP Midyear 2020 Clinical Meeting and Exhibition)

Appendix 4.1 Abstract for 80th FIP World Congress



Pharmaceutical practice: Community pharmacy

FIPSUB-1847 /

Clinical reasoning of community pharmacists when responding to minor ailments

Arianne Diane A. Aninon* 1, Lilian Azzopardi1

¹Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

My preferred method of presentation is: Oral Presentation

Please fill in the presenting author's organization: Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta

Background: Pharmacist's clinical reasoning and decision-making are critical competency areas that should be investigated due to the increasing clinical involvement of the profession.

Purpose: To investigate and compare clinical reasoning process adopted by community pharmacists in Philippines and Malta when dealing with patients presenting with acute minor ailment concerns.

Methods: Community pharmacists in The Philippines (10) and in Malta (5) were observed as they interacted with patients presenting acute minor ailments in the community pharmacy setting. This was followed by a semi-structured interview with the community pharmacist. All verbal reports were audio/video recorded, transcribed and analyzed using protocol analysis.

Results: During the observation, 30 and 16 cases of responding to minor ailments were observed in The Philippines and in Malta, respectively. Patient requests were classified into two: seeking specific medicine (n=33) or advice (n=13.) respectively. Five predominant cognitive strategies when conducting clinical reasoning were identified: collect, assume, infer, act, and explain. When patients seek specific medicines, the pharmacists conducted reasoning only in 29% (Philippines) and 63% (Malta) of the cases, mostly through if/then and hypothetico-deductive approach, respectively. When patients sought for advice, pharmacists reasoned 100% of the time in which Filipino pharmacists utilized if/then approach (83%), whereas Maltese pharmacists tend to assess and decide medications by forward-chaining (50%). Conclusion: Pharmacist's clinical reasoning approach mostly followed the analytical decision making, which critically varied according to patient's request at the onset of the interaction.

References: Croft H, Gilligan C, Rasiah R, Levett-Jones T, Schneider J. Thinking in Pharmacy Practice: A Study of Community Pharmacists' Clinical Reasoning in Medication Supply Using the Think-Aloud Method. Pharmacy. 2017;6(1):10.

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Nusair MB, Cor MK, Roberts MR, Guirguis LM. Community pharmacists' clinical reasoning: a protocol analysis. *Int J Clin Pharm*, 2019;41:1471-1482.

Rutter PM & Harrison T. Differential diagnosis in pharmacy practice: Time to adopt clinical reasoning and decision making. Res Soc Admin Pharm. 2020. doi: doi.org/10.1016/j.sapharm.2020.02.020

Abstract 4.2 Abstract for 2020 ASHP Clinical Meeting

Poster Title: Clinical reasoning of community pharmacists for self-care recommendations

Poster Type: Descriptive Report

Submission Category: Professionalism and Career Development

Primary Author: Arianne Diane Aninon, University of Malta; Email:

arianne.aninon.17@um.edu.mt

Additional author:

Prof Lilian M. Azzopardi

Purpose: Pharmacist's clinical reasoning and decision-making are critical competency areas that should be investigated due to the increasing clinical involvement of pharmacists in the healthcare team. The aim of this study was to investigate and compare clinical reasoning process adopted by community pharmacists in two countries in Europe and Southeast Asia when responding to patient requests regarding acute minor ailments.

Methods: A comparative qualitative ethnomethodology study was conducted using a retrospective think aloud technique to examine the patterns of clinical reasoning and decision making processes between community pharmacists. Community pharmacists with at least 3-year work experience were observed in the workplace for an entire shift, and were subsequently interviewed. Interactions with adult patients concerning minor ailments, namely, headache, cold and flu, muscle pain, and cough, were documented. All verbal reports were audio/video recorded, transcribed and analyzed using protocol analysis. This study was approved by the relevant Ethics Boards.

Results: Fifteen community pharmacists were recruited to participate in the study and during the observation 46 cases of responding to minor ailments were observed. Patient requests were classified into two: seeking specific medicine (n=33) or advice (n=13.) respectively. Pharmacists integrate objective and context-related knowledge as cues to generate clinical

action. Five predominant cognitive strategies during clinical reasoning were identified: collect, assume, infer, act, and explain. When patients seek specific non-prescription medicines for acute minor ailments, the pharmacists conducted reasoning only in 29% (Southeast Asia) and 63% (Europe) of the cases, mostly through if/then and hypothetico-deductive approach, respectively. When patients sought for advice on the ailment, pharmacists reasoned 100% of the time in which Southeast Asia pharmacists utilized if/then approach (83%), whereas pharmacists practicing in Europe tend to assess and decide medications by forward-chaining (50%). Inconsistency was observed significantly among the Southest Asia practice suggesting that based on Miller's clinical skills hierarchy, they may have the knowledge at cognition level, but cannot demonstrate or perform the skill in actual patient care settings.

Conclusion: Pharmacist's clinical reasoning approach mostly followed the analytical decision making, which critically varied according to patient's request at the onset of the interaction. The results of this study highlights how pharmacists arrive at clinical decisions to treat minor ailments.