# Educational contents for a patient-centred undergraduate pharmacy curriculum

Ines Nunes-da-Cunha

Fernando Fernandez-Llimos

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Nunes-da-Cunha I, Fernandez-Llimos F. Educational contents for a patient-centred undergraduate pharmacy curriculum. Lisbon: CIPF; 2017

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ISBN: 978-989-20-7578-5

Published by: CIPF

English edited by American Journal Experts, LLC (Durham, NC, USA)

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The edition of this book is supported by national funds through the FCT, The Portuguese Foundation for Science and Technology, within the project UID/DTP/04138/2013.

A edição deste livro é financiada por fundos nacionais através da FCT – Fundação para a Ciência e a Tecnologia, I.P., no âmbito do projeto UID/DTP/04138/2013

Pharmacy education has a responsibility of preparing not only for the present but also for the future, even innovating for the future and guiding the course of the profession.

Alan Brands, 1969

Minutes of the Interim Meeting. Am J Pharm Educ 1969;33:298

## **Foreword**

The focus of the pharmacy profession has shifted from products to a patient-centred practice. Worldwide pharmacy education has attempted to adapt to this change in the profession. In countries such as Australia, Canada, New Zealand, and the United States, curriculum changes are focused on clinical models, allowing pharmacy graduates to become more competent professionals in patient-centred care. This shift could be why these countries have been more successful in the implementation of pharmaceutical services, some of which are reimbursed. In Europe, with the Bologna Declaration and the creation of the European Higher Education Area, there was an attempt to change the pharmacy curriculum. However, an analysis of European undergraduate pharmacy curricula indicates that such curricula continue to include a heavy load of basic sciences, but few courses have educational contents that prepare students for a patient-centred practice.

This work's primary objective is to create a catalogue of educational contents for the undergraduate pharmacy curriculum that focuses on preparing students for a patient-centred practice. This catalogue was not intended to be a catalogue of courses but instead a compilation of contents taught in countries that have widely implemented pharmaceutical services.

The catalogue of educational contents was created through a qualitative analysis of syllabi from schools of pharmacy in Australia, Canada, New Zealand and the United States. The line-up of categories and educational contents did not have a hierarchical order of importance, and the authors are open to collaborative work to further develop the catalogue.

This catalogue of educational contents can assist in the creation of a pharmacy curriculum that prepares students for a more patient-centred practice. Therefore, it is necessary to rigorously align the competencies to be achieved and the corresponding contents to be taught. The relationship between competencies and educational contents must be bi-directional, i.e., the need to achieve new competencies generates

new contents, and the emergence of new contents can lead to the acquisition of new competencies.

The authors

# Table of contents

Foreword	V
Table of contents	.vii
1. Background	1
1.1 Evolution of the profession and pharmacy education	1
1.1.1 Context	1
1.1.2 The role of the pharmacist and pharmacy practice	2
1.2 Changes in pharmacy education	3
1.2.1 Pharmacy studies in the United States	3
1.2.2 Pharmacy studies in Europe	5
1.2.2.1 The Bologna Process: creation of the European Higher Education Area	5
1.2.2.2 Training for pharmacists	6
1.2.3 Pharmacy studies in other countries	7
1.3 The pharmacy curricula	9
1.3.1 The importance of the curriculum	9
1.3.2 Designing a curriculum and syllabus	9
1.3.3 Structure of the pharmacy curriculum	12
1.3.4 Creating competency frameworks for pharmacy	14
1.3.5 Use and misuse of competencies	17
2. Creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum	21
2.1 Method for creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum	21
2.1.1 Location of educational contents	22
2.1.1.1 Selection of the countries and schools of pharmacy	22
2.1.1.2 Selection of the courses	22
2.1.2 Data extraction	23
2.1.3 Analysis of the programme content	23
2.1.4 Quality assessment of the coding	24
3. Findings	25
3.1 Creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum	25
3.2 Quality assessment of the process	29
4. Recommendations	31

Glossary	33
References	37
Appendix	45

# 1. Background

### 1.1 Evolution of the profession and pharmacy education

### **1.1.1** Context

In 1993, the second meeting of the World Health Organization (WHO) on the pharmacist's roles in the healthcare system highlighted the importance of the more active participation of pharmacists in evaluating not only the results of taking medicine but also other aspects related to healthcare. In 2001, the resolution of the Committee of Ministers of the Council of Europe also stressed the need for pharmacist involvement in evaluating the results achieved through the use of medicines. Since then, and with the rise of the concept of pharmaceutical care, pharmacists have made an increasing commitment to improve patient health by achieving concrete pharmacotherapy results. Thus, in the late twentieth century, the global pharmacy profession shifted from a product-oriented to a patient-centred practice. With these changes in the profession, pharmacy education has also attempted to adapt to this new reality.

Schools of pharmacy, guided by World Health Organization recommendations, have taken steps to provide students with the necessary education and training to qualify them for the responsibility of this new role. WHO recommended an appropriate balance of the curricular components of basic sciences, pharmaceutical sciences, biomedical and clinical sciences, socioeconomic and behavioural sciences with practical experience. It also recommended the introduction of courses related to the implementation of patient-centred care (e.g. communication skills). In addition to these curricular changes, teaching methodology has become more oriented towards problem solving and practice issues, and a continuous review of undergraduate curriculum outcomes, content and process is essential to ensure their consistency with the profession's needs. Additionally, the International Pharmaceutical Federation (FIP) supports the improvement of pharmacy education to emphasize both clinical education and patient-centred care curricula. 6

### 1.1.2 The role of the pharmacist and pharmacy practice

In 1997, WHO "agreed that contemporary and future pharmacists must possess specific knowledge, attitudes, skills and behaviours in support of their roles". To summarize these roles, the concept of a "seven-star pharmacist" was created. Each star corresponds to a function: caregiver, decision-maker, communicator, leader, manager, lifelong-learner, and teacher. The pharmacist's function as a researcher was added later. 8

As a caregiver, the pharmacist should integrate the healthcare team responsible for patient care. The pharmacist plays an important role in this respect, adapting the team's knowledge, skills and attitudes to provide high-quality pharmaceutical services.<sup>7</sup>

In the nineties, WHO recognized the evolution of pharmacy practice by promoting the concept of "pharmaceutical care," which it states provides optimum therapeutic results in the use of medication through the active participation of the pharmacist as a member of the healthcare team.<sup>1</sup>

Pharmaceutical care represents an extensive concept that involves the "active participation of the pharmacist in the assistance of the patient through the dispensing and monitoring of pharmacological treatment in co-operation with doctors and other healthcare staff, in order to achieve results that improve the patients' quality of life". This concept also includes involvement in activities that promote good health and prevent disease.<sup>9</sup>

Currently, the scope of pharmacy practice covers all activities that are carried out by the pharmacist and directed to the patient with the aim of improving the drug-use process and minimizing the negative outcomes associated with medication. Dispensing prescriptions, advising on symptoms and self-care related to common ailments, managing drug therapy, counselling and patient education, pharmacovigilance, etc. are some examples of pharmaceutical services that contribute to the rational and economic use of medicine.<sup>8, 10</sup>

With the evolution of the pharmacy profession, new clinical pharmacy services were created. Australia, Canada, the United States, the United Kingdom and New Zealand are examples of countries in which services not only have been implemented but also (in some cases) have begun to be reimbursed by healthcare systems or insurance. However, the successful implementation of pharmaceutical services was not significant in other countries. For years, the barriers to the implementation of services in different settings have been studied. In these studies, the perceived barriers include not only the usual lack of time, payment and institutional support but also the lack of clinical pharmacist education and training. Surprisingly, these barriers appeared to be common to developed and developing countries for different pharmaceutical services. <sup>11-14</sup> One recent study of barriers has been clear in its conclusions: the main barrier to the implementation of clinical pharmacy services is the pharmacist's mind-set. The truth is that discussing clinical training and discussing mentality are two sides of the same coin. <sup>15</sup>

It appears obvious that pharmacy education must be in line with pharmacy-training needs to prepare professionals for clinical practices that involve these new services.

### 1.2 Changes in pharmacy education

Worldwide, pharmacy education has seen changes associated with the evolution of the pharmacy profession. Australia, Canada, the United States and New Zealand lead the list of countries that have adapted their curricula to accommodate such changes in the pharmacy profession as it moves towards clinical and patient-centred care. The need to educate students in direct patient care has been discussed. Efforts to improve the pharmacy curriculum have focused on areas such as clinical pharmacy or social, administrative and behavioural pharmacy. 20-22

### 1.2.1 Pharmacy studies in the United States

In the United States (US), organizations such as the American Pharmacists Association (APhA), the American Association of Colleges of Pharmacy (AACP), and the Accreditation Council for Pharmacy Education (ACPE) have defined the skills and outcomes that enabled the provision of optimal pharmaceutical care and adopted principles, skills and standards for teaching this new practice of pharmacy.

The main change in pharmaceutical education was marked by the creation of the doctor of pharmacy (Pharm.D.) degree as the sole degree required to enter practice. 23,24 The ACPE, the agency for the accreditation and quality of professional degree programmes in pharmacy, adopted the first accreditation standards and guidelines for the professional programme in pharmacy in 1997. Since then, the standards that lead to the doctor of pharmacy degree have been refined and adapted to ensure that pharmacy graduates are prepared to satisfy patient-centred practice requirements in collaboration with other healthcare professionals. 25-27 Colleges and schools of pharmacy initiated the implementation of the Pharm.D. in the 2000/2001 academic year, and the transition was completed in the 2004/2005 academic year.<sup>26</sup> To meet the needs of patient-centred care, colleges changed their Pharm.D. curriculum based on the ACPE standards. The ACPE requires a minimum of 2 academic years or the equivalent college-level course work prior to admission into a Pharm.D. programme (4 academic years). 26 Pre-professional education was to be the foundation of the professional programme by providing basic sciences, liberal and general education and a general view of pharmacy as a health sciences profession.<sup>28</sup> In the professional program, the curriculum was established to include an appropriate balance of biomedical, pharmaceutical, social/behavioural/administrative, and clinical sciences, all of which are essential to pharmacists' development. Furthermore, pharmacy experience must be integrated into the curriculum to ensure that the students have opportunities to engage in patient-centred care activities in various settings. The training period is in the 4<sup>th</sup> year of the Pharm.D. programme and takes place through a series of "advanced pharmacy practice experiences" (APPE) in different settings. The duration of the APPE must be at least 1440 hours (i.e., 36 weeks) and should primarily involve direct patient care. The required APPE must include primary, acute, chronic, and preventive care among patients of all ages and develop pharmacist-delivered patient care competencies in a community pharmacy, hospital or health-system pharmacy, ambulatory care and inpatient/acute care general medicine. In addition, the student is allowed to choose different elective experiences based on his or her individual interests, such as research, management, drug information, education, managed care, long-term care, hospice care, and home healthcare. Beyond the APPE, students must have at least 300 hours of "introductory

pharmacy practice experiences" (IPPE). The IPPE introduces students to the profession and allows them to assume direct patient care responsibilities under proper supervision. The time spent in these experiences should be balanced between community pharmacy and institutional health-system settings.<sup>26, 29</sup>

This curriculum reform decreased the number of courses related to the basic sciences and increased the number of courses related to clinical care.<sup>30</sup> The curriculum was changed to provide clinical experimental models and has improved the competencies relating to evidence-based practice and patient-centred care.<sup>31</sup>

Over the years, the ACPE standards have been revised to respond to the needs of the pharmacy profession and to continue to respond to the Institute of Medicine's (IOM) recommendations for improving medication safety and patient outcomes. This institute suggested 5 competencies that healthcare professionals should attain during their education: the provision of patient-centred care; the employment of evidence-based practice; the use of interprofessional work teams; the application of quality improvement; and use of informatics.<sup>27</sup>

The American College of Clinical Pharmacy sets Standards of Practice for Clinical Pharmacists that "serve as a reference for those designing and assessing clinical pharmacy education and training programs". 32

### 1.2.2 Pharmacy studies in Europe

### 1.2.2.1 The Bologna Process: creation of the European Higher Education Area

With the aim of creating a harmonized European Higher Education Area (EHEA), in June 1999, European ministers of education from 29 countries signed the Bologna Declaration.<sup>33</sup> The main idea was to allow students from any higher education institution to begin, continue and complete their education and obtain a European diploma that would be recognized in any university of any Member State. To do so, it was necessary for European institutions of higher education to work in an integrated and harmonized way. In this context, higher education institutions should create an identical base structure, offering courses and specializations that are similar and comparable in terms of content and duration and confer diplomas that are recognized as equivalent both academic and professionally. The Bologna Declaration aimed to

increase the competitiveness of the European system of higher education and the promotion of the mobility and employability of graduates in Europe. To achieve these general objectives, the following objectives were defined:

- a) The adoption of a system of easily readable and comparable degrees;
- The adoption of a system essentially based on two main cycles undergraduate and graduate;
- The establishment of a system of credits (ECTS—European Credit Transfer and Accumulation System);
- d) The promotion of mobility and the free movement of students, teachers and researchers in a European context;
- e) The promotion of European co-operation in quality assurance with a view towards developing comparable criteria and methodologies;
- f) The promotion of the European dimensions in higher education, particularly with regard to curricular development, interinstitutional co-operation, mobility schemes and integrated programmes of study, training and research.<sup>33</sup>

Currently, 48 Member States<sup>a</sup> participate in the Bologna process after having fulfilled the condition and accession procedures.<sup>34</sup>

### 1.2.2.2 Training for pharmacists

In Europe, pharmacy education is recognized by Directive 2005/36/EC of the European

Parliament and the Council of the European Union, which replaced Directives 85/432/EEC and 85/433/EEC of the European Communities Council.<sup>35</sup> Subsequently, Directive 2013/55/EU of the European Parliament and the Council amending Directive

2005/36/EC regarding the recognition of professional qualifications was released. 36

In accordance with the implementation of the Bologna Process, it was established that the pharmacy degree would be organized in two training cycles with a duration of at

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<sup>&</sup>lt;sup>a</sup> Austria, Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, the United Kingdom (since 1999), Croatia, Cyprus, Liechtenstein, Turkey (since 2001), Albania, Andorra, Bosnia and Herzegovina, the Holy See, the Russian Federation, Serbia, The Former Yugoslav Republic of Macedonia (since 2003), Armenia, Azerbaijan, Georgia, Moldova, Ukraine (since 2005), Montenegro (since 2007), Kazakhstan (since 2010), and Belarus (since 2015).

least five years, composed of at least "(a) four years of full-time theoretical and practical training at a university or at a higher institute of a level recognized as equivalent, or under the supervision of a university; (b) during or at the end of the theoretical and practical training, six-month traineeship in a pharmacy which is open to the public or in a hospital under the supervision of that hospital's pharmaceutical department."<sup>36</sup>

Sixty European credit transfer and accumulation system (ECTS) credits are required to complete each academic year, and 300 ECTS credits are required at the end of the five years of study. Each ECTS credit corresponds to approximately 25-30 hours of study. <sup>36</sup>

### 1.2.3 Pharmacy studies in other countries

In Australia and New Zealand, before becoming registered pharmacists, students normally complete a four-year bachelor of pharmacy degree or a graduate-level master of pharmacy (M.Pharm.) degree, a three-year programme that has been offered since 2003 by some universities. After completing one of these university degree programmes, graduates must participate in an approved intern training programme accredited by the Australian Pharmacy Council (APC). 37 This internship is composed of 12 months of supervised practice in a hospital or community pharmacy. 16 As of 1998, pharmacy programmes must be accredited by the APC and approved by either the Pharmacy Board of Australia or the Pharmacy Council of New Zealand. This accreditation ensures both the quality of the education and training and that the pharmacy programme meets the approved accreditation standards for the profession. The Accreditation Standards for Pharmacy Programs aim to reflect pharmacists' initial training, which should provide the foundation for graduates to work in different settings. These standards assist in the design and delivery of pharmacy programmes and are regularly reviewed to keep pace with changes in the profession, e.g., with a review of the curriculum content. According to the standards, "the curriculum of the pharmacy programmedemonstrates congruency with contemporary pharmaceutical sciences, pharmacotherapeutics and pharmacy practice and the pharmacy learning domains". 37 The pharmacy learning domains, based on the Indicative Syllabus for UK pharmacy degrees,<sup>38</sup> consist of a list of items grouped into six domains that are to be taught in the pharmacy curriculum to focus on clinical education. <sup>16</sup> In New Zealand, the Health Practitioners Competence Assurance Act 2003 (HPCAA), which regulates the pharmacy profession, states that clinical competence, cultural competence, and ethical conduct must be integrated into the learning objectives of pharmacy programmes.<sup>39</sup> As in the pharmacy curriculum in the US, curricula in Australia and New Zealand balance and integrate the basic sciences, applied pharmaceutical sciences, social sciences, and clinical sciences. In these two countries, it is expected that at the end of the internship, graduates achieve the competency standards that are critical to the practice of contemporary pharmacists.<sup>40-42</sup>

In Canada, pharmacy education has undergone changes to keep pace with the evolution of the profession. In some Canadian universities, the entry-level degree for the profession is the Bachelor of Science in Pharmacy (B.Sc. Pharm.), whereas others are changing the entry-level degree to the Pharm.D. The programmes require a minimum of 5 years of education in a 1+4 or 2+4 model. 17 Both programmes are accredited by the Canadian Council for Accreditation of Pharmacy Programs and must comply with the standards established by this entity. The accreditation standards establish the goals to be achieved with the pharmacy curriculum to prepare students for the clinical responsibilities of a patient-focused practice. Like in the US, the pharmacy curriculum in Canada must offer a balance of coursework in biomedical sciences, pharmaceutical sciences, behavioural, social and administrative sciences, clinical sciences, and practical skills. Practical experience helps the student develop the necessary clinical skills to assist patients in different clinical environments. 43 In Canada, the Association of Faculties of Pharmacy of Canada (AFPC) established the educational outcomes for first professional degree programmes in pharmacy programmes with the aim of emphasizing the pharmacist's patient care responsibilities.<sup>44</sup>

The United Kingdom (UK) signed the Bologna Declaration, and its pharmacy curriculum is based on the European-required syllabus. However, the UK curriculum has some differences from the curricula in other European countries: it is necessary to complete a master of pharmacy degree (M.Pharm.), a 4-year programme (in other countries, pharmacy programmes are 5-6 years); complete one year of practical training in a community or hospital pharmacy (this workplace training is independent of the degree); and pass a registration exam before entering practice.<sup>45, 46</sup> M.Pharm.

programmes in the UK are accredited by the Royal Pharmaceutical Society. This body establishes an indicative syllabus for the UK pharmacy degree courses and lists 51 items that should appear in a syllabus in six domains (the patient; medicines: drug action; medicines: the drug substance; medicines: the medicinal product; healthcare systems and the roles of professionals; and the wider context).<sup>38</sup>

### 1.3 The pharmacy curricula

### 1.3.1 The importance of the curriculum

There are many definitions of what a curriculum is, but in general, the term refers to the set of experiences and objectives to be achieved by students during their educational process.<sup>47</sup> The curriculum aims to provide students with the knowledge, skills, behaviours, and attitudes that prepare them for professional practice,<sup>47</sup> all of which play an important role in professional identity formation.<sup>48</sup> Therefore, to prepare students to practice patient-centred care, it is important to increase the connection between the curriculum content and how it relates to students' future practice. Noble *et al.* suggested that pharmacy educators consider including significant interactions with patients throughout the curriculum using simulations, actors, or real-life patients, enabling the students to perform the role of a pharmacist.<sup>48</sup>

### 1.3.2 Designing a curriculum and syllabus

According to UNESCO, a curriculum is a systematic and intended packaging of competencies (i.e., knowledge, skills and attitudes that are underpinned by values) that learners should acquire through organized learning experiences in both formal and non-formal settings. <sup>49</sup> Curriculum development must meet society's needs; in this sense, the university should be able to identify the educational objectives and competencies that a graduate must acquire to practice his or her chosen profession. In the case of pharmacy, the curriculum should prepare students to enter a pharmacy practice with the necessary competencies that enable them to respond to health-related needs. <sup>50</sup> These needs are constantly changing, making the design of a curriculum a process that is always in progress.

Koster *et al.* offer suggestions for designing a pharmacy curriculum: use a competency framework; consult stakeholders ("consultation of the outside world is necessary to

align the competencies of recent graduates to the local professional and healthcare needs"); think ahead; integrate content and skills; appoint curriculum coordinators; avoid overburdening; use authentic learning activities and assessment tasks; adopt frameworks for cognitive and skill development; use curriculum mapping for internal quality enhancement; ensure management continuity; develop educational expertise and specialization; and develop scholarship in teaching and learning.<sup>51</sup>

The curriculum should "be expressed in comprehensive and user-friendly documents, such as curriculum frameworks; subject curricula/syllabuses, and in relevant and helpful learning materials, such as textbooks teacher guides; assessment guides". 52

A course syllabus is the principal outcome of curriculum development.<sup>53</sup> A syllabus is a document that includes descriptions and course plans. This instrument enhances student learning, assists faculty teaching, increases communication between faculty members about courses, and improves curricular quality.<sup>54, 55</sup> A syllabus should be created as a manual and a type of contract between the professor and the student.<sup>53,56, 57</sup> A learning-centred syllabus should be designed to ensure that students, when reading this document, understand what is required to achieve the course educational objectives.<sup>58</sup>

There are several components that a course syllabus must include: 53, 54, 56, 59

- General course information (course title and course code; term/quarter/semester; location and time of class; credits/units/time and student workload required; pre-requisites/co-requisites; course description)
- Course instructional team (instructor names; office hours and contact information; additional information)
- Course goals (general aims for the course/course purpose)
- Course objectives (skills, knowledge and attitudes that students need to acquire). Specific learning outcomes (competencies)
- Course content (description of course content including the sequence of topics/readings; learning activities/assignments)

- Time schedule/course plan (schedule/course plan; lecture and lab topics; landmark events, assessments, due dates; daily assignments linked to the calendar)
- The learning environment (learning and teaching methods; a list of required and recommended texts; course materials and attire)
- Student assessment and grading (grading procedure; grading scale and method;
   missed assessments; grade posting; the consequences of a failing grade;
   additional grading information)
- Technical, classroom, and academic policy information (syllabus changes; last course revision date; students with disabilities and special needs; rights and responsibilities of the student and faculty)
- Expectations of professionalism (ethics and professional conduct; behaviour; work habits)
- Additional information (e.g., charts, study suggestions, information on how to access the course website, advice for preparing for assessments/exams, appendices)

The syllabus can be used as an instrument to demonstrate that a course prepares the student for the objectives established in the curriculum. <sup>56</sup> To do so, the syllabus should also include a summary on how the course content relates to the competencies, which means an alignment between the learning outcomes, learning activities/assignments and assessment. <sup>60, 61</sup> The learning activities are used to develop each outcome, and the assessment tasks are used to assess each outcome.

Curriculum mapping is used for the evaluation and the continuous quality improvement of undergraduate pharmacy programmes. Curricular mapping allows for the identification of "courses that needed content revision and renewed alignment with program outcomes". Curriculum review and mapping is a process that "increases communication and collaborative efforts regarding instructional strategies, course content, assessment methods, and expected program outcomes among faculty members and other stakeholders." However, "this process ensures that the curriculum reflects the goals not only of the academic institution but also of the profession,

making the endpoints of the professional program visible to all involved."<sup>64</sup> Articles on mapping pharmacy curricula around the world have emerged in the literature.<sup>66-68</sup>

### 1.3.3 Structure of the pharmacy curriculum

The curriculum and course content taught in the pharmacy programme vary from country to country. Some studies have compared pharmacy curricula across the European countries and grouped courses for pharmacy degrees into different subject areas. According to the 1994 report of the Advisory Committee on Pharmaceutical Training, before the implementation of the Bologna Declaration, undergraduate pharmacy degrees varied significantly in length among European countries. For example, the total number of hours of instruction (excluding practical training/internship) ranged from 2141 in Ireland to 4670 in the Netherlands. Another consideration is the substantial differences in the distributions of the total number of hours of required courses by subject area. "Chemical subjects" assume the greater number of hours of required courses, ranging from 25-46% across European countries, with Germany's degree more focused on chemistry. Physics/mathematics/computing/statistics (3-13%) and social aspects of pharmacy/law (1-16%) were the subject areas that had a minimal focus on the European curricula.<sup>69</sup>

In the 2011 PHARMINE report, the courses of the undergraduate pharmacy curriculum were categorized into 7 subject areas. "Medical sciences" represented the main subject area (28%), followed by "chemical sciences" (24%), "pharmaceutical technology" (15%), "biological sciences" (11%), "physics/mathematics" (6.4%), "generic subjects" including traineeship (6.4%) and "law/society/ethics" (6.2%). The report stated that countries with more industrial pharmacists have pharmacy degrees that are more oriented towards the chemical sciences and pharmaceutical technology. Similarly, countries with more hospital pharmacists have pharmacy degrees that are more oriented towards the medical sciences. This finding could erroneously lead the reader to believe that many pharmacy degrees in Europe have a clinical focus. For this report, the "medical sciences" subject area included a mix of courses such as human anatomy and physiology, pharmacology, toxicology, parasitology, bio-analysis (of body fluids), radiochemistry, the dispensing process, drug prescriptions, prescription analysis, over-the-counter (OTC) medicines, skin illness and treatment, homeopathy,

phytotherapy, drugs in veterinary medicine, pharmaceutical care, pharmaceutical therapy of illness and disease, etc. According to the ACPE course categorization, some of these courses are part of the clinical sciences, whereas others belong to biomedical/basic sciences (e.g., anatomy and physiology) or pharmaceutical sciences (e.g., pharmacology).<sup>26</sup>

A study of the evolution of the European pharmacy curriculum was conducted by comparing the results from the 1994 study with the 2011 PHARMINE report. 71 A decrease in the number of hours related to the chemical sciences (from 33% to 26%) and an increase in the number of hours related to the medical sciences (from 19% to 28%) were found. According to these results, it appears that changes in the European curriculum have led to more clinical courses and that the pharmacy education is in line with international recommendations.<sup>71</sup> However, a recent study comparing the patient-centred care in pharmacy curricula in the US and the EHEA showed that higher education institutions in European countries, despite curricular revisions after the Bologna Declaration, maintain a greater focus on basic sciences and a lower load of clinical sciences in pharmacy curricula than those in the US. In this study, the course contents in the syllabi were analysed and each course was classified into one of four categories: social/behavioural/administrative pharmacy sciences, clinical sciences, experiential, or other/basic sciences. The 4-area categorization system was created based on the "Curricular Core – Knowledge, Skills, Attitudes, and Values" section of the ACPE standards. According to this study, although there are also differences in the social/administrative sciences and experiential courses, the main differences between the US and the EHEA curricula involve the clinical sciences (16% in the US versus 4% in the EHEA) and the basic sciences (49% in the US versus 72% in the EHEA).<sup>72</sup>

Some authors claim that the pharmacy profession relies on the basic sciences, demanding a high load of these courses in the curriculum.<sup>73, 74</sup> However, professional bodies demand that pharmacists, as health professionals, must possess the clinical skills that allow them to have a patient-centred practice. For this purpose, a proper balance between basic sciences, pharmaceutical sciences, and sciences that prepare students for a patient-centred practice (such as clinical sciences and social, behavioural, and administrative aspects associated with pharmaceutical practice) is

necessary. Although there was a reduction of the basic sciences and an increase in clinical sciences in some schools of pharmacy,<sup>30</sup> the curricular change in European countries maintained their focus on the basic sciences.<sup>72</sup> To be in line with WHO and FIP recommendations, schools need to review their curricular content to ensure that graduates are competent in patient care.

In an attempt to achieve an appropriate balance between educational content from various areas and following the ACPE standards,<sup>27</sup> some US schools of pharmacy have adopted an integration of the curricular content. In these schools, the courses are linked to each other, and the content taught in one course is related to the information provided in another. Curricular integration can occur with content from courses that are taught at the same time in the programme (horizontal integration) or that are taught in different stages of the curriculum (vertical integration). The curriculum integration consists of the integration of contents from the basic sciences with clinical sciences and the integration of theory and practice. 75-78 Pharmacy integration of biomedical, curricula with a complete pharmaceutical, social/behavioural/administrative, and clinical sciences are also being developed.<sup>79</sup>

### 1.3.4 Creating competency frameworks for pharmacy

Competency-based education frameworks are increasingly common among health professionals. 80-82 The development of competency frameworks for pharmacy education and practice has grown worldwide; such frameworks have been used in the design, development, and review of the pharmacy curricula. 83

In 2007, the Competency Development and Evaluation Group (CoDEG) published the second edition of its General Level Framework (GLF), a Framework for Pharmacist Development in General Pharmacy Practice used in the United Kingdom. This framework can be used by pharmacists working in hospital, community pharmacy, and primary care and provides guidance on a competency framework that supports the development of pharmacists as safe and effective general-level practitioners. <sup>84, 85</sup> The GLF has been adapted for use in Australia <sup>86</sup>, Singapore <sup>87-90</sup>, Croatia <sup>91-93</sup> and Serbia <sup>94, 95</sup>.

With the aim of supporting the educational development of pharmacy practitioners, the FIPEd (FIP Education Initiatives and partnerships with WHO and UNESCO) created a

global competency framework (GbCF). <sup>96</sup> This framework, which works as a mapping tool and changes with the evolution of the profession, contains a core set of competencies included in the standards of practice for pharmacists from countries such as Australia, <sup>40</sup> Canada, <sup>97, 98</sup> New Zealand, <sup>42</sup> Thailand, the United Kingdom, <sup>99, 100</sup> and the US<sup>101, 102</sup>. In the FIP framework, competencies are described using behavioural terminology. One hundred behavioural competencies are categorized into the main domains of Pharmaceutical Public Health, Pharmaceutical Care, Organization and Management, and Professional/Personal topics. <sup>96</sup>

In Europe, several projects are sponsored by the European Union and European Association of Faculties of Pharmacy (EAFP) with the goal of creating a European competency framework for pharmacy (e.g., PHARMINE, PHAR-QA, PHAR-IN). 103 Inspired by the FIP global competency framework and other competency frameworks, the PHAR-QA project (Quality Assurance in European Pharmacy Education and Training) has been developed. 104 This project aimed to create a harmonized competency framework for pharmacy practice that can be used as the basis for a quality assessment system of university pharmacy education in Europe. Initially, this project produced a list of 27 major competences<sup>b</sup> that reflect a pharmacist's activities, grouped into three domains: Patient Care Competences, Personal Competences, and Management and Organizational Structure Competences. For each of the 27 major competences, an average of five supporting competences resulted, totalling 140 proposed competences for pharmacy practice. After an evaluation of the proposal competences by an expert panel, there were 68 competences for pharmacy practice, grouped into 13 domains. 105 The PHAR-QA project asked European academics, students, and practicing pharmacists (community, hospital, industrial, and pharmacists working in other professions) to rank the competences required for pharmacy practice. The results of PHAR-QA show that competences in the areas of "drug interactions", "need for drug treatment" and "provision of information and service" were ranked highest, whereas those in the areas of "ability to design and conduct research" and "development and production of medicines" were ranked lower. 106 Overall, there is a high level of agreement on the importance of competences among the various areas of

<sup>&</sup>lt;sup>b</sup> We maintained the terms used by the PHARM-QA project, although we might not agree with them.

pharmacy. There is mainly a consensus between hospital and community pharmacists regarding "patient care". The competences were rearranged in a second round of the project, resulting in 50 competences organized into 11 domains (Personal competences: learning and knowledge; values; communication and organizational skills; research and industrial pharmacy. Patient care competences: patient consultation and assessment; need for drug treatment; drug interactions; drug dose and formulation; patient education; provision of information and service; monitoring of drug therapy). The European Pharmacy Competences Framework defined and ranked the competences required for pharmacy practice in line with the European directive on the recognition of professional qualifications. The second round of the second round of the second round rou

Several countries have established or are working to create their own competency frameworks for pharmacists. In Ireland, the aims of the competency framework for pharmacists, inspired by the FIP global competency framework, are to state the educational standards, curriculum development, and learning outcomes for undergraduate students. This framework organizes competencies into six domains: professional practice; personal skills; supply of medicines; the safe and rational use of medicines; public health; organization and management skills). One hundred and seventy-eight behavioural statements are given for each competency to demonstrate how individuals who have a given competency will behave in practice. <sup>110</sup>

In Spain, the CIN/2137/2008 Ministerial order is the Spanish transposition of the European directives, establishing the requirements of the curriculum and competencies that students should acquire for the practice of pharmacy.<sup>111</sup>

In Portugal, the *Ordem dos Farmacêuticos* (the body that regulates the pharmacy profession) has recently created a competency framework to promote excellence in pharmaceutical interventions in various professional areas: community pharmacy, hospital pharmacy, pharmaceutical industry, and regulatory affairs. To acquire each of these competencies, the contents of the programmes are to be taught so that students achieve these competencies.<sup>112</sup>

A recent study compared the Australian, Canadian, British and American pharmacy learning outcome frameworks with the global competency framework from the FIP.

The main finding of that work was an alignment of the same basic elements of public health, pharmaceutical care, and personal attributes described within the GbCF, with the learning outcomes described in each country's framework. Elements such as communication with patients, personal behaviour, safe and effective practice and the updating/renewing of practice and continuing professional education/development appear in all educational learning outcomes frameworks and in the GbCF. The pharmacy curriculum in these countries appears to be in line with the concept of pharmacists as patient-oriented medicines experts. Interestingly, teamwork and leadership, including in the Australian, Canadian and American learning outcome statements, were not mentioned in the GbCF. <sup>113</sup>

Several competency frameworks have been developed for pharmacy practice at the national and international levels, and their implementation and use in pharmacy education has been reported in numerous articles.<sup>51, 83, 114-118</sup> Although the development of a competency framework is important to ensure the acquisition of competencies by graduates, it is necessary that curricula be designed to ensure that students acquire these competencies.<sup>50</sup>

### 1.3.5 Use and misuse of competencies

There is no doubt that education should be based on the acquisition of competencies and that a competency framework may assist in the development of pharmacy curricula. However, it is also important to note that a competency-based education must align "teaching strategies, educational practices, learning opportunities and settings, evaluation system, and research activities with this organizational principle in the curriculum".<sup>81</sup> For that reason, a perfect alignment between competencies and learning contents is crucial for graduates to acquire the necessary competencies for pharmacy practice. However, an ongoing review of undergraduate pharmacy curricula revealed the existence of three different situations. The first of these situations, which is the expected, is an appropriate alignment between competencies and contents. One example of this situation is that of a Canadian university (CAN\_0363)<sup>c</sup>, in which there is an alignment with the AFPC educational outcomes for Canada's entry-to-practice

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<sup>&</sup>lt;sup>c</sup> The authors preferred to keep the identity of the universities used as examples in this chapter hidden and refer only to their internal codes.

pharmacy programmes.<sup>44</sup> For example, in the "Pharmacy Practice Management" syllabus, there is an alignment between the content of "key concepts related to operational management, strategic planning and marketing strategies and methods to incorporate these concepts into pharmacy practice" and the 4.5 AFPC outcome ("Manage to maintain the sustainability of the practice"). In one Australian university (AUS\_0042), there is a perfect alignment between learning outcomes, learning activities and assessment tasks. However, at that university, the learning outcomes used are not exactly the same as those established in the National Competency Standards Framework for Pharmacists in Australia.<sup>40</sup> Instead, this university created its own pharmacy curriculum outcomes.

The second situation is the lack of alignment between competencies and educational contents. Although a given country might have developed a competency framework, the curriculum of a university in that country might not be aligned with it. For example, one Irish university (IRL\_1285) ignores the existence of a core competency framework for pharmacists<sup>110</sup> and does not report any alignment between competencies and contents. A similar situation was identified at a New Zealand university (NWZ\_1534) that ignores the competence standards for the pharmacy profession.<sup>42</sup>

The third and probably the most worrying situation is the deliberately misleading alignment between competencies and contents. A paradigmatic example of this situation can be seen in Spain. In 2008, an officially approved ministerial order established the competencies that students must acquire for the practice of pharmacy. However, most Spanish universities' syllabi report a misleading alignment between the competencies and their educational contents. For example, a Spanish university (ESP\_1741) aligns the "Parasitology" course with competencies such as "learn to apply the scientific method and acquire skills in handling legislation, sources of information, literature, protocol development", "design, prepare, deliver and dispense medications and other health products of interest", "identify, evaluate and assess the problems related to drugs and medications, as well as participate in pharmacovigilance activities", and "develop communication and information skills, both oral and written, to deal with patients and users". Another example is the frequent alignment of "Biochemistry" with competencies such as "develop

communication and information skills, both oral and written, to deal with patients and users" (e.g., in ESP\_1737, ESP\_1738, ESP\_1739, ESP\_1741, ESP\_1748, ESP\_1996), "design, prepare, deliver and dispense medications and other health products of interest" (e.g., in ESP\_1737, ESP\_1739, ESP\_1996), "identify, evaluate and assess the problems related to drugs and medications, as well as participate in pharmacovigilance activities" (e.g., in ESP\_1737, ESP\_1739, ESP\_1996). The most extreme case of this misleading alignment occurs in two Spanish universities (ESP\_1737 and ESP\_1739) that align "Biochemistry" with all of the general competencies included in the Spanish ministerial order.

Although the definition of a competency framework is necessary for curriculum design, it might not be sufficient. Unfortunately, the previous examples cited here show that some universities do not use the competencies properly. A perfect situation would consist of a robust competency framework produced by the profession, with disciplines having all their course contents perfectly aligned with each topic in the competency framework and having this alignment clearly stated in the course syllabi. To properly create this perfect scenario, competencies and educational content must be mapped into competency frameworks.

# Creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum

# 2.1 Method for creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum

According to the FIP, educational programmes must be designed (curricular content, teaching and learning methodologies, educational outcomes, etc.) to ensure that the competencies needed to enter pharmacy practice are achieved by all graduates. Additionally, "all courses and elements of the curriculum should be 'mapped' (cross-referenced) to the expected competencies and educational outcomes." <sup>50</sup>

From a theoretical point of view, there are three methods of presenting the definition of a curriculum's educational contents. In the first method, a limited number of people decide what should be taught in the curriculum based on their knowledge, interests and way of thinking. A second method would involve creating an expert panel composed of individuals appointed by professional bodies and employers to determine the necessary profile and job characteristics for pharmacists — that is, the competencies that must be acquired and the educational contents that should be taught to achieve these competencies. A third method is the benchmarking method, which involves analysing what others have done and attempting to adapt their methods with adjustments and improvements. 120

After more than 40 years of experience in the world of pharmacy practice, it would not be logical to design a curriculum from scratch, and using the benchmarking method to define the educational contents appears to be a more rational method. Thus, we aimed to create a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum with a method that is free of any bias associated with individual interests, compiling the experiences of countries that have extensively implemented pharmaceutical services.

To create a catalogue of educational contents for a patient-centred pharmacy practice, we used the benchmarking method with the educational contents of pharmacy curricula from Australia, Canada, New Zealand and the US through a qualitative analysis of the educational contents included in these countries' syllabi for courses in the area of pharmacy practice.

### 2.1.1 Location of educational contents

### 2.1.1.1 Selection of the countries and schools of pharmacy

The selection of Australia, Canada, New Zealand and the US was based on a) their wide implementation of pharmacy services; b) the official language in these countries is English, the academic *lingua franca*;<sup>121</sup> and c) the fact that these countries' curricula have been transformed consistent with more clinical models, integrating courses from clinical pharmacy and social, behavioural and administrative sciences.

The websites of all schools of pharmacy in Australia, Canada, the US and New Zealand extracted from FIP Official World List of Pharmacy Schools were searched. Our analysis included schools with curricula in English whose course syllabi were all available online.

### 2.1.1.2 Selection of the courses

For the content analysis, all courses with educational contents in the area of pharmacy practice were included in the study. A course was considered to be in the area of pharmacy practice if its topics were listed under the clinical sciences and social/behavioural/administrative sciences, according to the ACPE "Guidance on the Science Foundation for the Curriculum" (Table 1).<sup>26</sup> Courses whose content involved exclusively pharmacology or pharmacotherapy were excluded from the analysis.

Table 1 – Foundation in sciences for the pharmacy curriculum suggested by ACPE

	Basic Biomedical Sciences	Pharmaceutical Sciences	
-	Anatomy and Physiology	- Medical Chemistry	
-	Pathology/Pathophysiology	- Pharmacology	
-	Microbiology	- Pharmacognosy and Alternative and	l
-	Immunology	Complementary Treatments	
-	Biochemistry/Biotechnology	- Toxicology	
-	Molecular Biology/Genetics	<ul> <li>Bioanalysis/Clinical Chemistry</li> </ul>	
-	Biostatistics	<ul> <li>Pharmaceutics/Biopharmaceutics</li> </ul>	
		<ul> <li>Pharmacokinetics/Clinical</li> </ul>	
		Pharmacokinetics	
		<ul> <li>Pharmacogenomics/genetics</li> </ul>	
		- Extemporaneous	
		Compounding/Parenteral/Enteral	
	Social/Behavioural/Administrative Pharmacy Sciences	Clinical Sciences	
	•	- Pharmacy Practice and Pharmacist-	
-	Healthcare Delivery Systems	<ul> <li>Pharmacy Practice and Pharmacist-</li> </ul>	
	Face amics / Dharmasa as a series	•	
-	Economics/Pharmacoeconomics	Provided Care	tion
-	Practice Management	Provided Care - Medication Dispensing and Distribution	tion
-	Practice Management Pharmacoepidemiology	Provided Care - Medication Dispensing and Distribution Systems	tion
- - -	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs	Provided Care  - Medication Dispensing and Distribute Systems - Pharmacotherapy	
- - -	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs History of Pharmacy	Provided Care  - Medication Dispensing and Distribute Systems  - Pharmacotherapy - Pharmacist-Provided Care for Special	
- - -	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs History of Pharmacy Ethics	Provided Care  - Medication Dispensing and Distribute Systems  - Pharmacotherapy  - Pharmacist-Provided Care for Special Populations	
-	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs History of Pharmacy Ethics Professional Communication	Provided Care  - Medication Dispensing and Distribute Systems  - Pharmacotherapy  - Pharmacist-Provided Care for Special Populations  - Drug Information	
- - -	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs History of Pharmacy Ethics Professional Communication Social and Behavioural Aspects of	Provided Care  - Medication Dispensing and Distribute Systems  - Pharmacotherapy  - Pharmacist-Provided Care for Special Populations  - Drug Information  - Medication Safety	
-	Practice Management Pharmacoepidemiology Pharmacy Law and Regulatory Affairs History of Pharmacy Ethics Professional Communication	Provided Care  - Medication Dispensing and Distribute Systems  - Pharmacotherapy  - Pharmacist-Provided Care for Special Populations  - Drug Information	

### 2.1.2 Data extraction

For each of the schools, complete programme content for each course was collected regardless of the course title listed on the website (syllabus, course schedule, course content, course description, etc.). To complete the set of documents provided on the Internet, the email addresses of the professors responsible for each of the courses were found, and they were asked to collaborate by submitting any additional information that would complete the material posted on the Web. If there was no response, the email was resent up to three times at intervals of 7 days.

### **2.1.3** Analysis of the programme content

Using the ACPE "Guidance on the Science Foundation for the Curriculum" as a coding framework, an initial coding tree was created with possible categories in which the educational contents of the evaluated courses could be grouped. A thematic analysis

of the educational contents described in the syllabus of the courses included for analysis was performed. Using an iterative process and based on the grounded theory, however, however

### 2.1.4 Quality assessment of the coding

To evaluate the completeness of patient-centred educational contents in the undergraduate pharmacy curriculum, a quantitative analysis was performed for 8 schools of pharmacy that provide complete, rich syllabi for all of their courses on their webpage for the academic year 2016/2017 (AUS=2, CAN=2, USA=4). A complete and rich syllabus was defined as one that in addition to describing course content provides information about course goals (competencies) and course objectives (skills, knowledge and attitudes that students need to acquire), units/time required and prerequisites/co-requisites, instructor contact information, the learning environment (facilities and teaching methods, required and recommended texts, and materials and attire), time schedules/course plans, assessment methods, technical classrooms, and college policy information.<sup>54</sup>

The percentage of patient-centred educational contents in the undergraduate pharmacy curriculum taught at each of these universities was calculated using the final version of the catalogue, which was obtained after cleaning the results of the coding process.

# 3. Findings

# 3.1 Creating a catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum

From the 149 schools of pharmacy included in the list of the FIP for the four countries selected, 110 schools were found appropriate for the study (Australia = 15; Canada = 5; US = 89; and New Zealand = 1). Of the 8,733 courses that appeared in the teaching programmes of those schools, 1,703 (19.5%) were listed as part of the pharmacy practice area and presented syllabi with detailed information about programme content. The distribution of this percentage was not homogeneous: Australia, 33.2%; Canada, 35.2%; the US, 18.0%; and New Zealand, 29.6%. In addition, in 595 of these courses, the email address of the professor appeared; that professor was then asked for additional information. Following those requests, 61 (36.1%) of the professors responded to the first email sent, 83 (49.1%) responded after the second request, and 25 (14.8%) responded after the third request. Ultimately, 28.4% (n=169) professors answered the request, and 20% (n=119) sent additional information.

The initial coding tree, created following our interpretation of the ACPE guidelines, had 39 categories organized into 3 hierarchical levels. Given that the qualitative approach allows the addition or modification of the categories during the process of reading the information analysis, the categories were adapted. Following the analysis of the 1,703 syllabi and 119 sets of additional information sent by the professors, a final coding tree with 4 hierarchical levels and 355 content topics was obtained.

The first hierarchical level consists of four large groups in which the area of pharmacy practice, divided as follows: Clinical Sciences Aspects, Social and Behavioural Pharmacy Sciences Aspects, Administrative Pharmacy Sciences Aspects, and Miscellaneous (Table 2).

Table 2 –Two higher hierarchical levels to code the educational contents for a patient-centred pharmacy curriculum

### 1. Clinical Sciences Aspects

- 1.1. Pharmacy Practice
- 1.2. Pharmacist-Provided Care
- 1.3. Medication Dispensing and Distribution Systems
- 1.4. Patient Assessment
- 1.5. Medication and Patient Safety
- 1.6. Drug Information and Literature Evaluation

### 2. Social and Behavioural Pharmacy Sciences Aspects

- 2.1. Sociological Aspects of Pharmacy Practice
- 2.2. Patient-Reported Outcomes
- 2.3. Professional Communication
- 2.4. Ethics
- 2.5. Public Health

### 3. Administrative Pharmacy Sciences Aspects

- 3.1. Healthcare Systems
- 3.2. Economics/Pharmacoeconomics
- 3.3. Practice Management and Leadership
- 3.4. Pharmacy Law and Regulatory Affairs
- 3.5. Informatics and Health Technology

### 4. Miscellaneous

- 4.1. Research Design
- 4.2. History of Pharmacy

The "Clinical Sciences Aspects" block is the largest with 6 groups and 29 subgroups, covering topics related to patient care, the processes associated with patient care, and clinical health outcomes. The "Social and Behavioural Pharmacy Sciences Aspects" block, with 5 groups and 18 subgroups, contains topics on the relationship with the patient and society (in the role of public health). The "Administrative Pharmacy Sciences Aspects" block, with 5 groups and 16 subgroups, provides the procedural and technological aspects that support the role of the pharmacist as a health professional. The "Miscellaneous" block includes cross-sectional contents for the blocks above, such as the design and interpretation of research and the history of pharmacy (Tables 3 to 6).

Within the subgroups, 355 topics were taught in some of the schools of pharmacy in Australia, Canada, the US and New Zealand (Appendix).

#### Table 3 - Categories of the Clinical Sciences Aspects block

# 1. Clinical Sciences Aspects (total number of content topics= 154)

- 1.1. Pharmacy Practice
  - 1.1.1. Profession of Pharmacy and Contemporary Practice (number of content topics= 8)
  - 1.1.2. The Role of the Pharmacist on the Healthcare Team (number of content topics= 4)
  - 1.1.3. Areas of Practice and Career Paths (number of content topics= 3)
- 1.2. Pharmacist-Provided Care
  - 1.2.1.Introduction to Pharmacist-Provided Patient Care and Patient-Centred Pharmacy Services (number of content topics= 5)
  - 1.2.2. Counselling and Patient Education (number of content topics= 8)
  - 1.2.3. Advising Symptoms and Self-Care (number of content topics= 6)
  - 1.2.4. Health Promotion and Preventive Care Services (number of content topics= 6)
  - 1.2.5. Disease State Management Follow up (number of content topics= 5)
  - 1.2.6. Medication Management Service (number of content topics= 4)
  - 1.2.7. Improving Adherence (number of content topics= 7)
  - 1.2.8. Clinical Interventions Service (number of content topics= 3)
  - 1.2.9. Medication Use Process and Quality Use of Medicines (number of content topics= 4)
- 1.3. Medication Dispensing and Distribution Systems
  - 1.3.1. Prescription Process (number of content topics= 3)
  - 1.3.2. Preparation and Dispensing of Prescriptions (number of content topics= 7)
  - 1.3.3. Distribution Systems (number of content topics= 8)
  - 1.3.4. Drug Administration (number of content topics= 2)
- 1.4. Patient Assessment
  - 1.4.1. Obtaining a Patient History (number of content topics = 5)
  - 1.4.2. Patient Screenings (number of content topics= 8)
  - 1.4.3. Physical Assessment (number of content topics= 6)
- 1.5. Medication and Patient Safety
  - 1.5.1. Medication Errors (number of content topics= 11)
  - 1.5.2.Patient Safety (number of content topics = 5)
- 1.6. Drug Information and Literature Evaluation
  - 1.6.1.Drug Information Concept and Applications to Clinical Practice (number of content topics= 3)
  - 1.6.2. Drug Information Resources (number of content topics= 6)
  - 1.6.3. Asking and Answering Drug Information Questions (number of content topics= 5)
  - 1.6.4. Drug Literature Evaluation (number of content topics = 5)
  - 1.6.5. Evidence-Based Clinical Practice (number of content topics= 5)
  - 1.6.6. Professional Writing (number of content topics= 4)
  - 1.6.7. Pharmacy and Therapeutics Committee (number of content topics= 3)
  - 1.6.8. Health Information (number of content topics= 5)

Table 4 – Categories of the Social and Behavioural Pharmacy Sciences Aspects block

# 2. Social and Behavioural Pharmacy Sciences Aspects (total number of content topics= 83) 2.1. Sociological Aspects of Pharmacy Practice 2.1.1. Sociological, psychological, and behavioural aspects of pharmacy practice (number of content topics= 7) 2.2. Patient-Reported Outcomes 2.2.1.Patient Humanistic Outcomes (number of content topics= 6) 2.3. Professional Communication 2.3.1.Communication Concepts (number of content topics= 6) 2.3.2. Patient Communication (number of content topics = 4) 2.3.3.Interprofessional Communication (number of content topics= 4) 2.3.4. Active Listening and Empathic Responding (number of content topics= 2) 2.3.5. Assertiveness and Resolving Conflicts (number of content topics= 2) 2.3.6. Special Communication Situations (number of content topics= 4) 2.3.7. Presentation Skills (number of content topics= 3) 2.4. Ethics 2.4.1. Ethical Concepts (number of content topics = 8) 2.4.2. Personal and Professional Conduct (number of content topics= 5) 2.4.3. Ethical Problems and Dilemmas (number of content topics= 4) 2.4.4. Privacy of Health Information (number of content topics= 3) 2.4.5. Ethics in Research (number of content topics= 2) 2.5. Public Health 2.5.1. Public Health Pharmacy (number of content topics= 11) 2.5.2.Epidemiology and Pharmacoepidemiology (number of content topics= 5)

Table 5 – Categories of the Administrative Pharmacy Sciences Aspects block

2.5.3. Pharmacovigilance (number of content topics = 4)

2.5.4.Infection Prevention and Control (number of content topics= 3)

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3. Administrative Pharmacy Sciences Aspects (total number of content topics= 100)
   3.1. Healthcare Systems
        3.1.1. Healthcare Delivery Systems (number of content topics= 11)
    3.2. Economics/Pharmacoeconomics
        3.2.1.Economic Principles (number of content topics= 5)
        3.2.2. Health Economics (number of content topics = 5)
        3.2.3.Concepts of Pharmacoeconomics (number of content topics= 7)
    3.3. Practice Management and Leadership
        3.3.1.Pharmacy Management and Leadership Concepts (number of content topics= 9)
        3.3.2.Pharmacy Business (number of content topics= 9)
        3.3.3. Pharmacy Practical Operations (number of content topics= 11)
        3.3.4. Accounting and financial management (number of content topics = 5)
        3.3.5. Human Resources (number of content topics = 4)
        3.3.6. Personal and Professional Management (number of content topics= 6)
        3.3.7. Marketing and Promotion (number of content topics= 5)
        3.3.8. Professional Effectiveness (number of content topics= 4)
    3.4. Pharmacy Law and Regulatory Affairs
        3.4.1. Health and Drug Policy (number of content topics = 6)
        3.4.2.Pharmacy Law (number of content topics = 6)
    3.5. Informatics and Health Technology
        3.5.1.Pharmacy and Health Informatics (number of content topics= 4)
        3.5.2. Health Technology (number of content topics = 3)
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Table 6 – Categories of the Miscellaneous block

- **4. Miscellaneous** (total number of content topics= 18)
  - 4.1. Research Design
    - 4.1.1.Introduction to medical research (number of content topics= 6)
    - 4.1.2.Biomedical studies (number of content topics= 4)
    - 4.1.3. Statistical principles and data analysis (number of content topics= 3)
  - 4.2. History of Pharmacy
    - 4.2.1. History of pharmacy profession (number of content topics= 5)

The catalogue of contents presented in this book should not be viewed as a curricular plan, and the categories presented do not represent disciplines. The topics presented here resulted from an extraction, coding, and synthesis process of the educational contents included in the course syllabi analysed.

The categories and educational contents presented in this catalogue do not correspond to a list of topics in hierarchical order of importance.

To create a pharmacy curriculum that prepares students for a patient-centred practice, it would be necessary to allocate the educational contents in this catalogue to the courses and to align that content with corresponding competencies. For each course, a complete syllabus should be created presenting general course information; the instructional team; the course purpose; the course objectives and specific learning outcomes (competencies); a description of educational contents to achieve these competencies (topics and learning activities), a time schedule or course plan; information about the learning environment; student assessment and grading; technical, classroom, and academic policy information; and ethical and professional conduct.

# 3.2 Quality assessment of the process

To obtain a proxy for assessing the quality of the catalogue-compilation process, a quantitative analysis was performed to determine the proportion of the 355 topics that were taught in each of the 8 schools of pharmacy and whether they were taught in a superficial or in-depth manner. We considered a topic to be superficially taught if only the name of the topic was mentioned in the syllabus. Another criterion that helped us decide whether a topic was covered superficially or in-depth was the number of hours dedicated to each theme. If the syllabus included good coverage of

the details described in the catalogue of contents for each of the 355 topics, the content was considered in-depth. For example, if a particular topic was taught for 5 minutes in one university and 2 hours in another university, we would conclude that the second university taught the topic in more depth.

The results show that although the four countries have a curriculum that prepares students for a patient-centred practice, all of them could still be improved (Table 7).

This analysis is subject to a reporting bias because it was based only on what has been reported through the course syllabus of all disciplines of the undergraduate pharmacy curriculum. Contents not clearly described in the course syllabus may have led to an underestimation of the amount of educational contents taught.

It is also important to consider that the curriculum analysis of these 8 schools of pharmacy may have overestimated the percentage of patient-centred content provided to an individual student because we analysed the syllabi of all courses, including the syllabi of electives courses. Since it is not possible for students to choose all of the elective courses, none of them could complete all of the patient-centred topics taught at their university.

Table 7 – Percentage of topics included in the catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum taught at the analysed universities<sup>d</sup>

	AUS_0028	AUS_0038	CAN_0363	CAN_0366	USA_1884	USA_1923	USA_1941	USA_1951
Number of contents taught superficially	104	132	167	168	158	190	160	179
Number of contents taught in depth	55	30	54	94	94	65	126	59
Total	159	162	221	262	252	255	286	238
%	44,78	45,63	62,25	73,8	70,98	71,83	80,56	67,04

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<sup>&</sup>lt;sup>d</sup> The authors preferred to hide the identity of the universities analysed by using only their internal codes.

# 4. Recommendations

- Pharmacists are healthcare professionals, and their education and training must be patient-centred. The entry-level degree for the profession is limited in duration, so it is necessary to ensure an adequate balance between the basic sciences and clinical sciences.
- 2. Education should be based on the acquisition of competencies, and a competency framework assists in the development of pharmacy curricula. Competency frameworks should not be created by universities alone but in collaboration with professional societies and employers. Employers and regulators should define job profiles and corresponding competencies required for a pharmacist position.
- Universities must follow competency-based education, but each competency
  must be perfectly aligned with the educational contents that are necessary for
  students to achieve it.

# **Future works:**

- The content catalogue resulting from this benchmarking exercise could be considered a contribution to the creation of a pharmacy curriculum that prepares students for a patient-centred practice. It is now necessary for a panel of experts in each of the major categories to develop the contents, align them with the corresponding competencies, estimate the workload required for instruction, assign tasks to be completed by the students, and stipulate in which courses should be taught.
- This catalogue of educational contents can also be used as an instrument to check the completeness of patient-centred educational contents in any university's undergraduate pharmacy curriculum.

# Glossary

**Behavioural competency:** typical behaviour observed when effective performers apply motives, traits or skill to job relevant tasks.<sup>84</sup>

Clinical pharmacy: describe the work of pharmacists whose primary job is to interact with the healthcare team, interview and assess patients, make specific therapeutic recommendations, monitor patient responses to drug therapy and provide medicines information.<sup>8</sup>

Clinical pharmacists: are licensed pharmacists with specialized advanced education and training who possess the clinical competencies necessary to practice in teambased, direct patient care environments.<sup>32</sup> Clinical pharmacists work primarily in hospitals and acute care settings and provide patient-oriented rather than product-oriented services.<sup>8</sup>

**Competencies:** Knowledge, skills, behaviours and attitudes that an individual accumulates, develops, and acquires through education, training, and work experience. <sup>96</sup>

**Competency-based education and training:** Competency-based education and training focuses on the ability of the students and practitioners to deploy skills, attributes and knowledge to perform specific tasks and, more broadly, a clinical or healthcare role or function (defined by research team).<sup>124</sup>

**Competency framework:** A complete collection of competencies that are thought to be essential to performance. <sup>96</sup>

**Core competencies:** Core competencies are considered to be essential competencies. They may exist within a workforce role or span across different workforce roles. 124

**Curriculum:** systematic and intended packaging of competencies (i.e. knowledge, skills and attitudes that are underpinned by values) that learners should acquire through organized learning experiences both in formal and non-formal settings.<sup>49</sup>

**Learning outcomes (i):** a statement of what a learner is expected to know, understand and be able to do at the end of a period of learning emphasizing the application of the ability, capacity or skill to accomplish a task. 113

**Learning outcomes (ii):** are promoted as a means of describing the outcomes of a qualification and comparing qualification types. Learning outcomes encompass the three dimensions of: **Knowledge** (what students know or understand); **Skills** (what students can do or how they apply their knowledge and understanding); **Competencies** (the context in which knowledge and skills can be applied. This dimension includes both specific and generic competencies, the latter often referred to as graduate attributes or qualities in the higher education sector).<sup>40</sup>

Patient-centred care: Any care that is respectful of and responsive to individual patient preferences, needs, and values, and ensures that patient values guide all clinical decisions. 125

**Pharmaceutical care:** the responsible provision of medicines therapy for the purpose of achieving definite outcomes, to improve patient's quality of life. <sup>96</sup>

**Pharmaceutical services:** represent all the services that pharmacists require to resolve a patient's drug therapy problems. These services range from the provision of medicines information to patient counselling to medicines distribution.<sup>126</sup>

Pharmacy education: refers to the educational design and capacity to develop the workforce for a diversity of settings (e.g., community, hospital, research and development, academia) across varying levels of service provision and competence (e.g., technical support staff, pharmacist practitioners, pharmaceutical scientists, preservice students) and scope of education (e.g., undergraduate, post-registration, continuing professional development, practitioner development, lifelong learning).<sup>127</sup>

**Pharmacy practice:** the provision of medications and other healthcare products and services and to help people and society to make the best use of them.<sup>8</sup>

**Social pharmacy:** The study of social and behavioural factors influencing medicine use including medicine- and health-related beliefs, attitudes, rules, relationships and processes. It may deal with the study of social aspects of medicines (e.g. drug research

and development, production and distribution of medicines, drug information, control of supply) or the perceptions and use of medicines by consumers (e.g. factors affecting adherence, understanding of side effects). It draws upon disciplines such as sociology, social psychology, psychology, political science, education, communication, economics, history and anthropology.<sup>40</sup>

**Syllabus:** is the outcome of curriculum development and contains both an instructional plan and details of the instructional process to be used within a defined unit of study.<sup>53</sup>

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# **Appendix**

# Catalogue of educational contents for a patient-centred undergraduate pharmacy curriculum

# **Educational Contents from Category of Clinical Sciences Aspects Block**

1	Clinic	cal Sciences Aspects	Page
	1.1	Pharmacy Practice	49
	1.2	Pharmacist-Provided Care	52
	1.3	Medication Dispensing and Distribution Systems	62
	1.4	Patient Assessment	68
	1.5	Medication and Patient Safety	73
	1.6	<b>Drug Information and Literature Evaluation</b>	76
2	Socia	ll and Behavioural Pharmacy Sciences Aspects	
	2.1	Sociological Aspects of Pharmacy Practice	
	2.2	Patient-Reported Outcomes	
	2.3	Professional Communication	
	2.4	Ethics	
	2.5	Public Health	
3	Admi	inistrative Pharmacy Sciences Aspects	
	3.1	Healthcare Systems	
	3.2	Economics/Pharmacoeconomics	
	3.3	Practice Management and Leadership	
	3.4	Pharmacy Law and Regulatory Affairs	
	3.5	Informatics and Health Technology	
4	Misc	ellaneous	
	4.1.	Research Design	
	4.2	History of Pharmacy	

# 1.1 Pharmacy Practice

# 1.1.1 Profession of Pharmacy and Contemporary Practice

# Introduction to the profession and practice of pharmacy

- Foundational concepts of pharmacy practice
- The role of the pharmacy profession
- The philosophy, socialization, and practice of the profession of pharmacy
- The definition and important of professionalism as it relates to modern-day pharmacy practice
- What is professional practice?
- The eight star pharmacist (WHO)

# **Evolution of pharmacy practice and industry trends and developments**

- The transition of pharmacy from product-focused to patient-focused practice and the difficulties in managing this change
- Events and factors internal and external to pharmacy that drive change in practice (e.g. health systems, political, socio-economics, and cultural diversity)

# **Contemporary pharmacy practice**

- Factors that influence contemporary pharmacy practice, roles, responsibilities and expectations within the healthcare system
- The principles of and skills, attitudes and behaviours required for contemporary pharmacy practice
- The "languages and tools" used in contemporary pharmacy practice with emphasis on medical terminology

# Different pharmacy practice models

- The factors that have led to the types of pharmacies found in different parts of the world
- Practical aspects of pharmacy practice in developing countries

## The different pharmacy organizations

 The roles and objectives of relevant professional pharmacy organizations and bodies and their relevance to contemporary pharmacy practice

# Professional practice guidelines and standards

- World Health Organization (WHO) and International Pharmaceutical Federation (FIP) guidelines, protocols or statements on the practice of pharmacy
- Professional standards of pharmacy practice, their place in practice, intention and use

# Pharmacy education and practice around the globe

- The education, training, and professional licensure requirements to become a pharmacist
- The gap between what is taught in pharmacy school and the knowledge needed to practice community pharmacy in the 21st century
- The similarities and differences in nursing, pharmacy and medical education

#### Future of the pharmacist and pharmacy practice

• The future direction of the profession

# 1.1 Pharmacy Practice

# 1.1.2 The Role of the Pharmacist on the Healthcare Team

#### Introduction to health professions

- The professional health practitioner
  - Basic competencies and skills needed to function as a healthcare provider
- The distinct roles and functions of nurses, pharmacists, doctors, and other professional members of the healthcare team

# Working in multidisciplinary teams

- Building interprofessional healthcare teams
  - Concepts: team building, team interaction, interpersonal teamwork, team based decision-making
- What is interdisciplinary practice?
  - Relationship-building values and the principles of team dynamics
- The importance of the multidisciplinary approach to patient care
  - Activities centred around interprofessional teams and how a team can provide optimal care to patients
  - Collaborate proactively with other healthcare professionals
- Role of the pharmacist related to interaction with other healthcare providers

# The clinical role of the pharmacist as a provider of patient-centred care

- Role of the pharmacist in optimizing the use of medicines and improving health outcomes
- The roles, rights and responsibilities of the pharmacist in providing healthcare in a variety of practice settings

(e.g. community, acute, assisted, and long-term care health systems)

Patient and other healthcare provider perceptions of pharmacists' capabilities

# 1. Clinical Sciences Aspects

# 1.1 Pharmacy Practice

# 1.1.3 Areas of Practice and Career Paths

# **Professional pharmacy practice in different settings**

- Current issues, operations and procedures in different pharmacy settings
- Structure of the pharmacy sector

The diversity of pharmacy and related areas in a modern healthcare system in which pharmacists practice

Ambulatory

(e.g. community pharmacy, primary care, compounding)

Institutional

(e.g. hospital, residential care/home health pharmacy)

Industrial

(e.g. production, quality, wholesale)

Academic

(e.g. research institutions)

Others

(e.g. army, professional pharmacy organizations, nuclear pharmacy)

# **Pharmacy practice career paths**

- Introduction to professional identity and career planning
- Variety of career pathways and emerging career opportunities within the pharmacy profession

# **1.2.1** Introduction to Pharmacist-Provided Patient Care and Patient-Centred Pharmacy Services

### The professional aspects of pharmacy in delivering a patient-centred care

Who are our patients and what their needs are

## The pharmaceutical care practice

- The nature and evolution of pharmaceutical care
- The values, principles and goals of pharmaceutical care
- Different models, strategies and processes utilized in the provision of pharmaceutical care
- The varieties of pharmaceutical care practice opportunities available for pharmacists today

# **Patient-centred pharmaceutical care services**

- Concept of pharmacist-managed/patient-oriented pharmacy services directed at providing effective, safe, and cost effective drug therapy via outcomes monitoring and assessment
- Justifying, planning, development, implementation, management and evaluation of patient care services
  - Conduct a thorough needs assessment for the proposed service
  - Methods and requirements to implement patient care services
  - Tools and resources to conduct a patient care service

     (e.g. physical space requirements for a service, professional requirements)
  - The economic, clinical and humanistic outcomes of a clinical pharmacy service
- Barriers and facilitators of providing pharmaceutical care
  - Strategies to address barriers without compromising service quality
- The provision of pharmacy services in multiple environments
  - Innovative and emerging value-added pharmacy services
- Payment for pharmacy services
  - Success stories from practicing pharmacists who have implemented pharmaceutical care services and have received reimbursement for their efforts

#### Quality assessment and improvement of pharmaceutical care services

- Quality improvement and their impact on patient outcomes
- Selection of quality improvement strategies and plans for implementation

(e.g. screening/recruitment of high-risk patients, process measures for monitoring, design of an evaluation plan)

 Monitoring the quality of professional services (e.g. clinical audits, evaluation of interventions)

# **Continuum of patient care**

- Responsibility of providing continuing care to the patient
- Strategies to improve the continuity of patient care as patients move between healthcare settings

# 1.2.2 Counselling and Patient Education

# Introduction to the clinical counseling

- Patient counselling concepts
- Clinical counselling techniques
- Counselling in pharmacy practice
  - Development and delivery of patient counselling to optimize health outcomes
- Technology employed to promote patient counseling

(e.g. telephone counselling)

# Pharmacist as patient educator and health information provider

- How educating and empowering patients
- Access, analyse and apply relevant educational strategies and the best method to provide counseling/education
- Develop population-based patient education programs
- Design and develop appropriate educational materials for patients, caregivers, and health professionals

## **Process of patient counseling**

- Interactive patient counseling technique using open-ended questions when dispensing prescriptions
- Gather, organize, and summarize information to the patient
  - Delivery of patient information using consumer medicine information leaflets

#### Assess patient understanding

- Assess patient's existing understanding of therapeutic goals and regimen demands
- Apply patient education techniques to help ensure that information is provided in an understandable way

(e.g. emphasize important points; give reasons or tell why key pieces of advice should be followed; use terms the patient can understand)

 Assess patient understanding of information provided by the pharmacist using a teach back process

Counsel and educate patients and caregivers regarding medication use, disease-state management, and health maintenance

- Counseling on the treatment and prevention of diseases and medical conditions
- Counseling about the appropriate use of medications and health products using a patient-centred approach
  - Patient information and counseling on new and refill prescription, over-thecounter (OTC) medicines, compounded medications, nutritional and dietary supplements, natural products, sterile products, etc.
  - Provide information and educate the patient about medications

(e.g. explain the purpose/indication for drug therapy; contraindications and precautions; potential adverse effects and their management; potential drug interactions; appropriate administration regarding drug usage, dosage, frequency and duration, route, technique, dose adjustments, and missed doses; and storage)

Counselling on the correct use of various drug delivery devices

(e.g. eye drops, ear drops, transdermal patches, nasal sprays, inhaler devices, devices for nebulization, self-administered subcutaneous medications)

Counselling on the use of home monitoring kits and point-of-care testing devices

# 1.2.2 Counselling and Patient Education (cont.)

#### **Motivational Interviewing**

- The basic concepts and principles of motivational interviewing, its spirit and essential strategies
- Skills of motivational interviewing (OARS: Open-ended questions, Affirmation, Reflective listening, Summarizing; and elicit change talk)
- Common therapeutic pitfalls in the consultation process and understand the nuances of using motivational interviewing techniques in community practice

# Involving patients in decisions in their care

- Building a therapeutic relationship with the patient
- Help patients identify and voice values and concerns they have that affect their choices about their care
- The pros and cons of choices relevant to patient values and concerns
- Shared decision-making
  - Definition and classification of the key components of shared decision-making
  - Involvement of patients in informed shared decision-making
  - Identify relevant information that must be understood by patients if they are to make informed decisions about medication use and be able to use medications appropriately

# **Drug Utilization Review (DUR)/ MedsCheck**

- Characteristics of DUR program
- How to develop a DUR programme to identify unsafe, abusive, or inappropriate medication prescribing and patient drug use patterns that require intervention
- The process and methods for Drug Utilization Review/Drug Utilization Evaluation
- Retrospective and prospective Drug Utilization Review

# 1.2.3 Advising Symptoms and Self-Care

#### Introduction to self-care

- Concepts of self-help, self-care, self-limiting health problems
- Economic, social, cultural and professional aspects of self-care
- The factors that lead patients to self-diagnose and self-treat their medical conditions
- The principles and strategies of self-care

# The role of the pharmacist in the management of self-limiting illnesses and self-care

- Professional responsibilities and technical requirements for the dispensing of self-care medications and products
- Assist patients in making self-care decisions

# Medical conditions that are appropriate for self-care

- Common medical conditions that are appropriate for self-care
  - (e.g. self-care for dermatologic, Head, Eyes, Ears, Nose, and Throat (HEENT), gastrointestinal disorders, allergy, cough and cold, pain, fever, oral health, topical parasites, nutrition)
- Identification, interpretation and differentiation the signs and symptoms of common self-treatable conditions

# **Categories of self-care medications and products**

- Nonprescription drugs or over-the-counter medicines
- Complementary and alternative medicine
   (e.g. nutraceutical products, dietary supplements, natural and herbals products, homeopathic remedies)
- Home testing and monitoring devices
- Durable medical equipment

# Patient assessment and consultation

- Assessment of a patient seeking nonprescription medications
  - Systematic approach to gather, interpret, and assess patient information in order to provide appropriate patient advice for common self-treatable conditions
  - Identification of situations where self-treatment is not indicated and provision a referral to the appropriate healthcare practitioner
- Product selection and recommendation for treatment and prevention of diseases
  - Appropriate self-care therapies selections and recommendation based on patient characteristics, disease, and drug specific information
  - Justify recommendations with supporting evidence from appropriate sources

# Non-pharmacologic therapy recommendations

- Non-pharmacologic treatment options for commonly encountered disease states and patient complaints
- Recommend appropriate non-pharmacologic therapy based upon patient-specific information (age, weight, height, lifestyle, occupation, etc.) and disease-specific information (pathophysiology, disease severity)

# 1.2.4 Health Promotion and Preventive Care Services

Prevention, health promotion and wellness theory and practice applied to the role of pharmacy

- Concepts of health promotion, preventive medicine, health maintenance
- The role and responsibility that pharmacists can play in promoting health and wellness and preventing disease, and how such roles relate economically to contemporary health system models
- Principles of health promotion and the historical context in which health promotion has evolved
- Health promotion and health education as a strategy to reduce illness and improve health outcomes

# Educate patients about wellness and disease prevention

• The ability of patients to assume active roles and function effectively on their own behalf in health promotion and disease prevention, detection, and treatment

# Health promotion strategies and methods

- Health promotion and disease prevention initiatives/programs
   (e.g. handwashing)
- Processes of health promotion programme planning, implementation, evaluation and sustaining
- Evaluate the need, progress, outcome, and efficiency of a health promotion intervention
- The use of health promotion materials

#### Lifestyle education

- What constitutes a healthy lifestyle and how it contributes to the prevention of chronic disease
- Lifestyle modification strategies and methods
- Strategies to prevent and treat risk factors associated with diseases
- Primary and secondary prevention strategies
- The essential elements of wellness and major areas of lifestyle modifications for all patients

(e.g. nutrition, physical activity, weight control, tobacco cessation, sleep success, stress management, emotional health and health behaviour change, management of lifestyles in chronic diseases)

# Disease prevention services

- Disease prevention services as part of patient or population specific care
   (e.g. pharmacy-based immunization program, pharmacy-based smoking cessation program, weight control program, substance abuse treatment programs, travel medicine recommendations)
- How pharmacists contribute to the delivery of effective, quality health and disease prevention services

# **Public health guidelines**

 National and international guidelines for the contribution of health professionals to the prevention and management of health problems

# 1.2.5 Disease State Management - Follow up

#### **Principles of basic disease states**

• The effect of a disease on the patient

### Introduction to disease state management

 Epidemiology and concepts of disease state management including management of various types of patients

(e.g. pediatrics and geriatric patients)

- The role of the pharmacist in management of patients with multiple diseases
  - Optimizing the role of patients in self-management of the disease
- Models and processes of disease state management
- New strategies for disease management (e.g. care plans, ambulatory care clinics)

## Pharmaceutical care plans

- The value of pharmaceutical care plans, counseling, and identification of therapeutic problems
- The components of a care plan
- The pharmaceutical care planning process
- Design, implement, monitor, evaluate, and adjust pharmaceutical care plans that are patient-specific and evidence-based which ensure effective, safe, and economical care
  - Follow-up with patients to evaluate their response to therapy
- Document a care plan using a concise, standardized process (data, assessment, intervention and monitoring plan)

#### Disease state management models

• Disease state management programs

(e.g. women's health; pediatrics health; cardiovascular system; respiratory system; dermatological system; allergic and immunologic disorders; gastrointestinal system; endocrine system; renal; neurology; mental health patients; infectious disease syndromes; palliative and manage end-of-life care)

- Disease state management in special populations and special situations (e.g. pre and post-natal care/infant care, pregnant and breastfeeding women)
- Interpret laboratory findings, clinical data and physical assessment to patient-specific disease management

# Disease management protocols in the delivery of pharmaceutical care

Guidelines for the evaluation and treatment of commonly encountered diseases

# 1.2.6 Medication Management Service

### **Medication management**

- Medication management and drug optimization in response to the needs of individual patients
- The basic principles of medication management
- Differences between the levels of medicines management services
- The pharmacist's role in managing drug therapy for patient populations in a variety of practice settings

# **Medication Therapy Management (MTM)**

- Overview of the MTM Service Model
  - Concepts and principles of MTM
  - The history and need for MTM services
- The development and implementation of MTM services in a clinic or community pharmacy setting
- The clinical and administrative aspects of providing MTM services
- How to provide MTM service in a safe, timely, efficient, effective, equitable and patient-centric manner
- The essential elements of MTM
  - (e.g. conducting the comprehensive medication review, creating a personalized medication list, medication action plan and physician communication document)
- Management of different MTM programs

#### **Medication reconciliation**

- Compare reconciled list with patient containers
- Perform and document medication reconciliation
- Creating the best possible medication list

#### Medication review

- Implicit and explicit criteria to identify inappropriate prescribing (e.g. Beers' criteria)
- Medication review process: steps for conducting a medication review
- Provision of comprehensive medication review in different practice settings

(e.g. Home Medication Review; Residential Medication Management Review; Hospital Medication Management Review)

# 1.2.7 Improving Adherence

Definitions of medication adherence, medication compliance, concordance, polypharmacy and medication persistence

- The problems of medication non-adherence
  - The incidence of and problems associated with drug overuse, underuse, and misuse

#### Potential barriers to adherence and causes of non-adherence

 Patient-related barriers to adherence and factors affecting non-compliance with drug and non-drug therapy

(e.g. cultural and religious influences on patient compliance and disease management)

• Healthcare system and provider-related barriers to adherence

# **Medication taking behaviour**

- The concepts of medication taking behaviour that are measured by commonly used instruments
- Instruments that measure patient beliefs and attitudes towards medication

## **Assessing non-adherence**

- How to detect inappropriate medication use
- Technology identifying non-adherence
- Assess patient adherence to medication regimens

(e.g. Morisky-8 Adherence scale)

- Compare and contrast self-reported medication taking behaviour with other methods of determining adherence, such as claims data, electronic surveillance, pill counts
- The limitations of self-reported medication taking instruments

# Creating an adherence service

- Process of defining, planning, implementing and evaluating an adherence service
- Develop a patient-specific plan to overcome barriers to medication adherence

# **Enhancing medication adherence/adherence activity**

- Strategies to encourage patient adherence to therapeutic interventions
- Patient-related and program-related behaviour change strategies that can improve adherence
  - Influencing behaviour
  - The impact of the health belief model on medication adherence
  - The factors which are important in influencing patient compliance
- The ways in which pharmacists can improve medication compliance
  - Motivational cues to enhancing patient compliance
  - Solutions to patients with poor adherence

(e.g. administration and reminder systems that meet regimen requirements and that the patient feels able to manage)

Patient care plans for improving compliance and healthy behaviours

#### Adherence Research

# 1.2.8 Clinical Interventions Service

# **Drug-related problems**

- The etiology and risk factors for drug-related problems
- Assess medication appropriateness and identify drug-related problems based on indication, effectiveness, safety, and convenience (IESC)
- Process to predict, identify, prioritize, solve and prevent actual or potential drugrelated problems

(e.g. duplication, dosage, drug interactions, adverse drug reactions, frequency, dosage form, indication mismatches, incompatibilities, allergies)

 Documentation of drug-related problems: classification, standards of practice and research

# **Drug-related needs**

 Assessing a patient's drug-related needs, including patient medication experience and patient-specific goals of therapy

# **Clinical intervention programs**

 Intervention strategies and practical interventions that pharmacists can perform in order to resolve drug-related problems

(e.g. provide additional information on medications if misunderstanding exists, tailor medication schedules if problem is forgetting doses, develop cues to taking medications, teach self-monitoring techniques, teach use of compliance aids, use motivational interviewing principles and techniques, refer to appropriate providers of care or other sources of assistance, confer with prescriber about simplifying regimen)

- Documentation and evaluation the effect of the intervention
- Technology for dealing and recording clinical interventions

# 1.2.9 Medication Use Process and Quality Use of Medicines

# The medication use process

- Patient-centred model of the medication use process
- The steps of the medication use process and the role of pharmacy and other disciplines in the process
- Mechanisms and approaches in improving medication use process in pharmacy practice
- Policies and processes used to effect change in the drug use process
  - (e.g. drug use evaluation, pharmacy and therapeutics committee functions, and medication therapy management services)
  - National and global changes in drug use

# The rational use of medication

- Rational use of drugs in caring for patients
- The principles and practices of safe, appropriate, and effective medication use
- The role of the pharmacist in optimizing the use of medicines and improving health outcomes

# The medication use evaluation

- The importance of drug utilization evaluation in pharmacy practice
- What is being used: an assessment of specific medications being used in certain situations and settings
- How is it being used: an assessment of the patterns of use (including how much, where, when, and by whom)
- Why is it being used: assessment of the reasons for medication use and the functions that drug products serve in society

# **Quality use of medicines**

- Principles of quality use of medicines
- Clinical governance as it relates to the quality use of medicines

(e.g. drug utilization review and evaluation, formularies, therapeutic guidelines)

- The role of the pharmacist in ensuring quality use of medicines in the individual patient with multiple medications
- Concepts of quality improvement and how these concepts can be used to improve the quality of medication use in collaboration with patients, physicians, pharmacists, administrators and regulators
- Medication quality assurance programs

(e.g. monitoring adverse drug reactions, drug and herbal product interactions, and medications errors)

# 1.3 Medication Dispensing and Distribution Systems

# **1.3.1 Prescription Process**

# **Introduction to prescription medicines**

- The prescription practice
- Medical and prescription terminology (standard abbreviations and symbols used on prescriptions and institutional medication orders)
- Principles, function and legal requirements of a prescription within the supply of medicines
  - Prescription requirements

(e.g. types, language, measures, patient data and profiles)

- The format and components of a typical prescription and institutional medication order
- Assess and prescribe as appropriate, with supporting documentation, including initiating pharmacotherapy, prescribing medications, adapting and modifying prescriptions, and refilling prescriptions
- Different methods of prescribing

(e.g. hand-written, electronic, faxed and phoned prescriptions)

Prescription documentation

# Healthcare professionals with prescriptive authority

- Independent and dependent models of prescribing authority
- Pharmacist authority to adapt, modify and prescribe; Prescription transfers

**Reimbursement for prescribing services** 

# 1.3.2 Preparation and Dispensing of Prescriptions

# Pharmaceutical calculations relevant to the practice of pharmacy

- The pharmaceutical application of calculations in order to accurately interpret, prepare and dispense a physician's order of prescription
- Dose calculations and adjustments necessary to compound, dispense, and administer medications

# Introduction to the medication dispensing process

- The service of dispensing prescription medicines
- Pharmacist's dispensing rights and responsibilities
- Legal, technical and professional aspects of dispensing prescriptions
- Dispensing medications in outpatient and inpatient settings
   (e.g. in community, hospital, home healthcare, long-term care settings)

# Process and procedure of dispensing medication

The main stages in the dispensing process

(e.g. the initial patient encounter, accepting a prescription, identifying if a prescription contains all legally required components, the patient profile review, processing the prescription, preparing/compounding the medication, labelling and packaging for extemporaneous preparation, checking the dispensed medication/checking the final product, counseling the patient or care-giver on the appropriate use and storage of the prescription)

 Processes in dispensing to minimize the making of errors and maximize the detection of errors

# Read and interpret/evaluate the prescription

- Knowledge needed to interpret prescription and medication orders (verbal and written)
- Basics of prescription validation
- Evaluate the appropriateness of a given prescription or medication order based on patient and disease-specific factors. Evaluate prescriptions for indication, effectiveness, safety, convenience (IESC)
- Evaluate new prescription orders, and consider how these new orders will impact on current therapy, prepare the new order, and address any and all potential problems that are identified
- Analyse a prescription/medication order for potential errors and omissions

# Dispensing different types of drugs/products

Dispensing different types of drugs/products

(e.g. dispensing extemporaneous and non-extemporaneous medicines; dispensing alternative brands (drug product selection and generic substitution); aseptic and cytotoxic dispensing; dispensing controlled drugs)

Prescription and non-prescription medication alterations specific for special population patients

# **Dispensing technologies**

- Technology and automation commonly found in practice settings in order to accurately and efficiently dispense medications
  - Computer software functions to process prescriptions
  - Integration of dispensing software with the electronic health record
  - Automated dispensing stations

# 1.3.2 Preparation and Dispensing of Prescriptions (cont.)

The development and maintenance of patient medication profiles

- Legal requirements of patient medication profiles
- Retrieve and assess information regarding medical conditions and drug treatments

# **1.3.3 Distribution Systems**

#### **Access to medications**

• The role of the pharmacist in medicines supply

# **Drug distribution systems**

- The drug supply/distribution chain
  - Supply of prescription medications
  - Unusual supply
  - Factors influencing the supply and availability of medicines
- Aspects of medication distribution process
- Managing drug distribution services
- The legal requirements for usual drug distribution
- How principles of pharmacoeconomics impact the medication distribution system
- The role of professional staff and support personnel in medication distribution

# Pharmacy technology and medication distribution models

 The evolution of pharmacy drug distribution systems and the impact on pharmacy services over time

(e.g. floor stock, unit dose, dispensing cabinets)

- Humanistic and technological factors involved in medication distribution processes
- Tools and technologies related to the drug distribution process in various practice settings
- Automation and central vs satellite pharmacies
- Automated systems for distribution and the role of automation in the practice setting
- Care of patients in pharmacy drug distribution and control systems
- IV admixture systems, chemotherapy and parenteral nutrition, unit-dose, pre-packing systems
- Unit dose distribution and advantages of its use

Pathways medications take from the manufacturer, through various distribution channels, to the consumer

- The process of drug distribution through community pharmacy channels
- Channels of drug distribution

(e.g. distribution chain for pharmaceuticals; distribution channels for biopharmaceuticals; distribution of medical devices; distribution of dietary supplements and cosmetics; the closed system of controlled substance distribution)

• Alternative channels of distribution and vulnerabilities of the system

How the medication distribution system supports the safe and effective use of medication

- Issues associated with safe and appropriate drug distribution in various practice settings
- Methods to identify, evaluate, correct, and prevent errors in the medication distribution system
- The development, implementation, and evaluation of practices that assure safe, accurate and time-sensitive medication

# 1.3.3 Distribution Systems (cont.)

How the medication distribution system supports the safe and effective use of medication (cont.)

- Comparison of several quality assurance strategies and choice of the most appropriate ones to evaluate the system
- Distribution of pharmaceuticals to inpatients
  - Compare and contrast centralized and decentralized drug distribution systems in a hospital setting
- How pharmacy information systems and automation is used to support safe and efficient drug distribution in a community or hospital setting

# Global and cultural awareness in medication supply

- Distribution of pharmaceuticals in developing countries
  - Drug shortages, rationing and emergency preparedness
  - Debate regarding drug shortages due to supply chain fluctuations and disasters, especially in relation to ethical dilemmas in the practice of pharmacy
  - The various stakeholders involved in the debates on drug shortages and how these viewpoints are important to pharmacists

# Storage and disposal of medications

- Stability, storage, toxicological and social issues relating to drugs
- Principles and procedures for drugs storage
- Ensure the integrity of drug products
- Storage and handling of drugs

(e.g. storage of parenteral or enteral products employing aseptic techniques)

Management of drug recalls, disposal of drugs, expired drugs

# Repackaging and labelling of pharmaceuticals

- Prepackaging requirements of drugs
- · Labeling and packaging requirements
- Label pharmaceutical dosage forms to comply with legislation and best practice

# **1.3.4 Drug Administration**

#### Introduction to medication administration

- Pharmaceutical products and the common dosage forms, routes of administration and related devices
- Knowledge and competencies necessary to safely and effectively administer medications

(e.g. safety measures involved in administering medications by injection; emergency protocol: adverse reaction planning)

Drug administration techniques

(e.g. appropriate intramuscular, subcutaneous and IV injection techniques)

• Administration of medication to children

(e.g. "teaspoon")

- Self-administration techniques
- Clinical nutrition support
- Supervised administration in the pharmacy

(e.g. methadone)

# **Drug delivery systems**

- Basic principles of drug delivery
- The appropriate use of drug delivery systems to ensure appropriate response to therapy of medications used in a variety of disease states
- Current dosage delivery systems and their components
- The interplay between medication delivery systems and medication safety
- Quality assurance and management of drug delivery systems in different practice settings
- Supervision of medication delivery systems in the institutional and community settings

### 1.4.1 Obtaining a Patient History

#### The clinical interview

Patient interviewing techniques

(e.g. introducing self, explaining purpose of the interview, beginning new areas of inquiry with openended questions, asking more personal questions later in the interview, clarifying patient responses, summarizing key information, organizing interview in logical and consistent manner)

How to conduct patient interviews with diverse patients/caregivers

(e.g. patients with cognitive impairment)

Ability to conduct a patient interview

(e.g. with gathers information about the patient's chief complaint/needs and medications)

- Identify appropriate information in a patient interview that will affect drug use (e.g. drug dose, schedule and medication adherence)
- Use identified information from a patient interview

(e.g. to select the appropriate resources to provide patient information on how to prevent disease exposure or transmission; to communicate a tailored therapeutic strategy as well as therapeutic alternatives to the prescriber or patient for the correction or prevention of drug-related problems)

# Acquisition of a comprehensive health history

- The basic principles and techniques of history taking and their different components of information
- Obtain necessary information from a patient

(e.g. to determine if guidelines regarding their care are being met)

- Obtain a complete medication history for a patient along with patient understanding of purpose and prescribed or recommended regimen for each medication
  - Assesses how each medication is actually being used

(e.g. frequency of use; number of doses missed in a typical week and reasons for missed doses; if appropriate, observes techniques of administration such as with a metered dose inhaler)

Assesses perceived problems with each medication

(e.g. difficulty administering medication, cost of medication, and inconvenience of dosing regimen)

- Assesses any side effects the patient may be experiencing with all medications being taken
- Assesses medication effectiveness

(e.g. patient perceptions of effectiveness of each medication or treatment regimen; how patient determines medication is working; how physician determines medication is working; results of lab tests or specific information on key indicators of treatment success, including patient-reported outcomes such as pain scores)

# Collect, assess and interpret patient information

 Collect pertinent information from the medical chart (health and medication history forms) or database

(e.g. information about prescription and nonprescription medications, herbal products and other dietary supplements, health and wellness information, patient lifestyle habits, preferences and beliefs, health and functional goals, socio-economic factors that affect access to medicine, allergies/adverse reactions, and disease)

- How to read and interpret patient charts
- Assess a patient's health status
  - The collection and assessment of subjective and objective data
  - Discriminate between reliable and unreliable patient information when you know their source
  - Identify the benefits of, and barriers to access to patient data during the patient care process

# 1.4.1 Obtaining a Patient History (cont.)

# Collect, assess and interpret patient information (cont.)

 Interpret relevant patient information/data to determine medication related needs (MRNs) for general and patient-specific scenarios

(e.g. demographics, social conditions, medical history/status, co-morbid conditions, physical assessment, laboratory/other diagnostic tests, medications, allergies)

- Compare and contrast (differentiate) therapeutic alternatives to meet a patient's MRNs by considering, for example, clinical efficacy, adverse effects, drug interactions, availability, affordability and adherence
- Select and justify the most appropriate therapeutic alternative to meet a patient's MRNs

### Organize and document patient information

- Organization and documentation of pertinent information from a patient interview, laboratory or diagnostic report, or from another provider's note
- The structure, development, and use of various documentation styles
  - Commonly used formats (e.g. SOAP note) and structures (e.g. charts)

### Patient records and systems

- Use of a patient documentation system to obtain and document patient information
- Creating, maintaining, management and utilizing individual patient records
- Create a patient database following completion of a medication history interview
  - Types of information gathering and formats for the database
- Understand need for interoperability of health records and data exchange and its impact on collaborative patient-centred care

# 1.4.2 Patient Screenings

### The role of diagnostics in the clinical continuum of patient care

- The importance of differential diagnosis in the clinical evaluation of a patient
- The fundamentals of laboratory medicine and its importance to screening, diagnosis, and evaluation of patients
- Patient assessment focused on clinical laboratory interpretation and monitoring

#### **Diagnostic tests**

- The use of several common diagnostic tests, utilized to screen disease and monitor patient response to selected drug therapy
- Different types of testing (lab, imaging, etc.) and how to critically judge information provided by various tests
- The appropriate lab test(s) to assess a particular organ system and selected diseases
- Determine the reliability of diagnostic testing in terms of sensitivity, accuracy, positive predictive value and negative predictive value
- The scientific rationale behind different methods of diagnostic testing
- Drugs and physiologic factors that can interfere with specific lab tests

# **Clinical laboratory testing**

- Knowledge and technical ability to order lab tests
- Understanding of how the test is performed and the appropriate techniques for measurement of: cholesterol, blood glucose, bone density, PSA, body fat analysis and other parameters, etc.
- The assorted techniques to obtain samples for testing
   (e.g. perform a fingerstick blood glucose using a blood glucose monitor)
- Laboratory testing in resource-limited settings
- Construct a differential diagnosis for a patient based on a variety of clinical scenarios

#### Interpretation of laboratory test results

- Introduction to laboratory values and the fundamentals of interpreting clinical laboratory test results to assist with the diagnosis or management of disease
- Identify normal and abnormal laboratory ranges and values for common tests
- The clinical implications of abnormal levels
- Important signs and symptoms associated with abnormalities of common laboratory values
- False positive and false negative results

# Wellness and health screenings

- Development and implementation of health-screening programs in a variety of pharmacy practice settings
  - (e.g. cardiovascular risk screening: 10-year risk for coronary heart disease (CHD) and the risk factors for CHD)
- The importance/role of well-care screenings in specific population
- Screening methods
- Screening and referral services (disease detection and advising patients/patient groups on the need for further medical evaluation)
- Screening for drug induced diseases

# 1.4.2 Patient Screenings (cont.)

# **Monitoring patient parameters**

- Monitoring parameters take into account drug, patient and disease specific data
- Establish intervals and frequencies for monitoring
   (e.g. check temperature twice daily, measure intake and output every 8 hours)
- Determine an appropriate monitoring programme to allow assessment of management goals
- Patient monitoring in inpatient, community and clinic settings

# **Therapeutic Drug Monitoring (TDM)**

- Concepts of therapeutic drug monitoring
- Techniques used for therapeutic drug monitoring by pharmacists
- Monitoring and evaluating the patient's response to therapy (therapeutic efficacy and safety)
- Medication alterations specific for special population patients
  - Dosage calculations, dosage adjustments and drug monitoring for positive/negative outcomes in special population patients

(e.g. geriatric, neonates, infants, children and pregnant, patients with renal and hepatic disorders, sickle cell, cystic fibrosis, genetic disorders)

# **OTC point-of-care testing devices**

- The various diagnostic tests available on the market
- The use and the strengths and weaknesses of performing rapid diagnostic tests in the ambulatory setting
- The role of home diagnostic and monitoring devices in the diagnosis, staging, and monitoring of various disease states
- Properly use and interpret select point-of-care screening technology (e.g. glucometers, bone densitometer, INR point-of-care device, at-home cancer tests)

# 1.4.3 Physical Assessment

# Introduction to physical assessment

- Patient physical assessment for diagnosis and monitoring, and the use of patient medical status inventories in pharmaceutical care
- Basic theory, terminology and techniques used in performing the major components of a physical exam
- Systematic approach to performing a physical assessment of a patient using four modes of assessment: inspection, palpation, percussion and auscultation
- Interpretation and evaluation of the patient physical state
- How physical assessment can be used to assess medication efficacy, toxicity, or side effects; and potential drug interactions
- Recognize physical findings that may be attributed to common disease states and pharmacotherapy

# Vital signs and general observation

- Height and weight (body mass index and waist circumference)
- Vital signs: respiratory rate, heart rate, blood pressure, temperature
- Identify when and why vital signs should be taken
- Variations in technique used to assess vital signs

(e.g. various methods and sites used to measure blood pressure; how to measure the radial and the apical pulse; compare tympanic, oral, and axillary methods of measuring body temperature; the technique for assessing respirations)

Ranges of acceptable vital signs for an infant, a child and an adult

# **Assessment of body systems**

- Symptom assessment (physical and psychosocial)
- Components of a physical examination

(e.g. Integumentary; HEENT (head, eyes, ears, nose, throat); Neck; Back; Breasts/axillae, epitrochlear nodes; Thorax and lungs; Cardiovascular and Peripheral vascular; Gastrointestinal/Hepatic/Renal; Abdomen; Endocrine Assessment; Lower extremities; Musculoskeletal; Neurologic Assessment and Mental Status Exam; Optional exams; Rectal examination in men; Genital and rectal examinations in women, and the changes that occur in the presence of disease or drug therapy)

- Pain assessment (determine a patient's pain level utilizing a pain scale)
- Physical assessment techniques using the appropriate devices and equipment for different organs and systems

(e.g. use of a peak flow meter in pulmonary assessment)

#### Principles of ECG and common abnormalities

 Principles of cardiac function and electrophysiology with a focus on systematic interpretation of cardiac rate and rhythm parameters for electrocardiogram

# **Emergency medical technician service**

- Topics in pharmacy emergency preparedness
   (e.g. anaphylaxis)
- Triage patients to the appropriate component of the emergency response system

# Basic life support and first aid

- First aid training
- The basic principles of cardiopulmonary resuscitation
- Principles of advanced cardiac life support and management of patients with acute cardiovascular emergencies

# 1.5 Medication and Patient Safety

### 1.5.1 Medication Errors

# The concepts of healthcare quality and medication safety

- Introduction to the problem of medication errors in healthcare
- The evolution of concern about medication errors, adverse drug events, medical error, and patient safety

# **Epidemiology of patient safety and medication errors**

 Epidemiology of patient safety and medication errors, ascertainment and analysis of medication error data

# The basic safety principles employed in the medication use process

- The types and causes of medication errors
- Strategies for improving the medication use process (e.g. medication use safety systems and medication error reduction programs)
- The role of medication safety resources and reporting systems

# Causes of medication errors, including human and systems factors

- Psychosocial aspects that contribute to medication errors
- Inter- and intra-personal aspects that contribute to medication errors
- Factors that may contribute to medication-related errors in a community practice setting

(e.g. dispensing under time pressure, stress)

- Role of drug names, drug packaging, labeling in medication errors
- Drug categories and abbreviations associated with error risks

#### Medication errors and their consequences on patients and healthcare in general

• The impact of medication errors on the individual patient and their family

# Mechanisms to promote medication safety

- The importance of medication error detection, reporting, evaluation and prevention
- The principles and procedures of medication safety initiatives
- The development of strategies to reduce the likelihood of medication incidents
- Role of the patient in preventing medication errors
  - Counsel patients to supply the necessary medical information to the healthcare team

# **Medication error detecting methods**

- The process for conducting an incident analysis (root cause analysis)
- The process for conducting a failure mode and effects analysis (FMEA)
- Identify medication errors based on their corresponding ISMP key element
- Resources to monitor and evaluate errors

# Medication error reporting systems and techniques to identify and categorize medication errors

- ISMP, Medwatch, MUE, guideline development
- Determine when to report an error and what information to include
- Compare and contrast mandatory vs voluntary reporting programs
- Integrate professional responsibility to report and analyse medication errors

# 1.5 Medication and Patient Safety

# 1.5.1 Medication Errors (cont.)

# **Medication safety practices**

- Pharmacy leadership in medication safety
- Risk management and medication errors
- Plan for system improvement to enhance medication safety
- The design of error-free medication systems
- The role of tall-man lettering in prevention of errors related to look-alike, sound-alike medications
- Medication prescribing, dispensing, and administration errors
  - Integrate communication skills to identify, reconcile, and prevent prescribing errors: methods to correct prescription errors through appropriate physician communications
  - Modify the pharmacy dispensing process to prevent dispensing errors
  - Effectively communicate drug information to those involved in medication administration
  - The importance of follow-up and monitoring in preventing errors

# **Supporting technology and automation**

- Compare/contrast computer systems and computerized physician order entry (CPOE) systems with regard to errors
- The role of automation in reducing errors
- How point-of-care technology can prevent medication errors

Significant medication error research

# 1.5 Medication and Patient Safety

# 1.5.2 Patient Safety

# Patient safety concepts and principles

- Difference between patient safety and quality of care
- Topics of the patient safety such as human factors, systems thinking, effective teamwork, safety culture and managing errors
- The importance of patient safety in the clinical setting

# Organizations and services related to patient safety

- Organizations devoted to assurance and advancement of quality healthcare
- The importance of organizational leadership and teamwork in improving safety
- Strategies for creating a safe working environment in the hospital and community pharmacy setting

# Methods of improving patient safety

- Communication strategies that enhance patient safety
  - Provide the basic information needed for a patient to safely achieve medication success
  - The importance of health literacy's impact on patient safety
- Management of medication use safety systems
  - The use of informatics tools to promote patient safety
  - Technologies and systems used to automate the medication delivery process and impact on patient safety
  - The different types of computer system features that can contribute to drug dispensing safety
  - Patient safety (triple check, use of computer dosing checks, REM's). Patient safety community (work flow, clutter, job assignments)
  - The requirements for a compliant Risk Evaluation and Mitigation Strategy (REMS) program

#### **E-prescribing and patient safety**

- The types of errors that can occur with e-prescribing software
- The types of errors prevented with e-prescribing software
- The role of clinical decision support as it relates to e-prescribing

Role of professional pharmacy societies, boards of pharmacy, governmental agencies, and legislation in promoting and improving patient safety

# 1.6.1 Drug Information Concept and Applications to Clinical Practice

# Philosophy and fundamentals of drug information practice

- Principles and procedures in the provision of drug information
- Drug information in the 21st century
- Information literacy
- How information can be used to change practice
- Information resources
- Drug information services

### Drug information retrieval processes, and analysis

- Systematic searching and hierarchy of information to support clinical judgement and patient care
- Use of drug information and medical references and resources to identify and retrieve pertinent scientific information
- Application of drug information and literature evaluation skills in the delivery of patient-focused care
- The application of drug information in various practice settings

### Manage medication information

- Fundamental skills needed for the provision of drug information in pharmacy practice
- Legal and ethical responsibilities of the pharmacist regarding the provision of drug information
- The differing drug information needs of healthcare professionals and patients
- Providing reliable drug information to health professionals and consumers
- The drug information provider role of the community pharmacist
- Scientific literature presentations

#### 1.6.2 Drug Information Resources

Basic principles of access and utilization of drug information resources in pharmacy practice

Drug information resources as a tool for providing pharmaceutical care

# Types of drug information and literature available and its role

- Multiple forms of drug literature including primary, secondary, tertiary, computerized databases and internet resources
  - Primary literature: the source (original clinical research articles)
  - Secondary literature

(e.g. extensive bibliographies, meta-analysis articles, review articles, clinical guidelines)

Secondary health science databases

(e.g. PubMed/Medline, Embase, OVID, International Pharmaceutical Abstracts (IPA), EBSCO and other library databases)

- Tertiary literature

(e.g. common references and texts books that pharmacists use in practice, internet information resources, mobile resources)

- The features and limitations of primary, secondary, and tertiary literature for use in clinical practice
  - The fundamental tools necessary to identify the quality of healthcare information available in primary, secondary, and tertiary resources
  - The strengths and weaknesses of the various databases
  - The role of the internet in providing accurate and timely drug information
- Identify valid and credible sources of drug information
- Ability to judge the reliability of various sources of drug information

# **Library resources**

- Drug information library resources and access to these resources
- Using libraries: classification systems, electronic searching

# Literature search methodology and techniques

- How to locate, search and access databases, texts, e-books, government resources, websites and various drug compendia
- Effective and efficient search strategies to find needed drug information from primary medical literature, drug references, and other evidence sources
- Efficient internet searching for drug information
  - Literature search engines for lay, professional, and scientific literature
  - Standard indexing-abstracting systems used in searching pharmaceutical/medical literature
  - Search techniques for on-line databases

# Utilization of technology for drug information

- Introduction to using pharmacy related information technology resources
- Use information technology systems to assist in the provision of drug information

# 1.6.2 Drug Information Resources (cont.)

### Drug industry and literature

- Relationship of pharmaceutical industry to drug literature
- Specific situations in which the drug manufacturer can serve as a source of information
- The pros and cons of drug industry sources

# 1.6.3 Asking and Answering Drug Information Questions

# The role and functions of a drug information pharmacist

• Problem-solving skills in the area of drug information retrieval and provision

# **Drug information questions**

- Drug information question formulation
  - Formulate answerable clinical questions given patient-specific information
  - Steps of asking a PICO question (Problem, Intervention, Comparison, Outcome)
- Skills required to handle different types of drug information questions

# Information request

- Classification and evaluation of information requests
  - Categorize questions (e.g., adverse effects, identification, drug therapy) to aid in gathering of background information and information retrieval
- Collect all pertinent data necessary to investigate a particular drug information request
- Determine whether the response requires rapid attention or may be delayed
- Assess the availability of colleagues, government agencies, support groups, etc. which may be beneficial in resolving specific requests

# **Concepts involved in responding to drug information requests**

- Analysis of the question
  - Define the question that needs to be answer
  - Ability to clarify questions before answering
- Conducting a systematic search
  - Apply knowledge of research methods and information sources to retrieval of appropriate information for answering drug information questions
  - Primary literature evaluation and critical thinking skills necessary to formulate prudent drug information responses and patient care recommendations
  - Synthesize the results from publications to support the answer to a clinical question
  - List all information sources used to answer clinical questions
- Formulating and communicating a response
  - Use the information gathered to formulate evidence-based answers
  - Provide complete, clear and concise written and oral responses to drug information questions at a level appropriate to the requester (e.g. professional or patient), including required references
  - The importance of using a systematic approach to answering drug information questions
- Document responses to information requests in a professional manner

#### Drug information centers

- History of drug information centers
- The functions, structure and services of a drug information center
- Role of the drug information specialist

# 1.6.4 Drug Literature Evaluation

#### Introduction to clinical literature evaluation

 Concepts of drug literature evaluation and application to pharmacy practice and patient care

(e.g. drug therapy decision-making, to make patient/population recommendations, to solve drug-related problems)

- Assessing the quality of information from a variety of sources
- Overview of the principles of bibliometric and medical/pharmaceutical literature evaluation

# Critical appraisal of pharmaceutical and medical literature

- Critical evaluation of primary literature/clinical guidelines focused on the provision of drug information for individual patients
- Systematic approach to critical appraise medical literature utilizing a structured framework

# Analysis and interpretation of pharmaceutical and medical literature

- Contemporary issues in the interpretation of biomedical research
- Drug literature analysis techniques
- Applied data analysis and biostatistics in the interpretation and critical analysis of biomedical literature needed to develop and utilize evidence-based recommendations for patients and healthcare practitioners

# The various types of research articles and critically evaluate these resources

- The basic structure of scientific/medical articles: abstract, introduction, methods, results, discussion, and conclusion
- Assessing appropriateness of study
  - (e.g. study design, quality of the data, statistical test selection and application, study limitations, bias/confounding, objective-methods cohesion, statistical analyses, and implications of the study results)
- Critical evaluation of internal validity, external validity, and impact on clinical care
- Evaluation of the strengths and weaknesses of the article, and recognize errors in study design or statistical methodology

# **Evaluating studies**

- Distinguish between various study designs (observational, randomized controlled trials, qualitative, etc.) and interpret their relative value and application to practice
- Evaluating a study: the ABCS (Applicability, Bias, Confounding, Significance)
  - How to evaluate studies of Therapy (Randomized Controlled Trials)
  - How to evaluate studies of Prognosis/Cohort Studies
  - How to evaluate studies of Harm/Case-control studies
  - How to evaluate studies of Harm (Observational Studies)

### 1.6.5 Evidence-Based Clinical Practice

# Introduction to Evidence-Based Medicine (EBM)

- Concepts and rationale for evidence-based practice
- The difference between the traditional medical paradigm and the EBM paradigm
- Principles and methods of EBM
- Interpreting the results of statistical tests that are relevant to evidence-based practice

# The notion of levels of evidence/herarchy of evidence

- The hierarchy of study designs as it relates to level of evidence
- Strategies to understand, question and evaluate evidence
- How to grade the level of evidence, based on the quality of the study

### Evidence-based clinical decision-making

- The roles of clinical evidence and evidence-based practice in clinical decision-making for patient care
- Evidence-based decision-making process
- Patient characteristics and medical evidence for clinical decision-making
- Make medication management and medication-related policy decisions for individuals or populations based on the best available evidence
- Make decisions based on available health sector data
- EBM resources

# Application of clinical trial results to patient care

- The usefulness of clinical trial data for making evidence-based practice decisions
- Interpreting clinical trial data and applying the data to patient cases to support therapeutic recommendations
- Landmark clinical trials that have influenced the way medications are used in clinical practice

# **Practice of evidence-based pharmacy**

- Identification, evaluation, and application of evidence relevant to improving clinical pharmacy practice and patient-centred pharmaceutical care
  - (e.g. assessing patients' drug-related needs; identifying, resolving, and preventing drug therapy problems; developing a care plan and plan for follow-up; communicating with a patient and the healthcare team)
- The role of the pharmacist in EBM

# **1.6.6 Professional Writing**

# **Professional writing for clinical practice**

- · Basic principles of scientific writing
- Use professional writing style and tone

# Practice and reflect on writing in professional, public, and academic genres

• The types of professional writing

(e.g. the résumé, the business letter, professional emails, the memo, articles, and journal writing)

Common forms of medical writing

(e.g. patient reports, clinical notes, case studies, protocols, care instructions, writing for a medical audience)

Academic writing

(e.g. writing abstracts, research reports, academic papers, literature reviews)

# How to write and prepare a manuscript/article for publication

• The process of writing and publishing an article

(e.g. analysing published literature, soliciting journals for interest, referencing, journal requirements/deadlines, peer review, and author rights/responsibilities)

- How journals are published and papers accepted for publication
- The publication and peer review processes of scientific journals
- Identify which journals are considered highly reputable
- The purpose of editorials that accompany major article publications

# Integrity in medical writing

- Copyright, appropriate use of sources and misuse of sources
- Strategies to avoid plagiarism

# 1.6.7 Pharmacy and Therapeutics Committee

The role and functions of a pharmacy and therapeutics committee

- The role of the joint commission and its specific requirements for pharmacy practice in the hospital
- The tools needed to conduct new drug evaluations and formulary reviews

The development, implementation and use of drug formularies in community and institutional settings and across the healthcare system

- How drugs are listed in hospital formularies
- The fundamentals of formulary management
- Propose and justify a medication addition or deletion to a health-system formulary

The rationale for clinical practice guidelines, the process by which they are developed, and potential limitations to their use

# 1.6.8 Health Information

### Contemporary health topics

- Distinguish among lay, professional, and scientific literature
- Systematic approach to retrieving health information
- The potential impact and implication of published information on current practices

# Facilitate appropriate consumer use of health information

• Literacy in the access and use of health information

### Health information technology

- Developing, evaluating, using, and maintaining healthcare information systems
- The availability, selection and use of electronic and printed sources of medical and pharmacy information

# Manage bibliographic data

- Principles of information management
- Formulate strategies for keeping current with the medical and pharmacy literature
- Correctly citing and referencing literature sources

**Factors affecting health information exchange** 

# **Educational Contents from Category of Social and Behavioural Sciences Aspects Block**

1	Clinic	al Sciences Aspects			
	1.1	Pharmacy Practice			
	1.2	Pharmacist-Provided Care			
	1.3	Medication Dispensing and Distribution Systems			
	1.4	Patient Assessment			
	1.5	Medication and Patient Safety			
	1.6	Drug Information and Literature Evaluation			
2	Socia	Page			
	2.1	Sociological Aspects of Pharmacy Practice	87		
	2.2	Patient-Reported Outcomes	89		
	2.3	Professional Communication	91		
	2.4	Ethics	101		
	2.5	Public Health	108		
3	Administrative Pharmacy Sciences Aspects				
	3.1	Healthcare Systems			
	3.2	Economics/Pharmacoeconomics			
	3.3	Practice Management and Leadership			
	3.4	Pharmacy Law and Regulatory Affairs			
	3.5	Informatics and Health Technology			
4	Miscellaneous				
	4.1.	Research Design			
	4.2	History of Pharmacy			

# 2.1 Sociological Aspects of Pharmacy Practice

# 2.1.1 Sociological, psychological, and behavioural aspects of pharmacy practice

# Introduction to sociological theories and concepts that impact health and healthcare

- Definition of health, wellness and wellbeing
- The differences between health and healthcare
- The differences between illness, sickness, and disease
- The social, emotional/psychological aspects of health and illness that patients often experience
- The social model of health. Variety of wellness models (including Rath and Harter)

### The foundations of social and behavioural pharmacy

- The social and behavioural issues that impact health including their influence on the pharmacist-patient relationship and the ability of the pharmacist to provide patient care
- The application of behavioural science principles to help understand the influence of humans on the appropriate delivery of pharmacy care services and drug use in society

# Introduction to psychology

- The ways in which individual psychology shapes and affects health and healthcare
- The major psychological theories (behaviouralism, cognitivism, developmentalism and psychoanalytic theories) and application of each of these theories to pharmacy practice and patient care
- Elements of behavioural psychology that are relevant to the practice of pharmacy
- Theoretical basis for human behaviour: development, conditioning, learning, motivation, perception, ability, personality, stress

# **Health behaviours**

- Overview of theoretical health behaviour models
- How theories of health behaviour can be applied to maintaining and improving health and wellbeing
- Behavioural aspects of patient-pharmacist interactions and doctor-pharmacist interactions

#### Factors that influence health behaviour

- The environmental, geo-political, socioeconomic, cultural, psychological and biological factors that influence the health and wellbeing of individuals, families, communities and populations
- How certain patient characteristics such as gender, race, sexual orientation, culture, religion, disparities, literacy, and health beliefs affect a patient's interactions in the healthcare system and enhance or compromise the effectiveness of treatment regimens

# Patient and professional behaviours

- Patient and health professional behavioural science principles
- Psychosocial processes that underpin patient health behaviours
- Understand, influence and modify patient behaviours
- Professional behaviours that help improve patient quality of life and patient safety

# 2.1 Sociological Aspects of Pharmacy Practice

# 2.1.1 Sociological, psychological, and behavioural aspects of pharmacy practice (cont.)

### **Health Behaviour Change**

- Health belief model
- Models and theories of behaviour change (Transtheoretical Model of Change) and stages of change model
- Principles and strategies of behaviour modification
- The process of behaviour change
  - The 5 A's Behavioural Intervention Protocol

# 2.2 Patient-Reported Outcomes

### 2.2.1 Patient Humanistic Outcomes

#### Economic, clinical, and humanistic outcomes (the ECHO model)

 The ECHO model as a framework of measuring program, procedure, or product effectiveness

# **Introduction to patient-reported outcomes**

- Definition and examples of patient-reported outcomes

   (e.g. quality of life, patient satisfaction, adherence, as well as a reduction in drug-related morbidity and mortality)
- Similarities and differences between patient-reported outcomes and professional reported outcomes
- How patient-reported outcomes are used by healthcare providers, researchers, policy makers
- The participation of patients in achieving positive clinical outcomes and maximizing their health-related quality of life

# Design an evaluation tool to evaluate an outcome

- Classical test theory and item response theory use in patient-reported outcomes instruments
- Psychometrics and questionnaire development
- Concepts of validity, internal reliability, sensitivity, test-retest reliability, generalizability, readability, respondent burden
- Methods by which survey questions and responses are chosen
- Cross-cultural applications

#### Health-related quality of life/health status measures

- The World Health Organization definition for health-related quality of life (HRQL)
- The domains and subdomains that are commonly assessed in HRQL instruments
- Wilson and Cleary model: relationship between physiologic, biologic, symptom, and functioning
- Preference weighting and utility analysis
- The concept of clinically meaningful difference in health-related quality of life (HRQL) research
- Generic or a disease specific HRQL instrument
- The term response shift and its implication to health-related quality of life (HRQL) studies
- Sources of existing health-related quality of life (HRQL) data (e.g. large datasets, registries, and proprietary datasets (MEDSTAT))

#### Satisfaction

- The theoretical foundation from which satisfaction is derived and used in healthcare assessment
- The various types of satisfaction measured in healthcare; specifically, satisfaction with medication; satisfaction with healthcare; satisfaction with health state
- The uses of satisfaction data, including use by accreditation agencies, payers (insurance companies, purchasers of healthcare), and research

# 2.2 Patient-Reported Outcomes

# 2.2.1 Patient Humanistic Outcomes (cont.)

#### Work-related outcomes: presenteeism, productivity, disability

- The concept of work and work outcomes
- The common domains constructing health and work-related outcomes
- The methods used to determine health and work related outcomes
- The findings of studies that evaluate health and work related outcomes
- Secondary data sets that contain patient-reported work-related outcomes

## 2.3 Professional Communication

# 2.3.1 Communication Concepts

# Introduction to communication

- What is communication?
- Basic principles, skills and techniques of good communication

   (e.g. listening skills, asking questions, providing empathy, understanding/managing confusion, understanding/managing conflict, and understanding/analysing nonverbal behaviour)
- · Communication models and styles
- Design, preparation, delivery, and critique of educational, informative, and persuasive communication methods
- Barriers to effective communication and strategies to overcome those barriers (e.g. environmental barriers to communication with patients)

# The components of effective interpersonal communication

- Introduction to factors and processes involved in interpersonal communication: source and receiver variables, and strategic interaction with different types of people
- Forms of communication: verbal (oral, written, visual) and nonverbal communication skills and strategies
  - Factors that may influence the effects and effectiveness of different forms of communication with different stakeholder groups
  - Written communication as an effective tool for interpersonal communication and documentation of recommendations and consultations
- Improving personal communication

# **Professional communication**

- · Professionalism in communication
  - Communicate pertinent information in concise and professional manner
  - Professional dress and appearance
- Ethical considerations in professional communication
- Communicating with impact

#### **Health communication**

- Influencing health through communication
  - Use of health information/communication as a health promotion strategy
- The essential elements and skills in the area of healthcare communications
- Communicate in lay and professional language, choosing strategies appropriate for the context and diverse audiences (strategies for patient-centred and colleague centred communication)
- Persuasion theory and the application of theory to health communication
  - How persuasion principles operate in all facets of healthcare

    (e.g. audience analysis and evaluation for health campaigns, pharmaceutical advertisements, and interpersonal influences on health behaviours)
- The most effective means to communicate opinions and concerns
  - (e.g. express one's knowledge and opinions to team members involved in patient care with confidence, clarity, and respect, working to ensure common understanding of information and treatment and care decisions)

# 2.3 Professional Communication

# 2.3.1 Communication Concepts (cont.)

# Aspects of communication associated with pharmacy practice

- The importance of communication in contemporary pharmacy practice (e.g. in the delivery of optimal pharmaceutical services )
- Application of communication principles and skills that enable development and maintenance of constructive interpersonal relationships in a variety of pharmacy practice settings

### Introduction to interviewing

- Principles of interviewing
- Interview patients and healthcare providers

### 2.3.2 Patient Communication

#### **Patient-centred communications**

- Theoretical principles for communicating effectively with diverse patients, their families and communities in a variety of context
- The ability to communicate in a clear and coherent manner
  - Information with patients, families, and healthcare team members in a form that is understandable, avoiding discipline-specific terminology
  - Evaluating patient comprehension

# The pharmacist-patient relationship and professional interaction

- The importance of the patient/pharmacist relationship and understand how to optimize interactions between them
- Principles required to develop positive relationships and promote positive therapeutic outcomes: engage, empathize, educate and enlist
- Different types of pharmacist-patient relationships
- Techniques, strategies and resources pharmacists use to enhance health-related interactions and interpersonal relationships with patients and care givers

# Communicating health and pharmaceutical information to patients

 Effectively and professionally communicate information related to healthcare, pharmaceutical care plans, population health, and other related information to patients

(e.g. inform patients of choices about their therapy)

- Negotiate decisions with patients about their therapy
  - Written and oral communication skills to facilitate a climate of empathy, shared decision-making, mutual support and trust with families and other caretakers
  - Effective methods for creating positive, therapeutic relationships with patients through the application of communication skills (empathy, assertiveness training, effective listening, clarification to ensure understanding, etc.) and other behavioural interventions
- Communication to improve patient outcomes in the healthcare environment
  - Foundations of clinical communication, including direct and indirect clinical communication techniques to increase the participation of patients in achieving positive clinical outcomes and maximizing their health-related quality of life
  - The pharmacist's role in using communication skills to enhance patient understanding of therapeutic regimens, improve medication adherence and empower patients to become more involved in their own healthcare
- The flaws in many of our traditional communications and assumptions when caring for patients

# Social Cognitive Theory (SCT) and behavioural theories applicable to health-related communication

- Definition of SCT and how it is associated with provider-patient communication
- Other behavioural theories' applicability to provider-patient communication

# 2.3.3 Interprofessional Communication

### Introduction to interprofessional communication

- The importance of professional communication in the interdisciplinary team
- Communication principles and skills necessary for successful interactions with peers, other health professionals and professional contacts
  - The inter- and intra-professional relationships of healthcare providers
  - How to effectively communicate with other healthcare professionals and document the interactions
- Models for in-depth interprofessional communication and behaviour within healthcare teams
- Recognize and understand how the uniqueness of other team members, including power and hierarchy within the interprofessional team, may contribute to effective communication and interprofessional tension

# **Organizational communication in pharmacies**

 Communicate effectively with peer pharmacists, technicians and other pharmacy staff to develop and maintain a positive and productive work environment

# **Communication with healthcare providers**

- Strategies and resources that can be used by pharmacists to enhance communication with prescribers and other healthcare professionals
  - Identification, extraction and interpretation of data to be communicated to other healthcare practitioners
  - Provide constructive feedback to peers
- Communicate with healthcare providers to demonstrate opportunities around collaborative patient care

(e.g. new drug therapy, hot topics, new patient-centred services)

- Communicate and collaborate with physicians, nurses, other healthcare providers, community members, policy makers and administrators in a considered and systematic way, focusing on patient best clinical outcomes
- Share information, ideas and solutions with other pharmacists and health professionals
- Effective communication and team collaboration to clinical decision-making
- Communicating with health professionals in a variety of settings
  - Apply approaches to communication with other healthcare professionals in special settings and with specific groups of people
- Special communication challenges that relate to pharmacists and other healthcare providers
- Obstacles to effective interprofessional communication and communication strategies to overcome obstacles
- Communicating with healthcare professionals to resolve issues
  - Effective professional communication techniques to solve prescription problems and provide drug therapy management in ambulatory pharmacy environments

# 2.3 Professional Communication

# 2.3.3 Interprofessional Communication (cont.)

#### Communication modalities with other members of the healthcare team

- · Verbal, written, graphic, and electronic communication with healthcare providers
  - Appropriate non-verbal, verbal, questioning and listening skills when communicating with other healthcare professionals
- Interprofessional communication formats

(e.g. SBAR, SOAP notes, chart review, pharmacist documentation)

- The importance of standardized interprofessional communication formats
- Compare and contrast different standardized interprofessional communication formats
- The various components of a SOAP note and where each should be placed
- Interprofessional communication calls
  - Communicate via telephone about a patient to resolve a medicated-related problem
  - Transcribe an oral order over the phone

# 2.3.4 Active Listening and Empathic Responding

#### Active listening

- The process of active listening
- Strategies for active listening and body language interpretation that enhance communication with patients
- Active listening skills and techniques
  - The importance of and apply effective listening skills to interview a patient regarding the patient's drug therapy needs
- Barriers to active listening

# **Empathic responding**

- Concepts of "caring" attitude, empathy and compassion
- Social support and emotion in healthcare
- Identify and describe empathic responding and responses used in communication
- Professional attitude with appropriate empathy during interactions with patients and other healthcare providers
  - Communicate in a non-judgmental, non-discriminatory and respectful manner
  - Appropriate verbal and non-verbal expression and display empathy and tact in work-related communication
  - Identify and respond empathically to patient concerns

# 2.3.5 Assertiveness and Resolving Conflicts

### Assertiveness in communicating

- Assertiveness and problem-solving techniques
- Identify and demonstrate assertiveness in communication with patients and healthcare providers, co-workers, managers, and employees
- Compare and contrast passive, aggressive and assertive behaviours
- Constructive criticism and providing feedback

# **Resolving conflicts with patients and others**

- The causes and mechanism of conflicts
- Conflict resolution
  - Conflict management techniques, and negotiation in multiple situations
  - Techniques to establish a harmonious working relationship or to defuse/prevent conflicts at the workplace
- The importance of effective communication to providing effective patient care and minimizing stress and conflict
  - Strategies to facilitate communication with difficulty patients and sensitive health situations

(e.g. angry patients)

- Apply critical thinking, problem-solving and scientific reasoning skills to prevent or resolve problems within the practice of pharmacy
  - Plan appropriate intervention strategies to address problems
  - Plan follow-up to verify problems are resolved and no new problems exist

# 2.3.6 Special Communication Situations

### Communication with specific populations

 Special communication challenges that relate to patients and strategies to overcome these

(e.g. based on gender, age, cultural, racial, socio-economic differences, heightened sensitivity)

Communicating with people of different ages

(e.g. child, adolescent, adult, older adult)

- Generational differences in communication
- Communication strategies to overcome potential sensory, language, and cognitive limitations in older adults
- Effective communication at the end of life
  - The communication needs of dying patients and grieving family or significant others
- Communication with patients with disabilities
  - Assess patients for physical/mental impairment impacting verbal and written communication processes
- Recognize fatalistic statements and appropriately communicate with a potentially suicidal person

#### Health literacy

- The importance of health literacy in patient communication
  - Implications of health literacy for public health and for various patient populations
  - Critically analyse certain disease states and assess how literacy impacts health and wellness with this disease
  - The connection between cultural literacy and health literacy and the ways in which campaigns can be designed to promote health in the context of culture
  - The connection between civic literacy and health literacy and the ways in which campaigns can be designed to promote wellness in the context of civic engagement
- Forces that affect health literacy including culture, health system demands, etc.
- Assess the patient's level of literacy and health literacy
  - The advantages and drawbacks of assessment tools (REALM, STOFHLA) used to measure health literacy
- Communication with patients of varying health literacy levels
  - Health literacy of indigent populations
  - Ability to effectively interact with patients with low literacy
  - Strategies for creating useful internet and print materials for use with patients of varying levels of health literacy
- Issues relevant to low health literacy
  - Limited health literacy as a barrier to patient education and appropriate strategies to overcome barrier

#### 2.3 Professional Communication

# 2.3.6 Special Communication Situations (cont.)

Deal with people from culturally and linguistically diverse backgrounds

- Introduction to cultural competence
  - Cultural diversity: Culturally diverse patients (e.g. Indigenous health)
  - The professional importance of recognizing cultural differences
  - Foundation for development of knowledge, attitudes, and skills required of culturally competent healthcare providers
  - Definitions and models of cultural competence, characteristics of culturally effective practitioners and workplaces
  - Cultural factors that facilitate/hinder communication
  - Cultural communication gaps in healthcare
  - Issues relevant to multicultural communication and the challenges of crosscultural and bilingual communication
  - Working with interpreters, legal and professional imperatives for cultural competence
- How to care for patients who are part of a different culture
  - Cultural sensitivity when interacting with patients
  - Communicate and dealing with people with different cultural beliefs, values, behaviours, practices, religions and languages
  - Ways that culture can affect healthcare beliefs and practices
     (e.g. interactions with patients with health-related and medication beliefs)
  - Strategies to appropriately adjust behaviour or communication style based on cultural and communication considerations in order to optimize patient care (e.g. implement a culturally proficient care plan)

Importance of integrating health literacy and cultural competence to provide quality patient care

#### 2.3 Professional Communication

# 2.3.7 Presentation Skills

#### **Group presentation skills**

- Skills in public speaking
- Present and defend ideas in a logical and effective order
- How to produce a team presentation
- Explain sometimes complex concepts to members of the team who might be from different science backgrounds

#### How to communicate effectively with various audiences

- Ability to present ideas, plans, and data in appropriate written and oral formats to succinctly and effectively communicate with various audiences
- Ability to prepare and deliver effective presentations to groups in a variety of healthcare education and professional settings
- Formal presentation to a professional audience
- Techniques to capture the attention of an audience

#### Communication and dissemination of scientific information in written and oral formats

- Communication skills that scientists need to speak directly, concisely and informatively about their work to colleagues and supervisors, conference audiences or specialist panels
- Methods for research dissemination that are used by many health professionals
   (e.g. papers and review articles, poster, podium presentations, seminars, round table presentations)
- Development of scientific materials to present findings of research studies
   (e.g. appealing posters and presentations, persuasive slides and other audiovisual materials)
- Develop the scientific content of the presentation and handle questions following the presentations

#### 2.4 Ethics

# 2.4.1 Ethical Concepts

# Introduction to ethical theories and principles

- Concept of ethical practice
- Distinguish ethics, morals and law
- Personal values and ethical principles in professional and social contexts

(e.g. autonomy, accountability and dignity, beneficence, veracity, equality and justice, and confidentiality, trust, honesty and integrity, non-malfeasance, respect)

- The primary ethical theories and the impact of social culture in their interpretation and application
  - Differences and similarities between a variety of ethical theories (e.g. consequentialism and non-consequentialism)
- What makes a situation unethical?
- Ethical analysis

#### Introduction to the field of bioethics

- Bioethical principles relevant to the healthcare environment
- The role and autonomy of the patient
- Rights and responsibilities of patients/consumers

#### Ethics and values of a health professional

- The concept of the duty to care
- Ethical issues in teamwork
- Values of the pharmacist as a provider of care

(e.g. ethical, benevolent, empathetic, competent, open-minded, prudent in making judgments, and devoted to serving others)

# **Ethics in pharmacy practice**

- Ethical issues facing pharmacists in today's healthcare environment
- Application of ethical principles, values and theories to pharmacy practice situations
   (e.g. in the provision of pharmaceutical products and services to patients)
- Ethical codes that guide the profession of pharmacy and application in a practice setting
- The interrelationship of pharmacy law and ethics, including legal/ethical workplace issues

(e.g. professional negligence/malpractice, patient privacy, and conscientious objection)

• The elements of a tort claim in the context of pharmacist malpractice

# Ethical decision-making in the context of professional health practice

- The background, history, theories, models and components of ethical decision-making in the professional medical environment
- The process of ethical decision-making
- Ethical decision-making principles to the provision of pharmaceutical care

#### Overview of healthcare business ethics

- Professional behaviour and ethical issues related to the development, promotion, sales, prescriptions, and use of drugs
- Ethical considerations: profit vs patients' best interests

# 2. Social and Behavioural Pharmacy Sciences Aspects

# 2.4 Ethics

# 2.4.1 Ethical Concepts (cont.)

#### Ethics and the pharmaceutical industry

- The history of ethical, legal and regulatory forces that have shaped the pharmaceutical industry
- Common criticisms of the pharmaceutical industry and recent legislative efforts to mitigate specific unethical practices

Classic cases that have shaped medical ethics

#### 2.4 Ethics

# 2.4.2 Personal and Professional Conduct

#### **Personal conduct**

- Personal responsibility
- Organizational and personal ethical norms

#### **Professional ethics**

- Introduction to the concepts and elements of professionalism and professional conduct
- Values and principles of professionalism

(e.g. empathy, compassion, honesty, integrity, accountability, altruism, service-orientation, trustworthiness, competency, desire for learning, confidence, tolerance, cooperation, leadership, autonomy, justice, punctuality)

- Domains of professionalism and self-assess level of professionalism in each domain
- The importance of self-assessing professionalism on an ongoing basis

# **Professionalism in pharmacy practice**

- The association between professionalism and pharmacists standards of conduct in pharmacy practice
- The civil liability, professional ethics, behaviours and attitudes of a pharmacist
- The pharmacist's professional responsibility to care for patients and to respect patients as autonomous individuals
- Understanding of right and wrong in terms of professional behaviour and patient care
- Difference between what is ethically required of professional pharmacists and what is legally required
- Respect for differences related to cultures, values, ethnicity, gender, sexual orientation, religion, language and socio-economic status and how these may impact health, health practices, and physical assessment
- Respect roles/responsibilities, and expertise of other health professions

#### Etiquette

- Professional meeting protocol and multicultural etiquette
- Telephone and electronic etiquette

The similarities and differences between personal and professional behaviour

#### 2.4 Ethics

# 2.4.3 Ethical Problems and Dilemmas

# Introduction to ethical problems and dilemmas

- The historical basis of ethical problems
- Ethical dilemma and the impact on the patient, pharmacist, physician, family
- The personal and professional resolution of ethical dilemmas in healthcare
- Process for evaluate, dealing and solving ethical dilemmas in pharmacy practice
- The moral options open to a pharmacist faced with a moral problem

# Ethical dilemmas commonly seen in clinical practice

Ethics surrounding reproductive healthcare decisions

(e.g. abortion, assisted reproduction, stem cells, cloning)

- Ethical issues regarding a pharmacist's responsibility to provide information and medication related to reproductive health

(e.g. contraception, pregnancy testing, pregnancy termination)

Ethical issues related to death and dying

(e.g. comas, end-of-life care, requests to die, physician assisted dying or euthanasia)

- Historical and contemporary theories and models of death, dying and the grief process from the perspective of the healthcare practitioner
- The importance of people's beliefs and practices surrounding death and dying and to be able to respond with sensitivity and respect to people whose beliefs and practices may differ from their own
- The ethical issues surrounding the pharmacist responsibility and ethical behaviour to provide information and dispense medication related to end-of-life care, including when provision/dispensing may be in conflict with personal moral beliefs or values
- Research and experimental treatments

(e.g. human subjects)

Individual rights and the public good

(e.g. vaccination, genetic testing and screening, right to refuse medication, stopping the global threat of AIDS)

- Spiritual considerations in patient care and therapeutic dilemmas produced by spiritual beliefs
- The ethical dilemmas relevant to pharmacy practice posed by drug shortages and disasters

# Conflicts of interest in pharmacy business and healthcare decision-making

- Questionable business practices in pharmacy
- The conflict of interest presented to pharmacists by community retailers supplying unhealthy, potentially addictive products

(e.g. tobacco, alcohol, junk food, and lottery tickets)

- Potential ethical dilemmas in pharmacy practice arising from interactions with the pharmaceutical industry and how to address them
- Legal and ethical expectations for the professional behaviour of the pharmacist when actions may be in conflict with personal beliefs and values

# 2. Social and Behavioural Pharmacy Sciences Aspects

# 2.4 Ethics

# 2.4.3 Ethical Problems and Dilemmas (cont.)

# **Conscientious objection by healthcare professionals**

- The necessary steps that a pharmacist must take when refusing to fill a prescription due to conscientious objection
- Legal principles governing a pharmacist's rights and responsibilities pertaining to refusal to fill a prescription due to religious or moral objection

#### 2.4 Ethics

# 2.4.4 Privacy of Health Information

#### Privacy

- The principles of privacy applicable to pharmacy operations
- The right to privacy as they affect the legal rights and responsibilities of patients, healthcare providers, and policy makers
- Preparing and maintaining records that respect a patient's privacy interests and comply with the law
- Legal and regulatory requirements, ethical standards, and organizational policies and procedures for protection of health information and maintaining privacy, and ensuring security

(e.g. collection, use, disclosure, access to, protection, and destruction of health information)

#### Confidentiality

- Maintenance of patient confidentiality and professional boundaries
- Professional obligations with respect to confidentiality

#### Informed Consent

- Patient consent form
- The appropriate elements of an informed consent document
- The quality of a consent form

#### 2.4 Ethics

# 2.4.5 Ethics in Research

#### Introduction to ethics in clinical research

- The historical progression of research ethics and oversight (e.g. Belmont Report)
- Overview of ethical and regulatory aspects of clinical research (ethics in human and animal research)
- The function of ethics committees

# Research using human subjects

- The circumstances surrounding the formation of the Declaration of Helsinki, The Nuremburg Code, and the USA's IRB process
- The process and requirements used to ensure proper review of pharmacy research involving human subjects
- The criteria used by the Institutional Review Board (IRB) to assess the ethical acceptability of proposed human subjects research studies in pharmacy
- The ethical obligations and responsibilities of pharmacists conducting human subjects research (both pre-clinical and clinical)
- Examples of lapses in judgment in clinical research (e.g. Tuskegee study of untreated syphilis)

# 2.5.1 Public Health Pharmacy

#### Introduction to public health

- The importance of public health as a science and its goal of maximum health for all
- Public health terminology and concepts

(e.g. health and disease; acute illness; chronic disease/illness; community health; illness behaviour; morbidity and mortality)

Historical development of public health

(e.g. food and water safety, sanitation and disease monitoring)

- The basic principles of public health, public health practice and the public health delivery system
  - Population vs individual health
  - Population health management
- Public health priorities and interventions
- Aspects of public health including organizations, administration, environmental social health problems

#### The determinants of health

- The major determinants that influence the health of populations and individuals (e.g. the biological, social, environmental, and economic determinants of health)
  - The social determinants of health

(e.g. poverty, ethnicity and culture, gender, age, income, education, employment, social status, state laws)

 The relationship between access to clean water, sanitation, nutrition, environmental degradation and pollution and risk of communicable and chronic diseases

#### The impact of disease on society

- Health and disease indicators
- The burden of disease: prevention and management of health problems

# **Measures of health**

- How health, illness and disability are measured, particularly the determinants of health
- Common measures of health

(e.g. morbidity, mortality, birth/death rates, health status, health-related quality of life (QOL), Quality Adjusted Life years (QALYs))

# Improving health outcomes from a public health perspective

• Principles of health improvement

(e.g. surveillance, basic/clinical sciences, intervention/translational science, prevention/health promotion)

# Public health practice from a pharmacy perspective

- How pharmacy practice interfaces with public health delivery in a variety of settings
- The challenges, tools, strategies and models of the intervention of the pharmacist in public health

# **Public health research**

• The role of public health research in ongoing clinical practice

# 2.5.1 Public Health Pharmacy (cont.)

# **Public health programs**

- The public health programs and role of pharmacist in these programs (e.g. immunization programs, needle exchange program, prevention of sexually transmitted diseases)
- Planning, designing, implementing, and evaluation public health education and health promotion programs and health information campaigns

#### Global health pharmacy and international health

- Geographic specific or global distribution of diseases and potential health hazards
- The key barriers that developing countries face in the provision of healthcare and their impact on the health of population and individuals

(e.g. healthcare system funding, healthcare worker migration, access to medicines)

- The disparities in healthcare and pharmaceuticals that are present in underserved, minority and rural populations on a global level
- The influence of the presence or absence of pharmacy-related services and initiatives on regional health
- Improve public health in places where health and healthcare delivery inequities exist and reduce health disparities
- Opportunities that exist for pharmacists in the area of global health service

# **Environment and pharmaceuticals and personal care products**

- How pharmaceuticals and personal care products are introduced into the environment
- Mechanisms available to limit this type of pollution
- Actual and potential cause/effect relationships between specific products/byproducts and types of wildlife
- Actual and potential cause/effect relationships between specific products/byproducts and humans

(e.g. reproductive effects)

# Disaster planning and emergency preparedness

 The role of the pharmacist as a health professional and citizen in the context of disaster management

(e.g. emergency response, disaster preparedness, humanitarian relief)

# 2.5.2 Epidemiology and Pharmacoepidemiology

# **Introduction to epidemiology**

Basic concepts and terminology in epidemiology

(e.g. epidemiology, pharmacoepidemiology, the host-agent-environment, medical surveillance, need for public health investigation, morbidity, mortality, outbreak and onset (epidemic), epidemic curve, incubation period)

- Principles of epidemiology as a diagnostic discipline of population health
- Methods of epidemiology in healthcare
- Epidemiologic measures

(e.g. measures of disease occurrence, frequency and risk, measures of association and impact)

- Epidemiological and database considerations
  - Accessing and using population health and demographic data
- The challenges and applications of epidemiology in pharmacy practice
  - How epidemiology is being used to evaluate contemporary health issues, with special emphasis on the role of prescription drugs and pharmacy services in selected diseases
- Epidemiological evidence and its limitations

#### **Clinical epidemiology**

- Clinical epidemiology, including abnormality, diagnosis, disease frequency, risk, cause, prevention, prognosis, and treatment outcomes
- Principles of clinical epidemiology relevant to pharmacy practice
- Clinical epidemiology in evaluating the implications of the introduction of new healthcare interventions, including procedures, diagnostic tests, devices and drugs

#### **Pharmacoepidemiology**

- What is pharmacoepidemiology
- Application of principles of epidemiology to the study of drug use and outcomes in large populations and methods for continual monitoring for unwanted effects and other safety related issues
- Concepts and methods used to measure the source, diffusion, and use of drugs in populations
  - Modern methodological concepts commonly utilized within pharmacoepidemiology

(e.g. propensity score methods)

- The utility of pharmacoepidemiologic methods as they apply to risk assessment, drug therapy selection, disease prevention and, programme and policy formulation
- Pharmacoepidemiologic issues affecting healthcare and pharmacy practice

# Epidemiological and pharmacoepidemiological studies and research

- Common epidemiological study designs and their strengths and weaknesses and common applications for each of these study designs
- The major analytical methods, calculations and research methods commonly used in epidemiology and pharmacoepidemiology research
- Sources of bias that may influence the validity of epidemiological research

# 2.5.2 Epidemiology and Pharmacoepidemiology (cont.)

# Epidemiological and pharmacoepidemiological studies and research (cont.)

• The application of epidemiological and pharmacoepidemiological research to areas of public health, health services research, outcomes research and related areas

(e.g. studies of disease occurrence in populations, drug utilization studies, international measures of drug consumption, studies that provide an estimate of the probability of beneficial effects in populations, or the probability of adverse effects in populations, and other parameters relating to drug use benefit)

- Factors that may potentially impact the quality of pharmacoepidemiologic research (e.g. choice of study design, data quality and common sources of bias)
- The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology)
   Guidelines

# The interaction between medication safety and pharmacoepidemiology/pharmacovigilance

- Professional and technical aspects of drug use control
- Poison control centers and clinical toxicology
- Regulation of controlled and dangerous substances
- Special problems involving the control of narcotics, poisons, and other controlled substances

# 2.5.3 Pharmacovigilance

# The field of pharmacovigilance

- Basic concepts of pharmacovigilance
- Methodological issues related to pharmacovigilance and post-marketing drug surveillance studies (Phase IV)
- Methods to enhance the role of pharmacists in pharmacovigilance activities

# Principles of adverse drug reactions and drug interactions

- What constitutes an adverse drug reaction
- The mechanisms underlying adverse reactions to drugs
- The frequency, causality, types of reactions, and drug effects on selected organ systems
- The occurrence, impact, and clinical aspects of adverse drug effects
- Detection, evaluation, classification and documentation of adverse drug reactions in the clinical practice setting
- Potential adverse effects of medications and strategies to reduce or prevent and manage the occurrence of such effects
- Identification of drug/drug, drug/laboratory and drug/food interactions
- Adverse reactions and Naranjo practice

#### Report adverse drug reactions

- Where and how to report adverse drug events
- The reporting mechanism for drug misadventures
- The development, implementation, and evaluation of systems to identify and report medication errors and adverse drug events

#### Surveillance systems for drug misadventures

- Appropriate systems (institutional and government) to report adverse drug reaction and medication errors
- Maintenance of vigilance for medicines use specific to certain population groups
- Methods for continual monitoring for unwanted effects and other safety-related aspects of drugs
- Methods for risk minimization (RiskMAPS and REMS programmes)

# 2.5.4 Infection Prevention and Control

# **Healthcare-associated infections**

- The relationship of the chain of infection to the transmission of infection
- Risk factors for infection and those individuals most at risk for acquiring an infection
- The incidence, transmission, and prevention of healthcare-associated infections

#### The maintenance of proper aseptic conditions

- General principle of primary and secondary engineering control and sterilization methods to the maintenance of proper aseptic conditions
- The role of healthcare equipment in the transmission of infection and the methods of disinfection of healthcare equipment
- The difference between medical and surgical asepsis

# **Infection control policies**

- The rationale and components of routine practices
- The rationale and components of additional precautions
- Basic analytic techniques to investigate and prevent infectious disease outbreaks and hospital infections
- Importance of documentation, policies and procedures relevant to institution, home infusion and compounding practices

# **Educational Contents from Category of Administrative Pharmacy Sciences Aspects Block**

1	Clinic	al Sciences Aspects	
	1.1	Pharmacy Practice	
	1.2	Pharmacist-Provided Care	
	1.3	Medication Dispensing and Distribution Systems	
	1.4	Patient Assessment	
	1.5	Medication and Patient Safety	
	1.6	5 Drug Information and Literature Evaluation	
2	Socia	l and Behavioural Pharmacy Sciences Aspects	
	2.1	Sociological Aspects of Pharmacy Practice	
	2.2	Patient-Reported Outcomes	
	2.3	Professional Communication	
	2.4	Ethics	
	2.5	Public Health	
3	Admi	nistrative Pharmacy Sciences Aspects	Page
	3.1	Healthcare Systems	117
	3.2	Economics/Pharmacoeconomics	120
	3.3	Practice Management and Leadership	125
	3.4	Pharmacy Law and Regulatory Affairs	138
	3.5	Informatics and Health Technology	142
4	Misce	ellaneous	
	4.1.	Research Design	
	4.2	History of Pharmacy	

# 3.1 Healthcare Systems

# 3.1.1 Healthcare Delivery Systems

# Introduction to the healthcare delivery system

Overview of the healthcare system

(e.g. history, evolution, future direction, public health policies, stakeholders, and major challenges for providers, payers, and users of the system)

- The basic structure, organization, composition, regulation and functions of the healthcare delivery system
- Social, political, and economic factors of the healthcare delivery system
- The barriers and enablers for optimal healthcare delivery system
- Healthcare costs, access and quality indicators for healthcare systems
- Factors of increasing pressure in the healthcare system

(e.g. the burden of chronic disease, the ageing of the population, new therapies, earlier diagnosis and increasing healthcare costs)

- Diversity/equity in healthcare
- Characteristics, causes, and effects of health disparities in the healthcare system
- Compare and contrast demand and need with respect to healthcare delivery
- Healthcare improvement mechanisms at the micro- and macro-system levels
- Assessment, planning, implementation, and evaluation of healthcare delivery

# International healthcare systems

- Comparison of healthcare delivery systems and pharmacy systems around the world
   (e.g. structure, financing, cost, quality indicators, recent reforms and innovations, their advantages and disadvantages)
- The differences in health outcomes between the various healthcare models
- Provision of healthcare, pharmacy and medicines in developing countries

# Models of delivery of healthcare services

- Healthcare systems and models currently in place through which patients receive directed care
- Models of healthcare systems

(e.g. Bismarck, Beveridge, National Health Insurance, Pay as you go, and the Cafeteria Plan/Ecology Model)

New models of care

(e.g. integrated care systems, medical home models of care, and accountable care organizations)

Methods to provide high-quality/low-cost healthcare to large patient populations

#### How each patient is moving through the health system

- The patient flow through different levels of care
  - (e.g. primary care (first point of contact), secondary care (community health services), tertiary care (hospital))
- How transitions of care affect the healthcare system and how community pharmacy contribute to transitions of care

# The financing of healthcare

- The various methods of financing healthcare delivery and the implications for risk sharing, cost containment, access, quality and potential for improvement
- The sources of funding of prescription drugs, hospital services, physicians services and other health services

# 3.1 Healthcare Systems

# 3.1.1 Healthcare Delivery Systems (cont.)

# The financing of healthcare (cont.)

- The difference between the sources of funding for health services and the private or public form of delivery/provision of health services
- Financing mechanisms and payment strategies to providers

#### **Healthcare reform**

- The basis for healthcare reform
- Reasons and goals for healthcare reform and potential opportunities for pharmacists
- Various perspectives on the future of healthcare delivery systems, their modification, change and reform including financial and other concerns
- The impact of changes in healthcare upon the principal actors including: patients, providers, insurers, financers, regulators, and corporate purchasers
- The elements influencing healthcare legislative reform and potential impact on the current and future pharmacy practice model

# **Health system pharmacy practice**

- The current place of the pharmacy profession in the healthcare system and its possible future, including levels of competence and specialization
- How pharmacy services and pharmaceutical products are integrated within the healthcare system

#### **Medication use system**

- The medication use system in both community and hospital settings

   (e.g. procurement, storage, prescribing, transcription, dispensing, administration, monitoring, and documentation)
- Pharmaceutical care delivery within a framework of the medication use system
- Principles for managing the medication use system
- Comparisons between medication use systems around the world and look at other controversies related to access, choice, and quality of healthcare

#### Insurance and reimbursement in pharmacy

- Introduction to pharmacy payment systems
- Health systems reimbursement structures and the fundamentals of reimbursement models from the governmental and private perspective
- Methods to obtain payment for prescription drugs, health goods, and patient-oriented professional services from both individuals and third-party payers
  - Work through the drug reimbursement system including strategies that affect drug selection
- The risks and benefits of various public and private insurance programs from both the perspective of the pharmacy provider and the patient
- How various forms of reimbursement can create different incentives to control utilization of healthcare
- The role of public and private insurers, pharmaceutical industry, and managed care on healthcare delivery
- The role of pharmacy with the various healthcare insurers
- Health insurance operations and how to help customers with their insurance options at the pharmacy counter

# 3.1 Healthcare Systems

# 3.1.1 Healthcare Delivery Systems (cont.)

The incidence and problems associated with overuse, underuse, and misuse in the healthcare system

 Concept of fraud, waste, and abuse and the major factors that contribute to drugrelated fraud and abuse

Indigent care programs in healthcare delivery at a local, national and international level

- Challenges in delivering care in low-resource settings
- Barriers to health and healthcare access in low-resource settings and vulnerable populations
- Tools and strategies to address the needs of specific vulnerable populations

# **3.2.1 Economic Principles**

#### Economic principles and concepts

The basic economic concepts

(e.g. utility, demand, supply, equilibrium price, the price system, price discrimination, elasticity of demand, scarcity, tradeoffs, goal seeking behaviour, markets, equilibrium, efficiency, equity)

- Principles of economics and their application in a variety of situations or settings
- Economics in operations

#### Microeconomics

The forces of supply and demand

(e.g. market forces, externalities, the environment, competition)

- The factors that cause a change in the demand or supply of a product or service
- The impact that a change in supply or demand will have on the equilibrium price and equilibrium quantity of a product or service
- The various types of market structures

  (e.g. perfect competition, monopolistic competition, oligopoly, monopoly)
- Consumer behaviour
  - The role and behaviour of the consumer in the healthcare system
- The nature of production costs
- Price setting by firms in a range of market types

#### Macroeconomics

- The larger scale aspects of the economic systems in which businesses operate
- The determinants of gross domestic product, inflation, unemployment, and the forces that affect the general rate of interest
- Discussions on economic (e.g. inflation) and social (e.g. employment) goals to be pursued at national and global level
- Ethical rationale and impact of government policies on the macroeconomic environment and business conditions
- The fundamental forces affecting international trade

#### **Economic analysis**

- Types of economic analysis
- The use of conventional economic analytical tools
- Limitations of economic analysis

# Economic outcomes assessment as tools in decision-making

 Principles in economic evaluation and decision analytic modeling, and critical appraisal of economic evaluation studies

#### 3.2.2 Health Economics

#### Introduction to health economics

Health economics

(e.g. definition, types, burden on healthcare system)

- Fundamental concepts behind rationing and economic evaluation of healthcare
- The economic principles that influence healthcare policies and systems
- Economic models of risky health behaviour

#### The economics of health and healthcare

- Costs of health
- Costs of disease

(e.g. financial, human, community, national, global)

- How the economics of healthcare is different from the economics of other industries
- The factors that can cause healthcare costs to increase
- The professional contributions that pharmacists make in reducing healthcare costs (e.g. economic and health consequences of preventable adverse drug events)

#### Economic issues for the health system

- Major economic dimensions of healthcare system and public health practices
- Sociologic and cultural diversity impact on the economics of the healthcare system
- Economic analysis applied to the management of health systems with special emphasis given to community and hospital pharmacies
- Applications of economic theories and health-related quality of life concepts to improve allocation of limited healthcare resources

#### **Economic evaluation of healthcare services**

- Methods used in economic evaluations of healthcare
- The techniques to evaluate healthcare economic data for application to the pharmaceutical care of patients and development of health policy
  - Measuring and assessing the economic and non-economic consequences of healthcare interventions, emphasizing drug therapy, and pharmaceutical services

How economic performance of the healthcare system could be improved

#### 3.2.3 Concepts of Pharmacoeconomics

#### **Introduction to pharmacoeconomics**

Basic concepts in pharmacoeconomics

(e.g. cost and costing, outcomes assessment and health-related quality of life, cost-of-illness, cost-minimization, cost-benefit, cost-effectiveness, cost-utility analysis and decision analysis using pharmacoeconomic modeling techniques, net monetary benefit, and sensitivity analysis)

- Problems and strengths associated with pharmacoeconomics
- Pharmacoeconomics standards, modeling, data sources, and uncertainty

#### The role of economics as they relate to pharmacy practice

 How pharmacoeconomics impacts pharmacy, regardless of what type of healthcare setting the pharmacist practices

(e.g. in drug utilization review and formulary development in hospital pharmacy)

- The principles and techniques of pharmacoeconomics to the evaluation of pharmaceuticals and pharmacy services, and its application to improve patient outcomes
- The key concepts of economics to issues in the pharmaceutical sector
   (e.g. drug insurance, drug research and development, procurement of generic drugs)
- Impact of economics on pharmaceutical use
   (e.g. drug product selections, medication non-compliance and other forms of risky health behaviours)
- Economic models of the pharmacist labor market
  - The methods of economic analysis to investigate how markets allocate resources, when they work well and the role for government when they do not work well

#### Pharmacoeconomic analyses

- The theory underlying pharmacoeconomic analysis
- Economic evaluation methods as applied to pharmaceutical products and services: cost-minimization analysis (CMA); cost-effectiveness analysis (CEA); cost-benefit analysis (CBA); cost-utility analysis (CUA); cost-of-illness analysis
- The role of pharmacoeconomic analysis in therapeutic, administrative and policy decision-making

(e.g. drug therapy decisions, formulary management, set prices, pharmaceutical reimbursement policies and decisions)

 Strengths and weaknesses of standard pharmacoeconomic approaches available to assess the economic impact of pharmaceutical interventions

# Measuring and estimating cost

- Measurement of cost and health benefits
- Principles of measuring and analysing costs and outcomes and techniques used to evaluate them across drug treatments
- Pharmacoeconomic analysis of the cost of drug therapy to healthcare systems and society
- The costs of healthcare interventions and the clinical and humanistic consequences of these interventions

# 3.2.3 Concepts of Pharmacoeconomics (cont.)

#### Pharmacoeconomic research and studies

- Pharmacoeconomic research in community pharmacy practice, medical centers and clinical trials
- Methodology employed in pharmacoeconomic research
  - The different pharmacoeconomic study designs and their strengths and weaknesses
- Critical evaluation of different types of published pharmacoeconomic studies in the medical literature
  - Critical appraisal of health economic evaluation studies (use of Drummond checklist)
- The main applications of evidence generated from pharmacoeconomics studies
  - How published evidence can be used to critically appraise the value of pharmaceuticals and pharmaceutical care in a variety of settings
  - How comparative effectiveness research can be integrated into clinical pharmacy practice and may help control costs of healthcare
  - Application of pharmacoeconomic research principles in the determination of alternatives producing the best health outcomes for invested resources
- Direct, indirect and intangible costs for pharmacoeconomic research projects

#### Health status measures

- Health-related quality of life and its role in patient outcomes research
- Based measures of health-related quality of life and quality adjusted life years
- Applications of economic theories and health-related quality of life concepts to improve allocation of limited healthcare resources
- Types of outcome evaluation and outcome measures
  - How to assess and interpret economic and health-related quality of life (HRQL) outcomes and sequelae of drug therapies within healthcare systems
  - Evaluation of the humanistic outcomes associated with drug therapy and the provision of pharmaceutical care on quality of life including the utilization of sensitivity analyses, decision analysis models, and discounting
  - Identify and interpret different health outcomes and measures of these outcomes
  - The methods to choose a cost-effective drug therapy for patient populations in order to achieve quality clinical, economic and humanistic outcomes

The common modeling approaches (decision-making tree and Markov model) used in pharmacoeconomics studies

- Basic steps and techniques in decision analysis
  - Basic management and decision analysis functions to evaluate the need for and document the effect of pharmaceutical care interventions in a variety of pharmacy practice settings
  - Apply decision-making strategies in a variety of healthcare settings
  - Design a decision tree

(e.g. calculate an expected cost and expected outcome using a decision tree)

# 3.2.3 Concepts of Pharmacoeconomics (cont.)

The common modeling approaches (decision-making tree and Markov model) used in pharmacoeconomics studies (cont.)

- Economic evaluation of pharmaceuticals and their use in decision-making
  - Apply principles of pharmacoeconomics and evidence-based medicine in making decisions regarding formularies and individual patient care
  - Economic factors that influence medication therapy decisions in contemporary health systems and payment for medication-related services
  - Make decisions on the cost effectiveness of therapeutic alternatives

# 3.3.1 Pharmacy Management and Leadership Concepts

#### Introduction to management

- Definition and analysis of management theory and management styles
- Management process and their application to professional activities
- The five core managerial sciences: human resource management, operations management, marketing, accounting, and finance

# **Pharmacy practice management**

- The role of management within pharmacy
- The role and responsibilities of the pharmacist as a manager (e.g. in disaster and crisis management)
- Management theories, models, and techniques used by pharmacists to ensure that patient care is delivered in an effective and efficient manner
- The basic principles of management (planning, organizing, directing and controlling resources) applicable to professional pharmacy practice and to the operation of a pharmacy
- The managerial aspects of pharmacy practice within the different settings of the healthcare system, with an emphasis on financial, material, operational, and human resource management
- Management tools, including informatics, needed to assess and address change, increase competitiveness, improve quality, and optimize patient services

#### Introduction to leadership

- Concepts, practices, principles and models of leadership as they apply to personal development, professional relationships, and pharmacy practice
  - Traditional and emergent paradigms of leadership
  - The relational leadership model
  - The five practices of leadership
- Leadership theories and their effects as it applies to healthcare
- What makes an individual a professional leader: the attributes and qualities of a good leader

# Leadership development in pharmacy practice

- Importance of leadership within the pharmacy profession and ways to influence
- Evolution of pharmacy leadership
- Relationship between ethics and leadership
  - Integration of the characteristics of ethics on leadership behaviour and its effect on the motivation of followers
- The leadership role of the pharmacist
  - Core leadership skills required by pharmacists

(e.g. strategic, focused, persuasive, open to feedback, decisive, visionary, empowering, emotional intelligence, building teams, problem-solving, evaluating others, value creation, managing finances, managing risk, marketing of healthcare, methods of negotiation, service-oriented)

- Specific goals of leaders to improve the practice of pharmacy
- Leaders in the pharmacy world

(e.g. pharmacy practice leaders from community practice, institutional practice, Health Maintenance Organizations (HMO) and managed care, biotechnology and clinical research)

# 3.3.1 Pharmacy Management and Leadership Concepts (cont.)

#### Leading and managing change

- Concepts of change management in the context of healthcare organizations and pharmacy practice
- The principles and components of change management: how to manage and implement change
- Organizational decision-making processes, methods of navigating change, and the leader's role in change
- Management of innovative changes in pharmacy practice

# Leadership and control in organizations

- Organizational culture and leadership in health
- Theories of organizational healthcare leadership, including power, conflict management, complex systems and structure
- The basics of management theory as applied to healthcare organizations
  - Fundamentals of managing a pharmaceutical organization unit in terms of procurement, human resources and clients in a business and professional framework
- Manage a positive work environment
  - Positive reinforcement strategies
  - Creating learning environments in organizations
- The key influences on the development of an organization's strategy

  (e.g. analyse those influences, propose appropriate strategic behaviour for an organization and demonstrate an understanding of how strategic change can occur within an organization)

# Managing risks in pharmacy practice

- Principles of risk assessment and risk management
- Identify and manage risks associated with the practice of pharmacy
- Risk management methodologies and risk reduction

# **Motivational theories**

- The various motivational theories
- Apply motivational theories to pharmacy practice

How to manage a project: project management issues

#### **3.3.2 Pharmacy Business**

#### **Introduction to business**

- The role of business in society and the role of profits
- Business management concepts, techniques, methods and models
- The various forms of legal business organizations
- Basic principles about business structures
  - Differences between business organizational structures

(e.g. LLC, sole proprietor)

- Business development, financial planning, and capital generation
- Business assessment tools

(e.g. SWOT, PEST, Porters 5 Forces)

Business ethics

(e.g. business ethics as they apply to the pharmaceutical industry)

- Professionalism and the duties of professionals in the business context
- Factors that contribute to overall business success
- External and internal environmental context of business and organizational practices

#### **Business strategy**

- Strategic business decision-making
- Business planning
  - General process of planning
  - Essentials and techniques of strategic business planning and sustainable business
- Strategic business plan
  - The purpose of a business plan
  - The components of a business plan

(e.g. executive summary, purpose, background, programme description, financial projections and conclusion/summary)

- How to create, develop and implement a business plan
- Strategic planning and prioritization in the different pharmacy and healthcare settings (e.g. strategic business plan for implementation of MTM services into a community pharmacy)
  - The roles and processes of strategic and business planning in pharmacy
  - Pharmacy business plan (contracts, proposals)

# Aspects of pharmacy business management

- Business and personnel management in pharmacy practice
- Business operations pertaining to pharmacy practice
- Healthcare policy in relation to the management of a pharmacy business

#### The dichotomy: business manager vs health professional

• Evolution of the role of the pharmacist in the pharmacy business management

#### Types of business for pharmacy

- The types of business unit formats that comprise the various pharmaceutical practices and their implications for business practice
- The most successful and non-successful pharmacy type businesses in the past 20 years
- Sustainable business models for the pharmacy and services offered

# 3.3.2 Pharmacy Business (cont.)

# Starting a business or new service

- Identifying and evaluating new services, new businesses, and a different way to do business
- What is involved in starting, owning and running an independent pharmacy business
- The design, development and completion of some of the steps necessary to open an independent pharmacy business
- Appropriate management procedures, estimates of capital requirements, and the mechanics involved with the initial operation of a business

#### **Small business ownership**

- Business ownership concepts
   (e.g. ownership/franchise issues, forms of ownership, transitioning ownership)
- The requirements for small business ownership
- The management and administration of a community pharmacy as a small business
- Variables of ownership and management which may impact business success

# **Buying and selling a pharmacy**

- Concepts related to purchasing and operating a pharmacy practice
- Business plan for the purchase of an existing pharmacy or developing a new pharmacy
- Complex partnerships agreements during the purchase of a pharmacy
- Being a business manager in an independent pharmacy
- Basic pharmacy management skills in the areas of legal forms of business ownership
- Policies and procedures required to own and manage a community retail pharmacy

# **Organizational planning**

#### 3.3.3 Pharmacy Practical Operations

# **Pharmacy work environment**

Pharmacy layout/design

(e.g. design workspaces and workflow that promote safe medication dispensing and confidential patient counseling and education)

- Safety in the workplace
  - The development of a culture of safety in the pharmacy workplace
  - Workplace health

(e.g. the importance of occupational health for maintaining a safe workplace)

- Safety procedures in the workplace

(e.g. safe handling of hazardous drugs and solid and hazardous wastes)

- Occupational safety and health administration regulations for the prevention of threats or injury

(e.g. needle stick injuries, guidelines for prevention and steps to take in the event of a blood-borne pathogen exposure)

- Pharmacy security
  - The requirements and strategies for pharmacy security and the basics of personal safety

(e.g. in the event of robbery)

#### Pharmacy operations management

- Operations management and its essential tasks
- Application of management principles to pharmacy operations in a variety of settings
   (e.g. community, health system, managed care)
- Economic, administrative, and human aspects of pharmacy operations
- Basics of pharmacy operations

(e.g. pharmacy workflow, practice activities, medication safety, topics of technology selection and automation in pharmacy, quality management, income statements, cash flow, inventory management, principles of effective customer service delivery)

- The roles of pharmacy managers in assuring the efficient operations and safety of a pharmacy practice
- Operations management in remote locations experiencing constraints on resources

# **Purchasing and managing inventory**

- Concepts of purchasing/procurement and inventory management: group purchasing organization (GPO), use of GPO and wholesaler, inventory control, pharmacy industry relations, shortages, value based purchasing
- The importance, both financially and operationally, of purchasing and inventory management to a pharmacy
- Drug acquisition, inventory management and storage
  - The drug acquisition process and inventory control methods
  - Inventory management (inventory costs, inventory levels, turnover, ordering stock)
  - Calculate inventory turnover rates and use this information to make purchasing, inventory control, and budgeting decisions

# Managing the supply chain system

 Clinical and operational implications related to drug distribution/supply chain issues including drug shortages, counterfeit drugs, and drug diversion

# 3.3.3 Pharmacy Practical Operations (cont.)

# **Drug shortages**

- Management of drug shortages
- The drug shortage problem and the impact on patients, pharmacies, physicians, and drug plans
- Contributors to the drug shortage problem
- The role of pharmacists in resolving drug shortages and tools to use at the patient level

#### Customer service

- Principles for ensuring good customer service
- Customer behaviour and customer relationship building and maintenance
  - Effectively deal with angry customers/customer complaints
  - Steps for dealing with "difficult" patients and customers
- Human Sigma as a model for customer service operations

#### **Quality management**

- Definitions and elements of quality and examples of quality deficits in healthcare
- · Quality and safety management
- Methods for ensuring quality in pharmacy practice
- Methods to explore and explain variation in quality, benchmarking (e.g. Root Cause Analysis, Healthcare Failure Mode and Effect Analysis)

#### Continuous quality improvement

- How to design, implement, and evaluate continuous quality improvement programs
- The quality improvement process and strategies
- Healthcare improvement mechanisms at the micro- and macro-system levels
- Adoption of quality improvement through comprehensive use of information technology and systems that reward rather than impede quality
- The use of data in continuous quality improvement initiatives

#### Measurement of quality

- Means to measure quality
   (e.g. process, outcome, balancing)
- Differences between measurement for improvement, measurement of accountability, and measurement for research

# Quality assurance and quality control

 The nature and importance of quality assurance in healthcare and its implications for pharmacy practice

(e.g. in promote safe medication use and systems management)

Quality assurance strategies and components of an effective quality assurance program

# 3. Administrative Pharmacy Sciences Aspects

# 3.3 Practice Management and Leadership

# 3.3.3 Pharmacy Practical Operations (cont.)

# Quality assurance and quality control (cont.)

- The implementation of quality control and assurance programs in a practice based environment
- Quality assurance agencies (e.g. JCAHO, NCQA)

# Outcomes evaluation of pharmacy operations/services

- Operations analysis
- Apply different outcomes measures to assess success/failure of service
- The types of outcomes a pharmacist would need to measure in a pharmacy-related service: the economic, clinical and humanistic outcomes of a clinical pharmacy service

# 3.3.4 Accounting and Financial Management

#### **Accounting concepts and principles**

- The role of accounting
- Fundamental accounting principles
- Basic management tools in the areas of accounting

(e.g. preparation of budgets and business plans, payroll and GST legislation, marketing, partnerships law, decision-making and the use of financial software to effectively understand the information provided by support staff to make effective business decisions)

- Common terms used in accounting records and financial reports
- Application of accounting concepts and techniques used to gain intelligence about all aspects of business operations
  - The use accounting information for decision support, analysing historical operations and planning and control future business activity

#### **Fundamentals of financial management**

Basic finance terms

(e.g. financial statements, financial ratios, benchmarking, budgeting, productivity, workload, interventions, cash flow, GST, business transactions, and business reports required for the accountant like Business Activity Statements)

- Budgeting and financial planning process: common types of budgets and budgeting techniques
- Financial ratios and application

(e.g. liquidity ratios, profitability ratios, turnover ratios)

- Identify cash flow problems and apply solutions to address
- Financial aspects of business
  - Goals of financial management
  - Financial planning, investment analysis, tax analysis, budgeting, and other aspects of personal and business finances
  - Financial assessment
- Financial systems for small business and health services management
- The financial expectations of a successful practice

#### Financial management in organizations

The financial challenges of healthcare organizations

(e.g. enhancing revenues, managing costs, accessing capital at reasonable rates, and ensuring the integrity of financial reporting)

Typical pharmacy organization's process of budget administration and associated implications

# **Pharmacy financial accounting basics**

- Financial management principles applicable to pharmacy practice day-to-day operations in various practice settings
  - Utility of financial ratios and basic financial ratios used in community and institutional pharmacy practices
  - Describe and integrate information from a pharmacy business unit into a balance sheet and income statement

# 3.3.4 Accounting and Financial Management (cont.)

# Pharmacy financial accounting basics (cont.)

- Analysis of the financial viability of a pharmacy business
  - Financial accounting and valuation when buying or selling a pharmacy
  - Loans and financing costs to establish and run a pharmacy operation
  - Financial aspects of pharmacy management
    - (e.g. personnel and insurance costs, fixed and recurring expenses, third party payments, receipt of payment, and revenue generation)
  - The financial aspects of the development and implementation of innovative clinical services in the community setting
- Cost control strategies for pharmacy
- Develop a financial plan to establish or maintain a pharmacy's operations

#### Clinical services reimbursement

- Comparative funding models for hospital and community pharmacy services
- Billing for pharmacy services
  - How do community pharmacies generate revenue in order to sustain the delivery of care?
  - Processes for billing for services in the community pharmacy setting
  - Reimbursement for pharmacists' services
     (e.g. type of reimbursement for pharmacists' MTM services)
- The various payers for pharmacy services
- The evidence that intervention-based reimbursement models change practice behaviour and contribute significantly to a pharmacy's revenue stream, and impact health system costs or patient outcomes (have value for payers)

#### 3.3.5 Human Resources

#### Introduction to human resources management

Principles of human resource management

(e.g. principles for interviewing, recruiting, hiring and terminating, training, developing, supervising, motivating, retaining, developing and rewarding of employees, and evaluating professional and non-professional staff)

- Designing, implementing and maintaining human resource management
- Recruitment strategies
  - Critical steps in recruitment and selection of employees
- Human resource practices that promote effectiveness, efficiency, cost-effectiveness and workplace satisfaction for professional and technical staff
- Contracts of employment
  - Employee responsibilities and rights in the workplace
  - Employee performance evaluations (performance management and performance appraisals)
  - The major categories associated with human resource disciplinary actions
- · Legal issues in human resource management

(e.g. discrimination, harassment, human rights, diversity)

# Human resources management applicable to pharmacy practice

- The supply of and demand for health professionals
- What are the key things you would look for in hiring a pharmacist?
  - Interview a candidate for a pharmacy position (e.g. appropriate job interview etiquette, questions, and answers)
- The pharmacy workforce
  - The organization, roles, and responsibilities of the health-system pharmacy staff
  - Management of staff within the practice setting, including pharmacists, technicians, and other supportive personnel
  - The role of teams in organizations (team work in the pharmacy)
  - Ability to coach and discipline pharmacy staff
  - Develop staffing plans and organizational chart
  - Workload management

# Organizational behaviour

- Principles of professional behaviour
- The role of emotions in organizational behaviour
- How job satisfaction, organizational commitment, job stress, and job turnover affect organizational behaviour and performance
- Organizational behaviour and human resource management that are relevant to professional and technical staff
- Organizational theory and behaviour for the management of people and processes in a healthcare organization

# Unions and unionization in pharmacy practice

# 3.3 Practice Management and Leadership

## 3.3.6 Personal and Professional Management

#### Personal resource management

- Principles of personal management
- Methods of personal continuous quality improvement

#### Personal and professional development

Personal and professional challenges

#### Professional development plan

- · Career as a process requiring planning, development, and management
- Development of professional portfolios, resume and a curriculum vitae
  - Tips on writing curriculum vitae

#### Continuous professional development

- The importance of continuing education/lifelong learning
  - Lifelong self-learning skills to maintain professional competence
- The importance of continuous improvement as a professional
- The stages of the continuing professional development (CPD) cycle and the learning skills required to effectively engage in CPD

## **Self-Assessment and reflection**

- Basic concepts and theories of self-assessment and reflection

   (e.g. critical reflection of assumptions, double-loop-learning and self-assessment strategies using multiple modes of application)
- Connections between self-assessment and reflection
- Career self-assessment
- Effectively self-assess and improve personal and professional abilities on an ongoing basis (continuous professional and personal development)

#### Professional networking

- The importance of professional networking as a method of self-marketing
- Methods of networking

# 3.3 Practice Management and Leadership

## 3.3.7 Marketing and Promotion

## The theory and practice of marketing

- Marketing concepts and principles
   (e.g. merchandising, policies for promotion)
- The various methods and strategies used by manufacturers to market their products
- Marketing of services and development of an implementation plan
- Marketing materials based on a target audience(s)

#### Healthcare marketing

Marketing process and communication strategies for healthcare products and services

#### Marketing and its purpose in pharmacy business strategy

- Marketing principles relevant to pharmacy practice
- How to formulate marketing plans and strategies as they apply to the profession of pharmacy and the pharmaceutical industry
- Marketing techniques and promotional strategies for pharmacy goods and services
- The role that consumer behaviour plays in the development, positioning and pricing of pharmaceutical goods and services

# Marketing of drugs

- The role and influence of the pharmaceutical industry and the controversies surrounding drug advertising
- Evaluation of drug advertising

## Market analysis and market strategies

- Evaluating the market and competitors
- Key trends in consumer markets

(e.g. principles of customer segmentation and analysis, retails share of the consumer, the changing role of retailing in consumer spending priorities, the influence of key demographic and social trends on consumer markets)

 The impact of consumer market trends on the pharmacy sector: opportunities and threats

# 3.3 Practice Management and Leadership

#### 3.3.8 Professional Effectiveness

#### Innovation and entrepreneurship

- The elements of entrepreneurship and entrepreneurial processes
- The importance of entrepreneurship and the roles that entrepreneurs have in pharmacy practice
- What is needed to be an entrepreneur in pharmacy today
- The needs and opportunities for pharmacists to develop innovative or entrepreneurial strategies to achieve professional goals and solve problems

# Time and stress management

- Theories and approaches to time management
  - Utilize organizational skills in planning and managing work time
  - Time management organization
  - Personal time management
- Develop and be able to troubleshoot schedules so that issues are solved with attention to the business requirements
- The role of stress in illness and how stress management is a key component in maintaining a personal well being
- Ways to handle individual stressors and to decrease stress
   (e.g. through relaxation techniques, time management, personal health and effective coping techniques)

# **Management of performance**

- Key performance indicators in areas of productivity, quality, on-going quality control, resource management
- Performance improvement and quality assurance
  - The various performance improvement strategies used in the healthcare industry (e.g. PDCA, Flow charting and PI methods, Root Cause Analysis (RCA), Failure Mode and Effects Analysis (FMEA), Lean thinking, six sigma)
  - The strengths and weakness of the respective models
- Tools to monitor, manage, and improve performance

## Managing productivity and work systems

- Concepts of productivity, effectiveness and efficiency
  - Personal and team effectiveness
- Analyse systems, to work in groups to identify how the system may fail, and to design improved systems
- Performance metrics/productivity
  - Workload measurement systems

# 3.4 Pharmacy Law and Regulatory Affairs

# 3.4.1 Health and Drug Policy

# **Health policy**

- Health policy concepts and regulation affecting health
  - The policy and political environment in which health services operate
  - Contemporary health policies and related issues that directly affect the organization of healthcare delivery, coverage, provision and provider reimbursement
- The process for formulating health policy and the impact of various health policies on health systems (e.g. healthcare access, healthcare quality, and healthcare cost), providers, and patients
  - The balance of power between different stakeholders in the development of health services policies and decisions
  - What facilitates or impedes the policy implementation and the influence of the stakeholders and the media in the management of health services issues
  - Policy challenges relevant to pharmacists, healthcare managers, policy makers, providers and consumers
- Global health policy and the interrelationship between global and domestic policy issues
- Public health policy
   (e.g. why the national drug shortages problem is a public policy issue?)
- The role of the pharmacist in healthcare legislation

# Regulatory agencies in healthcare and pharmacy practice

- The role of various government agencies in the regulation of healthcare and pharmacy practice
- Conceptual understanding of regulatory agencies and how pharmacy practically and ethically interacts with them
- Administrative agencies that regulate pharmacy
   (e.g. Drug Enforcement Administration (DEA), Food and Drug Administration (FDA))

# Introduction to regulation and drug policy

- Pharmacy's role in drug-policy decision-making
- The policy making process and current prescription drug policies so as to modify and influence policies that do not promote safe, effective and accessible drug therapy and provision of pharmaceutical care
- The legislation and regulation of medications and pharmaceutical products

   (e.g. the drug development process, production, testing, monitoring, marketing, procurement, storage, supply, sale and use of drugs, cosmetics and medical devices)
  - The laws regulating the pharmaceutical industry
  - Regulation of the quality, purity, strength, and labeling of medications

## The drug approval process

- Role of regulatory authorities during the process of drug approval (e.g. evaluation of the efficacy, safety and quality of new drugs)
- The general process and steps involved in the development of a new drug
- The four phases of clinical testing of a new drug

# 3. Administrative Pharmacy Sciences Aspects

# 3.4 Pharmacy Law and Regulatory Affairs

# 3.4.1 Health and Drug Policy (cont.)

# The drug approval process (cont.)

- The process by which a new chemical entity or device is approved for marketing
- The establishment and control of prices for new drugs, and the decision to list drugs for reimbursement

## Medicines regulation and scheduling

- Medication legal categories and classification systems (e.g. controlled, orphan, OTC, BTC)
- The process of the change of status from a prescription medication to a nonprescription medication

# **Investigational drug approval process**

 The statutory and constitutional arguments that underpin legal disputes over access to "investigational" drugs, as well as compare and contrast the various ethical and policy positions that inform these arguments

# 3.4 Pharmacy Law and Regulatory Affairs

# 3.4.2 Pharmacy Law

# Introduction to law and the legal process

- Jurisprudence and legal terminology
- The legal system, court systems and processes
- The nature of law and its sources both nationally and internationally
- The basic steps in the legislative process
- The role that administrative agencies play in promulgating law
- Elements of business and contract law

(e.g. contracts, torts, trade practices regulation, contract and consumer protection, property and intellectual property)

# Pharmacy practice legislation

- Brief history of pharmacy law: the interplay between pharmacy and the law
- The laws, rules and regulations that affect pharmacy practice and operations

   (e.g. regulation of pharmacy personnel, the functioning of pharmacy, provision of patient care and clinical pharmacy services, professional conduct, business conduct, hospital practice, prospective drug review and counseling)
- Regulations pertaining pharmacy registrations and licensure
  - Standards for pharmacy permits
- The laws and regulations that govern the prescribing and dispensing process

(e.g. legal requirements and regulation for written and verbal prescriptions, elements required on the prescription and pharmacy label, electronic prescribing, mail order, "internet" pharmacy, patient counseling requirements)

- The legislation relating to prescription medicines, OTC, complementary medicines, controlled substance, medical devices, drugs compounding, etc.

# Regulations governing pharmacist practice

- The laws, policies, standards, codes and guidelines that govern the roles of professionals in industry and pharmacy
- The pharmacist's rights, responsibilities and limits under the law
- The pharmacist's role in reducing liability by reducing drug-related misadventure
- The legal basis of pharmacy practice, including the administrative, civil and criminal laws that impact practice
- Pharmacist negligence and other liability concerns facing pharmacists
- Regulation of pharmacy professionals including, licensing, legal liabilities, continuing education, pharmacy operations, and operations in institutions
- Unlawful acts and consequences
  - Violations, penalties and disciplinary actions
- Professional liability insurance

# Professional pharmacy organizations and associations

- Overview of pharmacist professional organizations
- The role and importance of professional pharmacy organizations in shaping the profession

(e.g. in developing standards)

# 3. Administrative Pharmacy Sciences Aspects

# 3.4 Pharmacy Law and Regulatory Affairs

# 3.4.2 Pharmacy Law (cont.)

## Professional pharmacy organizations and associations (cont.)

 The importance of involvement in pharmacy organizational, regulatory, and state issues

(e.g. identify issues, pending legislation and regulations at local and national levels and how to make a positive impact)

- The efforts of pharmacy organizations to interact with legislative process
- Legislature and the detailed regulations issued by the board of pharmacy that govern the profession of pharmacy

#### Pharmacist licensure issues

Pharmacist and supportive personnel registrations and licensure

(e.g. licensure by examination; licensure by endorsement, requirements, fee; renewal of license; reactivation of license; continuing professional pharmaceutical education; continuing education credits)

Laws and regulations of other healthcare providers

# 3.5 Informatics and Health Technology

# 3.5.1 Pharmacy and Health Informatics

#### Introduction to pharmacy and health informatics

- The use of informatics in pharmacy practice
- Basic informatics terminology and definitions in relation to healthcare information systems

(e.g. data, information, hardware, software, networks, storage devices, operating systems, information retrieval, data warehousing, application, firewalls)

- Understanding of a microcomputer, computer software packages, graphical user interface, word processing, spreadsheets, graphical applications, e-mail, and the internet in preparation for use in pharmacy practice settings
- Pharmacy informatics principles and their application to safety and efficiency improvement of the medication use process
- The role of informatics in assisting clinicians in assuring, through decision support technologies, optimal medication use and quality
- The role of pharmacy informatics in healthcare delivery, including security, privacy, and confidentiality issues

# The use of computer software and pharmaceutical databases

- Computerized physician order entry systems (e-prescribing)
- Professional software programs used in patient care

   (e.g. dispensing software that allows the proper labelling of medications and the archiving of the drug history of patients)
- Database applications and records management (systematic creation, storage, reproduction, distribution, and retention of records)
- Electronic records used across the continuum of care (e.g. EHR, EMR, PHR) and their clinical, administrative and research uses
- The effectiveness and cost-effectiveness evidence for EHR integrated e-prescribing systems

#### The consumer/patient role within healthcare informatics

- The development of consumers as ePatients and health information seekers, using tools such as patient-controlled electronic health records
- e-Health literacy and the impact of the internet on access to information by patients

Future informatics needs in healthcare

# 3.5 Informatics and Health Technology

# 3.5.2 Health Technology

# Use of technologies in healthcare

- Evolution of healthcare technology and delivery
- Reasons for systematic processing of data, information, and knowledge in healthcare for patients and populations
- The benefits and current constraints in using information and communication technology in healthcare
  - The use of technology to improve patient care as well as increasing patient safety and error reduction
- The context and methods of health technology assessment
- Factors affecting the adoption of e-technology in pharmacy and medical practice
- The perspectives and roles of patients and providers when using technology in care

# **Current and emerging technologies for pharmacy practice**

- Overview of health technologies currently being used in healthcare practice, with a focus on their use and impact on care delivery
- Role and use of automation in health-system pharmacy (e.g. automation in medication dispensing)
- The availability of various technologies applicable to the delivery of pharmacy care, their impact on pharmacy practice, and their applications to patient care

   (e.g. point-of-care technologies)
- Pharmacy information technologies and their impact on the practice of pharmacy
- The development, deployment, and use of hardware and software technologies to enhance patient care including improvements in efficiency and safety

(e.g. robotic dispensing/picking, bar code medication administration, automated dispensing cabinets)

# **Telecommunications technologies**

- Differences between telehealth, telemedicine and telepharmacy, benefits and issues inherent in these health delivery models
- Providing services to communities without pharmacies using tele-pharmacy and telemedicine
- Mobile technologies available to healthcare providers and patients: mobile health (m-Health)

# **Educational Contents from Category of Miscellaneous Block**

	4.2	History of Pharmacy	150
	4.1.	Research Design	147
4	Miscel	laneous	Page
	3.5	Informatics and Health Technology	
	3.4	Pharmacy Law and Regulatory Affairs	
	3.3	Practice Management and Leadership	
	3.2	Economics/Pharmacoeconomics	
	3.1	Healthcare Systems	
3	Admin	istrative Pharmacy Sciences Aspects	
	2.5	Public Health	
	2.4	Ethics	
	2.3	Professional Communication	
	2.2	Patient-Reported Outcomes	
	2.1	Sociological Aspects of Pharmacy Practice	
2	Social	and Behavioural Pharmacy Sciences Aspects	
	1.6	Drug Information and Literature Evaluation	
	1.5	Medication and Patient Safety	
	1.4	Patient Assessment	
	1.3	Medication Dispensing and Distribution Systems	
	1.2	Pharmacist-Provided Care	
	1.1	Pharmacy Practice	
_	Cililica	i Sciences Aspects	

# 4.1 Research Design

# 4.1.1 Introduction to medical research

## Introduction to theory and practice of scientific research

• Philosophy of scientific research

#### Basic concepts in clinical research

- The clinical question being addressed in a research study: matching study design to the research question
- The differences between a population and sample. Sampling methods
- · Reliability, internal and external validity of a study
  - Threats to internal validity (confounding, bias, random error), hypothesis testing and scientific reasoning
- The common sources of bias in specific types of research studies
  - Common methods to control for confounding/reduce bias and interpret results

#### Research protocol and methodology

Development and design of research protocol and methodology

(e.g. planning a research question; critically appraising the literature; developing a testable hypothesis; designing a study and selecting a research method; obtaining ethics approval (if required); managing a research project; draw appropriate conclusions from research results; presenting research results)

# How to present a study

How to write academically

(e.g. introduction (title/source, authors, funding, study objective, background); methods (design, setting, sample population, inclusion criteria, exclusion criteria, intervention, major study endpoints, statistical analysis); results (patients, endpoints); discussion; evaluation (study strengths, study limitations, usefulness))

- The use of citation managers to organize articles
- How to Conduct a Peer Review
- Reporting guidelines

(e.g. CONSORT, STROBE)

# Assessment of the quality of research

How to assess the quality of research

#### Ethics in research

- The historical and philosophical underpinnings of research ethics
- Regulatory and ethical principles involved in human subjects research

# 4.1 Research Design

# 4.1.2 Biomedical studies

#### **Observational studies**

- Cohort studies
- Case-control studies
- Other observational studies: Cross-sectional studies, case reports
- Survey Studies
  - Survey instruments: design and interpretation
  - Measuring instrument accuracy

#### Experimental studies

- Main aspects of clinical trials in industry, academia and government settings
- The fundamentals of experimental design, implementation, and data analysis pertinent to pharmaceutical clinical investigations
- The responsibilities and the role of principal investigator of a clinical trial
- Randomized controlled trials (RCTs)
  - Design and planning of randomized controlled trials

     (e.g. Types of randomization; Blinding (single-blind study, double-blind study, triple-blind, double-dummy, open-label))
  - Sample size and power
  - Specific trial designs: active comparator trials; the crossover trial; the cluster randomized trial; the uncontrolled trial; the pragmatic trial; the pharmacokinetic trial
- Quasi-Experimental studies

#### Qualitative research studies

- Discuss when a qualitative approach may be advantageous to answer a research question
- Different methods of data collection in qualitative research
  - The attributes of the main methodologies (ethnography, phenomenology, grounded theory, case study) in qualitative research
  - The research interviews (including focus groups)
- The validity and reliability of a publication that uses qualitative research methods

#### Systematic review and meta-analysis

- Narrative reviews, systematic reviews, meta-analyses, indirect treatment comparisons (network meta-analysis)
- The steps of the review process

# 4.1 Research Design

#### 4.1.3 Statistical principles and data analysis

#### The basic biostatistical concepts used in the medical literature

Basic statistical concepts

(e.g. p values, confidence intervals, statistical vs clinical significance, type I and II errors, estimation, inference, hypothesis testing, analysis of variance, contingency tables, descriptive statistics, inferential statistics, sample size and statistical power, absolute and relative risk, intention-to-treat analyses, sensitivity and specificity)

- The basic principles of probability theory, population distributions and random sampling
- Types of variables (categorical = nominal = dichotomous; ordinal; continuous)

## The common statistical tests used in clinical research

- The appropriate statistical test(s) to analyse a given set of data that employ common research designs, and interpret results
  - Assumptions and concepts behind the choice of a statistical test
  - Statistical distributions: normal or non-normal (skewed, bimodal, exponential)
  - Compare and contrast nonparametric and parametric data, measures of central tendency, and measures of variability
- Statistical tests commonly employed in biomedical sciences and their basis for use
   (e.g. Chi-square test, t-tests, ANOVA, Correlation, survival analysis, Simple and Multivariate regression
   methods)

## Statistical data analysis

- Describe, compute and interpret basic medical statistics (ARR, RRR, OR, NNT, NNH, 95%CI, etc.)
- Appropriate use of statistical software package for entering, manage and analysing research data

(e.g. SPSS® and Microsoft Excel)

• Development of simple databases and spreadsheets for the analysis of data

# 4.2 History of Pharmacy

# 4.2.1 History of pharmacy profession

# Evolution of pharmacy as a profession from ancient times to the present

- The contributions of the ancient Mesopotamian, Egyptian, Chinese, Greek and Roman cultures to the development of pharmacy
- The evolution and implications of the profession from its historical roots to pharmaceutical care

(e.g. the historical evolution of the pharmacist's role from one focused on drug compounding and distribution to a patient-centred practice model and interprofessional collaboration)

• Evolution of pharmacy associations, education, pharmaceutical research, and manufacturing

# Historical events that have shaped today's professional pharmacy practice

- The emergence of pharmacy and pharmacists as a distinct profession and professionals
- Major milestones and contributors in the evolution of pharmacy
- Political, social, and economical considerations past, current, and future as they pertain to professional enculturation and pharmacy's progress as a healthcare discipline

# The history of medicines in different times and cultures

- Origins and development of drugs
- Minerals, selected drugs, and plants of historical value
- Significant drug discoveries
- The development of critical therapeutic agents that revolutionized the treatment of disease and how these discoveries affected the pharmacy profession
- The drug development process from laboratory to patient

The history of pharmacy, its role in the healthcare system, and interactions with other healthcare professionals

- The social, scientific, and economic development of medicine and pharmacy
  - The ways in which medicine and pharmacy pursued professionalizing in the late 19th and 20th centuries and how these professions define themselves in the 21st century
- History of hospital pharmacy
- Pharmacy retailing in the late 1990s: industry structure, ownership trends, store format trends, operational developments

#### Individuals who contributed to the evolution of pharmacy

• Individuals who can be considered heroes in the profession who have been instrumental in the adaptation of our healthcare system to provide access to quality healthcare

The edition of this book is supported by national funds through the FCT, The Portuguese Foundation for Science and Technology, within the project UID/DTP/04138/2013

A edição deste livro é financiada por fundos nacionais através da FCT – Fundação para a Ciência e a Tecnologia, I.P., no âmbito do projeto UID/DTP/04138/2013

# FCT Fundação para a Ciência e a Tecnologia

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