M.Pharm. Students

DISSERTATION ABSTRACTS

2
Global Pharmacy

5
New Services

8
Pharmaceutical and Regulatory Sciences

M.Pharm. Students

DISSERTATION ABSTRACTS

Global Pharmacy

Pharmaceutical Research in India

Mareena Cyriac

Background: India has a vast pharmaceutical industry. A number of industrial activities require a research-based aspect. Besides it involves pharmaceutical technology, vaccine development and regulatory measures. A significant part of the research carried out in India involves clinical trials.

Objective: To assess the requirements of pharmaceutical research in India and to find the merits and demerits of it.

Design: A systematic literature review is conducted to identify the regulatory requirements, for conducting clinical trials within India. The databases PubMed and Scopus are used for the literature review. The regulatory requirements of the different phases of clinical trial are evaluated. Strengths, weakness and challenges encountered in conducting clinical trials with in India are looked into.

Setting: Clinical trial Regulations

Main outcome measures: Identification of the regulatory requirements for clinical trials in India.

Results: Clinical trials conducted in India are regulated by the Central Drugs Standard Control Organization (CDSCO). The regulation supporting clinical trials in India is the New drugs and clinical trials rules, 2019.[1] The regulatory fees to conduct clinical trials in India are €3371 for phase I and €2247 for phases II, III and IV. The timeline of the drug controller general of India (DCGI) to evaluate an application for a clinical trial are 90 days for new drugs, investigational new drugs or drugs already approved outside India. While applications for drugs discovered, manufactured and developed in India are evaluated in 30 days.

Conclusion: A regulated and supported structure for clinical trial contributes towards growth within the pharmaceutical sector.

Reference:

1. CDSCO. New Drugs and Clinical Trials Rules 2019 G.S.R. 227(E). [cited 2024 Feb 15]. Available form: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTIzMA==

Pharmacy Practice in India and Malta: Comparative Analysis

Reshith Kunnath Rajappan

Background: Pharmacies play a crucial role in healthcare delivery systems, but their practices vary significantly across different countries due to regulatory, cultural and socioeconomic factors.

Objective: To provide insights into the similarities, differences, challenges, and opportunities in pharmacy services provision in India and Malta.

Design: A systematic literature review is conducted to assess regulatory bodies overseeing pharmacies, compare services offered in community pharmacies, and analyse pharmacy distribution in both countries. Recommendations for improving pharmacy practice in India and Malta are provided, along with suggestions for future research and policy development.

Setting: Community and hospital pharmacy in India and Malta

Main Outcome Measures: Comparative analysis of pharmacy practice in India and Malta

Results: Pharmacists are crucial in providing healthcare, especially in rural areas lacking physicians or where their services are costly. India requires reforms to boost job satisfaction among pharmacists, including higher salaries, recognition as healthcare professionals, and curriculum changes.[1] In Malta, pharmacy education enhances clinical practice but faces limitations. Further integration of pharmacists into healthcare could improve patient outcomes, with initiatives like prescribing rights, enhanced communication, and access to patient profiles to streamline care and reduce costs.[2]
Conclusion: Implications for community pharmacy and hospital pharmacy practice in Malta and India are identified and recommendations for future research and practice are proposed, highlighting areas for future potential interventions.

References:

1. Upadhyay K-A. Comprehensive Review of Community Pharmacy Services' Development and Effects. Journal of Drug Discovery and Development. 2023;7(1):1–7.
2. Parnis MJ. Attitudes and beliefs of patients about community pharmacy services [Internet] [Doctoral Thesis]. University of Malta; 2020 [cited 2024 Feb 15]. Available from: https://www.um.edu.mt/library/oar/handle/123456789/72738.

Pharmacy Education in India

Mariya Nellissery Sebastian

Background: Pharmacy education in India has a variety of standards and outlooks. The main aspect of pharmacy education involves different educational programmes, admission criteria, regulation and quality assurance, curricula and scopes of pharmacy education.

Objectives: To identify structure and challenges of pharmacy education in India and to compare pharmacy education in India with the European Union (EU).

Design: Systematic review is conducted to compare the educational programs available in India with the EU. Open access journal articles published in English on PubMed and Scopus are identified. Questionnaire covering subjects followed, length of course and challenges is developed, validated and disseminated. Interviews with 10 pharmacy graduates from India and 10 from the EU are held where challenges related to education are identified.

Setting: Department of Pharmacy, University of Malta.

Main outcome measures: Comparative analysis of pharmacy education in India and Malta.

Results: The variety of pharmaceutical programs offered in India include DPharm, BPharm, MPharm, PharmD, PhD and post graduate education. The entry point for DPharm, BPharm, PharmD programmes is 12 years of formal education in the sciences. The BPharm degree, which includes 150 hours of practice, allows graduates to register as pharmacists in India. In contrast to the EU, aspiring pharmacists must study for a minimum of 5 years which include 6 months of full-time practice in a community pharmacy. During the four years of B pharm degree students follow lectures in organic and inorganic chemistry, pharmaceutics, pharmacognosy, medicinal chemistry and biotechnology.[1] This is similar to what pharmacy students in the EU follow.

Conclusion: Comparative review of pharmacy education in India and the EU can pinpoint challenges and propose global solutions for advancing international pharmacy education.

Reference:

1. Basak SC, Sathyanarayana D. Pharmacy education in India. Am J Pharm Educ. 2010;74(4):68. doi: https://doi.org/10.5688/aj740468

Pharmaceutical Industry in India

Ann Mary Joshy

Background: India's pharmaceutical industry is robust and a major contributor on its economy. The global pharmaceutical sector heavily relies on India's production of active pharmaceutical ingredients.

Objective: To identify characteristics related to the pharmaceutical industry in India and compare it to Europe.

Design: A systematic literature review is conducted using PubMed and Scopus to identify characteristics pertaining to the pharmaceutical industry in India and Europe. The impact of Covid -19 on the development of the pharmaceutical industry is evaluated.

Setting: Pharmaceutical Industry

Main outcome measures: Characteristics of the pharmaceutical industry in India and Europe and respective impact of Covid-19.

Result: According to the 2021 annual report, the Indian pharmaceutical sector contributed 1.72% to the country's Gross Domestic Product (GDP) and generated approximately $42 billion in domestic revenue.[1] India ranks third globally in pharmaceutical production volume and 14th in terms of value. The industry is the leading global supplier of generic medicines, with a compound annual growth rate exceeding 10%, expected to reach $130 billion by 2030. India is home to approximately 3,000 pharmaceutical companies operating around 10,500 manufacturing plants. Key factors attracting pharmaceutical manufacturers to India include cost-effectiveness and supportive policies.

Conclusion: The pharmaceutical sector within India is deemed to be one of the strongest worldwide making India a major global contributor.[2]

References:

1. Unimarck Pharma (I) Ltd. How India Ranked in The Global Pharma Market in 2022 [cited 2024 Feb 14]. Available from URL: https://unimarckpharma.com/how-india-ranked-in-the-global-pharma-market-in-2022/

2. Malhotra P, Lofgren H. India's pharmaceutical industry: hype or high-tech take-off? Aust Health Rev. 2004;28(2):182-93.

M.Pharm. Students

DISSERTATION ABSTRACTS

New Services

Challenges in Pharmacist Prescribing

Czar Jamil Flores

Background: As the role of pharmacists evolves, the prospect of pharmacist-prescribing recognises the potential impact of this activity on healthcare delivery and exploring its utility is crucial for countries implementing and overseeing this practice.

Objective: To identify models of pharmacist prescribing and describe challenges and suggest proposals for development of a pharmacist prescribing framework.

Design: A systematic literature review to identify challenges and barriers in developing and implementing models of pharmacist prescribing strategies adopted in the involvement of this practice are described and proposals for the implementation in different practice settings are developed.

Setting: Pharmacist prescribing scenarios

Main outcome measures: Challenges in pharmacist prescribing and strategies adopted to overcome them.

Results: Preliminary literature analysis indicates that challenges for the development of pharmacist prescribing are at the level of patient expectations, professional perspectives and systems including the legislative framework.[1] From a study conducted in Saudi Arabia (2020), physicians were perceived as unsupportive of pharmacist prescribing due to their lack of awareness regarding pharmacists' capabilities and expertise.[2]

Conclusion: By identifying the barriers related to pharmacist prescribing and how models of pharmacist-prescribing have evolved, proposals for further development can be put forward.

References:

1. Faruquee CF, Guirguis LM. A scoping review of research on the prescribing practice of Canadian pharmacists. Can Pharm J. 2015;148(6):325-48. doi: 10.1177/1715163515608399.
2. Ajabnoor AM, Cooper RJ. Pharmacists' Prescribing in Saudi Arabia: Cross-Sectional Study Describing Current Practices and Future Perspectives. Pharmacy. 2020 ;8(3):160. doi: 10.3390/pharmacy8030160

Sustainability in Pharmacy

Alexander Jr Lim

Background: Pharmacy sustainability encompasses workforce, services, development, and green practices. This research targets workforce sustainability, critical for healthcare quality. The evaluation of the root causes of this workforce shortage and identification of strategies to address this predicament would contribute towards the improvement of pharmaceutical services.

Objectives: To identify aspects of pharmacy sustainability and to evaluate enablers and challenges for pharmacy workforce sustainability.

Design: A systematic literature review will be conducted to explore factors affecting pharmacy workforce sustainability using the databases, Pubmed and Google Scholar. It will focus on challenges faced by pharmacists and potential solutions to enhance professional sustainability.

Setting: Pharmaceutical workforce

Main outcome measures: Identification of shortcomings in the pharmaceutical workforce sustainability and propose mitigations strategies.

Result: When approaching sustainability in pharmacy, one aspect that is considered is the sustainability of professional pharmacy services and the need for frameworks which look into environmental, social, and economic domains.[1] For the social domain, workforce shortages including health workforce migration is an aspect that impacts high- and low-income countries.[2]

Conclusion: By identifying domains of sustainability, enablers, and challenges for pharmacy workforce sustainability, strategies for workforce planning can be guided accordingly.

References:

1. Crespo-Gonzalez C, Benrimoj SI, Scerri M, Garcia-Cardenas V. Community pharmacists' perspectives about the sustainability of professional pharmacy services: A qualitative study. J Am Pharm Assoc (2003). 2021;61(2):181-190. doi: 10.1016/j.japh.2020.11.004.
2. Christoph Aluttis, Tewabech Bishaw & Martina W. Frank (2014) The workforce for health in a globalized context – global shortages and international migration, Global Health Action, 7:1, DOI: 10.3402/gha.v7.23611

MyDispense in Pharmacy Education

Ravelyn Madlansacay

Background: MyDispense, developed by Monash University in Australia, is a simulation platform that aims to enhance pharmacy students' practical skills in a virtual setting.

Objective: To identify the application of MyDispense in pharmacy education.

Design: A systematic literature review is undertaken to identify countries where MyDispense is used, methods of application, student evaluation, and impact assessment. A proposal for the implementation of MyDispense is developed and evaluated.

Setting: Pharmacy Department, University of Malta.

Main outcome measures: Use and application of MyDispense in different countries, proposal for application of MyDispense in a pharmacy programme.

Results: Studies carried out in the Philippines and in Vietnam showed that using MyDispense as a simulation tool improved the pharmaceutical care skills of students, including prescription handling skills, patient counseling skills, and collecting patient information. MyDispense activated critical thinking during delivery of patient-centered care and enhanced communication skills.[1,2]

Conclusion: MyDispense is a promising tool in pharmacy education to promote confidence of pharmacy students for their future profession.

References:

1. Pagaran AM, Matute EMS, Agad GL, Dabon MAS, Dungog VRA, Omargas BLE, et al. Confidence Level in Pharmaceutical Care Skills and Experiences Using MyDispense Virtual Simulation Among Pharmacy Students in The Philippines. International Journal of Research Publication and Reviews. 2023; 4(6): 1506-1518. https://doi.org/10.55248/gengpi.4.623.45486
2. Nguyen KTT, Dao MLC, Nguyen KN, Nguyen HN, Nguyen HTM, Nguyen HQ. Perception of learners on the effectiveness and suitability of MyDispense: a virtual pharmacy simulation and its integration in the clinical pharmacy module in Vietnam. BMC Medical Education. 2023; 23:790. https://doi.org/10.1186/s12909-023-04773-5.

Extended Services in Community Pharmacy

Jhon Vincent Reyes

Background: Community pharmacists have expanded their roles beyond conventional medication dispensing to offer extended services addressing diverse healthcare needs.

Objective: To recognise extended services offered in a community pharmacy setting in different countries.

Design: A systematic literature review is carried out to define 'extended services' in community pharmacy for different regions. The literature seeks to identify models of service, pharmacoeconomic outcomes and patient satisfaction. An analysis of services offered by community pharmacies in Malta is undertaken by compiling this information from local pharmacies and social media.

Setting: Community pharmacies

Main outcome measures: Services offered from community pharmacy.

Results: Extended services are reported in the literature for 26 different countries, with pharmaceutical care services being the most commonly offered.[1] From a global picture of extended services, medication counseling has been shown to decrease drug-related issues in Europe, particularly in the Netherlands, leading other nations, especially Australia, to promote the practice of prescribing pharmacists. The most often extended service is medication review, which is carried out in ten countries, including China, Russia, Sudan, and the United Arab Emirates.[2]

Conclusions: By identifying examples of services provided, analysing outcomes and patient perspectives, proposals for relevant and feasible services can be put forward.

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1. Shirdel A, Pourreza A, Daemi A, Ahmadi B. Health-promoting services provided in pharmacies: A systematic review. J Educ Health Promot. 2021;10:234. Doi:10.4103/jehp.jehp_1374_20.
2. Nordin N, Hassali M, Sarriff A. A global picture of extended services, perceptions, and barriers toward its performance: A systematic review. Asian J Pharm Clin Res. 2017;10(11):417. Doi: 10.22159/ajpcr.2017.v10i11.19884.

M.Pharm. Students

DISSERTATION ABSTRACTS

Pharmaceutical and Regulatory Sciences

Procurement of Safe Medical Devices

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Background: This study investigates procurement practices for medical devices in Switzerland, Singapore, and South Korea. These countries are the first three countries that have been listed as WHO-Listed Authorities having proven regulatory excellence and procurement efficiency thereby offering valuable lessons for enhancing patient safety.[1]

Objective: To analyze best procurement practices of medical devices in order to compile a framework that best fits a small member state such as Malta, aiming to enhance patient safety.

Design: This study uses document analysis to evaluate medical device procurement policies from Switzerland, Singapore, and South Korea, aiming to pinpoint best practices applicable to Malta. Literature review collecting relevant laws, guidelines, and standards adopted in procurement of medical devices is carried out. A content analysis and thematic synthesis is undertaken to identify effective regulatory strategies and practices that can be adapted to fit Malta in an effort of improving Malta's procurement system of medical devices in the interest of patient safety.

Setting: The healthcare systems of Switzerland, Singapore, and South Korea.

Main Outcome Measures: Identification of effective procurement strategies, regulatory compliance, stakeholder engagement, and quality assurance processes.

Results: This study indicates that safe medical device procurement depends on strong regulatory standards, clear procurement practices, and stakeholder collaboration. Examining Switzerland, Singapore, and South Korea reveals a unified approach focused on regulatory adherence, certification, and procurement strategy.

Conclusion: Recommendations put forward through the study findings aim at providing Malta with a strategic framework to improve its medical device procurement system, thus boosting healthcare quality and patient safety.

Reference:

1. World Health Organization (WHO). Landmark listing of first three countries as WHO-listed regulatory authorities [Internet]. Geneva (Switzerland): WHO; 2023 [cited 2024 Feb 13]. Available from: https://www.who.int/news/item/31-10-2023-landmark-listing-of-first-three-countries-as-who-listed-regulatory-authorities