Medicines Management

Subjects: Others
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Medicines management, as the handling of medications and medicinal products by healthcare professionals, consists of prescribing, dispensing, distributing, administration, patient education, follow up and monitoring, and is regulated by law.

Keywords: Medicines Management ; Law ; patient safety

1. Introduction

Health care is a complex system in which patients often experience harm resulting from the healthcare process itself [1][2]. It is too frequently accompanied by adverse events and medical errors [3], which are often preventable [4]. The World Health Organization (WHO) indicates that harm is caused in approximately one in 10 hospitalized patients, with at least 50% of these harms being preventable. Estimates show that 421 million hospitalizations take place worldwide every year and that during hospitalization about 42.7 million adverse events occur, and 18.3% of adverse events are attributed to medication errors [5]. A systematic review of 25 studies conducted in 27 countries showed that 2.9–21.9% of patients were affected by at least one adverse event, many of which were medication-related, and 34.3–83% could be prevented [6]. Beside deaths and serious adverse drug reactions (ADRs) in community settings, 128,000 patient deaths from prescribed medicines are reported annually in hospitals in the USA [7]. Therefore, measures for improving the quality of healthcare ensure or optimise patient safety “as the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum” [8]. These efforts have gained critical international significance: in 2004, the founding of the World Alliance for Patient Safety by the WHO provided an initiative to focus on and improve the quality of care and patient safety. This alliance cooperates with health-related partners, e.g., with the 24 participating ministries of health or National Patient Safety Agencies, to achieve global improvement in healthcare, including the prescribing, dispensing and administering of medicines [9]. The European Commission (EC) intensified further developments to improve the safety of health care in Europe with the Luxembourg Declaration on Patient Safety in 2005. This indicates that 50% of all preventable adverse events are a consequence of ‘medication errors’, and has led to the development of specific recommendations to Europe-wide institutions, national authorities and healthcare providers [10][11].

Medicines Management and Law

The overall goal of healthcare interventions is to ensure safe and high-quality patient care [12] through the safe and effective use of medications for the treatment of diseases [13]. There is a growing demand for the prescription of medications to treat age-related and chronic diseases worldwide. As an example, in Organisation for Economic Co-operation and Development (OECD) countries in 2017, the retail trade in pharmaceuticals accounted for one-fifth of all healthcare expenditures, averaging $564 per person [14]. Medicines have the ability to prevent, treat and cure diseases, but errors in the medication process that determines how medicines are used can cause damage. Therefore, the nature of pharmacotherapy demands that systems be in place to ensure the correct use of medicines, and that all transactions relating to medications be governed by appropriate laws and regulations [10].

According to the WHO Constitution (1946), “the highest attainable standard of health is a fundamental right of every human being”. Therefore, legal considerations are taken up by all countries through domestic or constitutional law to ensure access to high quality and safe health care [15]. It regulates behaviours or procedures that must be followed by individuals for maintaining human health, controlling or changing personal and professional behaviours [3].

In most cases, such laws regulating medicines management contain a legal definition of a medicine, which also influences what can be purchased over the counter and when a prescription is required to obtain a medication. This provides a framework for governments to monitor the use of medications in the workplace, and defines how and according to which guidelines medications can be administered, including provisions for emergency situations [13]. Nonetheless, there are international differences in regulations for medicines management. In the United States, the Food and Drug Administration

(FDA) of the U.S. Department of Health and Human Services pursues the protection of public health, which includes monitoring the safety and efficacy of medications. In many ways, the Drug Amendments of 1962 by the FDA is a model followed by other countries [16]. Within the European Union (EU), medicines law consists of European Commission directives and regulations that member states incorporate into national law [10].

Principles of medicines management developed based on laws and regulations should be unambiguously communicated through guidelines to healthcare professionals for indispensable use in clinical practice [17][18]. From the prescription to the administration of a medicine to a patient, physicians, nurses and pharmacists collaborate as a multidisciplinary team. However, problems can arise due to the unclear legal arrangements for medicines management [17]. Costs arising from additional hospital stays, litigation costs, hospital-acquired infections, loss of income, disability, and medical expenses have been reported as $6 to $29 billion annually [5].

Legal considerations to ensure patient safety through safe medicines management are therefore at the top of the political agenda, but there is a paucity of integrated knowledge.

2. What Are the Legal Considerations for Medicines Management in Healthcare Settings?

Measures to guarantee the implementation of legal initiatives and regulations for safe medicines management depended on the education of healthcare staff and monitoring the implementation of safety regulations. Unmet educational needs in pharmacology and medicines management, as well as ineffective evaluation of medication practice, represent common issues affecting patient safety across healthcare disciplines [19]. Knowledge of the law and legal considerations surrounding medicines management is often under-represented in healthcare curricula [20]. However, the development of medicines management competencies requires appropriate clinical education and supervision [21][22] and should encompass the appropriate use of standard checklists and the development of action plans to remove the gap between policymaking and implementation in practice [23]. Standardised safe medication checklists as monitoring tools have been proven to be effective in preventing lapses and reducing the incidence of adverse events by ensuring the implementation of the law and adherence to related guidelines [24].

It highlighted the need for standardised tools to guide the implementation of legal initiatives and facilitate the participation of healthcare providers and patients in medicines management. Structures and processes that standardise care are key to preventing medication errors [25]. Surveillance systems should encompass all aspects of the medication cycle, including prescribing, distribution, administration and monitoring [26]. Systematized, formal and documented processes help to identify and address medication errors and adverse events while they are still containable, and before harm occurs to patients [18][27]. Risk assessment tools and corresponding standards, and/or national guidelines for monitoring and handling certain high-risk medications increase the safety of administration, and similar process should be applied to encourage reporting of errors [28][29].

It indicates that reporting of ADRs is suboptimal and would be improved by a more robust legal framework. An ADR is an unintended and harmful reaction in the patient to a medicine associated with any administered dose, which can lead to life-threatening conditions, persistent disability, hospitalization, and even a patient's death [30][31]. Under-reporting of ADRs has been attributed to limited knowledge among healthcare providers and limited durability of related educational interventions [32]. Additionally, poor awareness of the risks of under-reporting, particularly underestimation of these risks, inappropriate reporting tools, delayed or no feedback on reported ADRs, and fear of legal liability have been mentioned as common barriers to reporting ADRs [33]. Most reporting systems and electronic medical records contain no specific category for ADRs [34]. Training activities to rationally prescribe, distribute, and monitor medications with close follow-up for adverse reactions, and reporting mechanisms, are the main steps to improving pharmacovigilance [35][36][37]. Although national error reporting systems exist in many countries, the number of ADRs reported remains low and the quality of reports is often poor [18][34]. An intervention programme using the incorporation of legal aspects of medicines management and education via posters, lectures and electronic distance learning can enhance the knowledge and attitudes of caregivers towards reporting [18][38][39].

According to the findings, the prescription and administration of medications should be directly addressed by the law. The presence of the law unifies the area of accountability among healthcare providers, allowing patients to benefit from medicines' therapeutic effects as well as protecting them against medications' harmful effects [39]. Clear laws and regulations for medicines management are the required underpinnings for clinical practice guidelines, which support safe and effective handling of medicines by healthcare providers [40]. Medication errors happen often when healthcare providers have insufficient knowledge about rules, modify rules or do not follow them in full [41]. Therefore, regular education to update knowledge and understanding of the medico-legal aspects of patient care is required to ensure

quality of care [42]. All healthcare professionals have a duty to follow rules and regulations for safe medication practice. If these cannot be followed because of systemic deficiencies, professionals are obliged to report system shortcomings and suggest remedies [43]. It is thus the responsibility of healthcare managers to ensure that safety systems are in place and to ensure patient safety through the consideration of legal, regulatory, ethical, humanistic and practical considerations in addressing medication adverse events [44].

Incorporating medicines management programs into the electronic health record system was found to be important. Structured medication interventions using computerized decision support systems improves the appropriateness and accuracy of medication regimens among hospitalized patients [45]. In spite of current shortcomings in updated protocols for new medications, the use of electronic systems for medication prescription may improve patient safety through enhancing interprofessional communication and accountability [46]. For example, the use of digital devices that remind patients to take a pill, verify the actual intake, and collect and send related data to a remote computer system have been helpful. However, this raises questions about patients' rights to autonomy and potentially violates privacy rights through the secondary use of patient data and healthcare providers' data, which has implications for liability [47][48].

Individual and shared responsibility were required for the successful implementation of legal initiatives supporting medicines management. However, barriers to shared responsibilities included: the lack of knowledge of ADRs and reporting systems, incompatibility between the law and the healthcare context, and lack of recognition of healthcare staff roles in medicines management. While there is no consensus about which healthcare profession is most suited to medicines management roles, it is accepted that trained and competent staff should assume these critical roles [49][50]. Shared decision making as a means of acknowledging power differentials and providing information about medicines should be routine in all areas of health care, but this aspect of medicines management is under-represented in existing literature [51]. Since medication errors involve different healthcare professionals, a collaborative approach, especially among vulnerable patients, has been suggested [52]. Collaboration through communication, sharing information and the provision of regular feedback can improve adherence to the principles of safe medication practice [25]. Nurses have the required knowledge and skills regarding medicines management and spend more time with patients than physicians and pharmacists, increasing their chances of detecting medicines discrepancies and near misses [53][54][55]. Therefore, nurses' role, accountability and knowledge of medications should be taken into account when strategies are devised to improve medicines management [18][52][56].

The law should support how to detect near misses and medication errors with a sentinel identity, help prevent patient harm and reduce its impact on patients. Medication errors with serious consequences for the patient health often remain under-reported [57]. Disclosing medication errors through the regular use of audit and failure mode, effect, and criticality analysis (FMECA) improves the performance of individuals and the reliability of healthcare systems [58]. Learning from near misses and errors improves the culture of safety [52][59].

Medication practice should consider patients' rights through the prescription of medicines with the fewest side effects, and patient participation by informing them of all possible adverse or undesirable effects. Patients' health and well-being depend on collaboration between patients and healthcare providers in a respectful alliance. Healthcare providers serve patients as their advocates and respect their rights by providing them with the decision-making capacity to be able to accept or refuse recommended medications [60]. Disguising medicines in food or drink is a common practice (43–71%) in the majority of nursing homes [61] and is accompanied with incomplete documentation and consultation with patients' representatives or other healthcare providers, contravening the law [61][62]. The preservation of patients' rights in the contemporary healthcare system is more complicated than the linear process of medication administration and should consider the whole process of medicines management [63][64]. Patients' rights should encompass the discussion of specific risks and benefits of proposed therapy with patients or their guardians and the documentation of informed consent to medicine administration in the medical record [65].

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