

Transformation of the Role of the Pharmacist

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Pharmacy emerged as an identifiable profession emanating from a nebulous background in which various actors delved in medicinal science and other aspects of healthcare. The profession of the pharmacist as a dispenser of medicines is expanding. The pharmacist's activities are also progressing into new healthcare fields.

therapy

pharmacist

medicines

1. Evolution of the Traditional Role of the Pharmacist in the Provision and Dispensing of Medicines

1.1. Changes in Medicines

There is an ongoing change from therapy with low M.Wt. chemical substances to that with high M.Wt. biologics ^[1] ^[2]. The latter are often nucleic acids, antibodies, enzymes, and other types of protein. Initially, this will affect specialized, hospital pharmacy then fundamental, community practice.

In the late 18th and early 19th centuries the discovery of endogenous chemical transmitters, and their receptors, gave rise to the receptor theory for the development of molecules mimicking neurotransmitters and hormones. From the 1950s onwards, the medicines developed were primarily small M.Wt. molecules. These were researched by pharmacological receptor theory and then developed and produced by chemical methods. These new drugs appeared in a ready-to-use form reducing the need for the preparation of individual prescriptions. They were largely orally administered.

Nowadays, large M.Wt. biomolecules or biologics are starting to replace these medicines ^[1]. Although biologics are researched using receptor theory as before, they are developed by biomolecular sciences, immunology, and genetic engineering, and produced with biotechnological processes. Biologics harbor the promise of better targeted therapy for diseases therebefore lacking in suitable remedies (certain viral diseases, vascular diseases such as macular degeneration in the eye, certain forms of cancer, etc.). They present new formulation challenges with innovative delivery systems, and novel pharmacokinetics of the active principle.

The expansion of the use of biologics is impacted by the economics and politics of therapy. Given that the pharmaceutical/biotechnological companies producing medicines work within a market economy, this expansion is affected by economic factors. The most profitable medicines, often the most expensive, now coming onto the market are of biomolecular/biotechnological origin ^[3]. Some are used in the top therapeutic classes such as anti-cancer treatment ^[4]. Thus they may be prescribed to substantial numbers of patients. The authorization for use of a

medicine entails a preliminary discussion on the equilibrium between recuperation by the company of the (large) amount of money invested in research and development, and the amount the government can afford to pay for treatment. An example of this was seen in the discussions over the purchase price of the new mRNA vaccines for COVID-19 and the implications of increased transparency in financial transactions on the availability of vaccines in economically less well-developed countries [5].

In the immediate future, most prescription drugs will remain (relatively) cheap, small M.Wt., chemical molecules. Between 2006 and 2009 British academics and National Health Service specialists developed a core list of the one hundred most prescribed medicines. This was revised in 2018. The list was stable over the decade concerned. The top three drug classes (estrogens and progestogens, phosphodiesterase inhibitors and serotonin receptor agonists) were small M.Wt. substances [6].

In the future pharmacists will have to adapt to the use of large M.Wt. biologics with complex pharmacotherapy, unique formulation and pharmacokinetics of substances often administered parenterally. As many are heat-labile they may require specific transport and storage facilities. Pharmacists may also have to adapt to a changing economic situation in which therapies are more expensive.

The development of biosimilars (follow-on or subsequent entry biologics) may attenuate the increase in the price of treatment [7]. Pharmacists can play a key role in the introduction and use of biosimilars [7]. Okoro [7] has proposed a specialty of "biotherapeutic pharmacy". Interventions by specialists in this subject could overcome the fears and misconceptions over the use of biosimilars (and biotherapeutics in general), advise on the addition of biosimilars to the healthcare formulary, organize the storage and dispensing of biosimilars, and play an essential role in clinical trials of biologics. Albeit a relatively recent systematic review of physicians' perceptions on the uptake of biosimilars showed that most (64–95%) showed concerns over pharmacist-led substitution of biologic medicines [8]. This goes to show once again that although a certain development in pharmacy practice may have a logical starting point in terms of the competencies of the pharmacist, progress in that area will also depend on acceptance by the triad: policymaker, patient and healthcare player.

1.2. Pharmacogenomics

Another major change in medicinal therapy is the development of pharmacogenomics. Pharmacogenomics is the study of how an individual's genetic make-up can affect a person's response to medicines. The use of genetic testing and pharmacogenomics optimizes medicine selection and dosage. It holds the promise of individually tailored therapy providing greater efficacy with fewer side effects [9]. It also may allow for the reintegration of medicines with actionable pharmacogenomic data. Classic pharmacogenomic markers were associated with metabolizing enzymes. Potential exists for the use of such data in the treatment with oncology-related medicines [10] and also in psychiatry [11], infectious [12], and cardiovascular [13] diseases.

For this specialized practice, pharmacists will need the required competencies. Pharmacogenomics can provide valuable pharmacodynamic and pharmacokinetic information that can be used by pharmacists in the assessment

and choice of drug therapy [14]. Pharmacists' roles may include the promotion of the optimal use and timing of pharmacogenomic tests, interpretation of the results of such tests, and education of healthcare professionals, patients and the public about the field of pharmacogenomics [15].

1.3. IT (Informational Technology) and AI (Artificial Intelligence)

Advances in IT are having a major impact on practice [16]. One example is the development of electronic prescriptions [16]. This ensures greater reliability and safety in repeated prescriptions in chronic illness and ameliorates the sharing of dispensing information between community and hospital pharmacists and between pharmacists and medical doctors.

Progress in IT combined with AI is opening new areas in tele-medicine and tele-dispensing. Tele-medicine is not only driven by such developments but also by decisions on policy and healthcare governance based on the relative responsibilities and cost effectiveness of different professionals [4].

IT and AI have been used in the creation of treatment algorithms for the monitoring of chronic treatment. For instance, pharmacist-managed warfarin protocols with computerized systems are being used to calculate the anticoagulant dose based on algorithms incorporating clinical factors and the International Normalized Ratio (INR) [17]. This system improves INR control with less bleeding in higher risk surgical patients.

Pharmacists have key leadership roles in healthcare driving the implementation, use and development of IT/AI services for electronic prescribing, dispensing, and prescription transfer.

1.4. Prescribing

1.4.1. Rectification of Prescriptions and Care Transfer

Approximately one in thirty patients are subject to medication harm that could be avoided [18] and in 25% of cases such harm is life-threatening. Pharmacist screening together with other methods could help in the detection of this problem. In a hospital pharmacy, a frequent clinical incident is medication-related error [19]. These errors often occur during admission and discharge of patients, raising questions about the interaction of the hospital pharmacist with other hospital staff, and with the patient's community pharmacist. In the Beks et al. study in seven Australian hospitals from 2016 to 2017, a "Partnered Pharmacist Medication Charting" model was established in which participating pharmacists completed a credentialing program to equip them with the skills needed to participate in medication-charting. The study showed that special training of hospital pharmacists in medication charting with other healthcare professionals can improve the situation [19].

This raises a general problem of IT/AI systems for transfer of care systems (for review see [20]). Several countries are developing pharmacist-led electronic care transfer systems to decrease the risks attached to discharge from hospital such as medication errors, care discontinuity, etc. with possible necessity for readmission. Several issues are at stake such as feedback, practitioner accountability, and automated flexibility for referrals. This move towards

an IT/AI solution could be determinant in freeing healthcare staff capacity in a cost-effective manner and, finally, improving patient safety.

1.4.2. Dispensing without Prescription and Prescription by Pharmacists

The pharmacist is legally responsible for the act of dispensing only. In some situations, however, responsibility goes beyond that, and pharmacists can lawfully dispense medicines without prescription. One example is the dispensing of opioid antagonists such as naloxone to rapidly reverse opioid overdose [21][22].

Pharmacists can also prescribe medicines in certain situations. Pharmacist prescribing is one of the most fundamental changes to the role of the profession and many countries are now rolling out pharmacist prescribing services. The latter requires prior post-registration experience of several years and completion of a curriculum on non-medical prescribing [23]. One example is pharmacist prescription of emergency contraception with hormones such as levorgestrel [24]. There is some evidence that pharmacists can prescribe to the same standards as doctors and that they may make significantly fewer prescribing errors when charting patients' medicines upon admission to the hospital [25]. Further studies are required on the impact of pharmacist prescribing on patient safety.

1.4.3. Antimicrobial Resistance

Antimicrobial resistance is brought about by inappropriate prescribing (especially in primary care) and sales, use of antibiotics outside the healthcare system, bacterial genetic changes, and insufficient investment in the development of new antibiotics [26]. Antimicrobial resistance is a major problem in primary care where viruses cause most infections. Here, pharmacists can play a decisive role in programs to promote antimicrobial stewardship [27][28].

Antimicrobial stewardship can include optimizing therapy by recommending an appropriate medicines regimen, duration of therapy and dosage route (switch from intravenous to oral), monitoring of therapy, and instructing healthcare workers and patients on the appropriate use of antibiotics. Pharmacists can also play a role in the use of antibiotics outside the healthcare system for instance in the case of unlawful dispensing of prescription-only medicines. This can be problematic with medicines such as antibiotics where such practice can increase the risk of developing antibiotic resistance [29].

2. Other Roles of Pharmacists in Healthcare

2.1. Public Health

Their 5–6-year degree course gives pharmacists in-depth knowledge of disease and therapy. In the context of ever-increasing healthcare budgets, governing agencies are looking at the cost-efficiency of the different actors in the global healthcare scheme and the ways to put pharmacy competencies to better economic use. Thus, the role of pharmacists in governmental policies are changing with greater involvement in the general health of the

population [30][31]. Examples of this are the roles pharmacists play in smoking cessation [32], limitation of excessive alcohol consumption and weight management [33], and syringe and needle exchange [34].

The evolution of the role of community pharmacists from substance- or product-oriented services to patient-centered services has given rise to the creation of the discipline of pharmaceutical care. This involves the management of acute situations such as chlamydia testing [35] and emergency contraception [24], and chronic diseases such as diabetes [36], arterial hypertension [37], HIV/AIDS, [38], hyperlipidemia [39], asthma [40], kidney disease [41], urinary tract infection [42], and depression [43]. There is also potential for pharmacist expertise in palliative care [44] and organ transplantation [45].

The effectiveness of pharmacists was confirmed in a meta-analysis of reviews published from 2007 to 2017 on the impact of community pharmacist-led interventions in chronic disease management [46]. Intervention improved adherence to medication, reduced admission rates for heart failure, and improved lung function in patients with respiratory conditions. The impact of pharmacists in primary care has been studied in another meta-analysis of thirty-eight reports [30]. The surveys recruited patients with cardiovascular disease or diabetes. Pharmacist interventions involved medication review delivered collaboratively with the general practitioner. These interventions lead to significant improvements in blood pressure, glycosylated hemoglobin and cholesterol.

Competencies for pharmacy practice will further develop within the context of an interactive, global healthcare complex of responsibilities. One aspect is the creation of healthcare centers grouping the activities of pharmacists and other professionals (doctors, nurses...) [4][47]. This allows a more in-depth examination and management of therapy with a reduction in the multiplication of visits to different healthcare specialists often separately located.

2.2. Vaccination

The role of pharmacists in fighting infectious diseases was highlighted by the recent COVID-19 pandemic. The importance of pharmacists is underlined by the rapid response measures needed to mitigate the spread and impact of COVID-19 [48]. This latter European study showed that the pharmacists' role involves both their substance-oriented and patient-oriented competencies: organization of the supply and storage of (sometimes heat-labile) vaccines, distribution and delivery of vaccines, reconstitution of vaccine preparations, patient education, as well as actual vaccination.

The impact of the COVID-19 pandemic on practice is judged by many to be a major milestone in the recent history of pharmacy. Bragazzi, et al. [49] judge that "*The COVID-19 outbreak has unearthed new opportunities for pharmacists: community and hospital pharmacists have, indeed, played a key role during the COVID-19 pandemic, suggesting that a fully integrated, inter-sectoral and inter-professional collaboration is necessary to face crises and public health emergencies*" and go on to conclude that "*a new era in the history of pharmacies ('the post-COVID-19 post-pharmaceutical care era') has begun, with community pharmacists acquiring a more professional standing...*". The impact of the COVID-19 pandemic is such that many countries have changed or are envisaging changing the legislation on the responsibilities of pharmacists. Thus, in an Australian study Lee, et al. [50] concluded that

“Modifying legislation to allow pharmacists to administer approved COVID-19 vaccines will enable a trained and skilled workforce to be deployed to increase the rate of mass vaccination”.

2.3. Aging

Polypharmacy for the multimorbidity of the elderly is increasing due to several factors such as rising levels of multimorbidity with the aging of the population, disease-specific rather than patient-specific prescribing guidelines, and lack of evidence to support deprescribing [51][52]. This has several potentially negative effects: reduced adherence, adverse effects of medicines, increased utilization of healthcare services, frailty, cognitive impairment, and mortality. Most chronic diseases of the elderly are treated with medicines, thus pharmacists, with their extensive knowledge of pharmacotherapy and pharmacokinetics, can play a unique role in optimizing pharmacotherapy and decreasing polypharmacy [53]. To date reports on the impact of pharmacists are mixed [53] and more studies are needed to evaluate the real impact of the pharmacist and the ways in which this could be amplified.

One other potential role for the pharmacist with the aging population concerns the possible increase in allo- and xenotransplantation following end organ damage. Despite the protective effects of chronic pharmacotherapy on prevention of organ failure produced by chronic diseases such as arterial hypertension, diabetes, vascular disease, etc. aging is associated with progressive decline in function of the heart, kidneys, and other organs. This will potentially increase the demand for transplantation. There is evidence that transplantation pharmacists can improve outcomes such as adherence, morbidity and medication errors connected to transplantation [45].

The problems arising from the increase in longevity will also be met by enhanced use of IT and AI for home support and telemedicine [54], and biological revolutions such as the application of pharmacogenomics to diagnosis and choice of therapy. The final result will be a new form of “5P” care: predictive, preventive, personalized, participative, and proven. Pharmacists will have a primordial role to play in such progress [4].

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